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27 February 2026

REF: SHA/ 26786

APPEAL AGAINST NORTH EAST LONDON ICB DECISION TO REFUSE AN APPLICATION BY SPECIALS PHARMA LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT TC1-32 THE CUBE, YEWTREE AVENUE, DAGENHAM, RM10 7FN 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:
Specials Pharma Ltd
PCSE on behalf of North East London ICB

NHS Resolution

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1 The Application

By application dated 11 June 2025, Specials Pharma Ltd ("the Applicant") applied to North East London ICB ("the Commissioner") for inclusion in the pharmaceutical list at TC1-32 The Cube, Yewtree Avenue, Dagenham, RM10 7FN 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 box blank.

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

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

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 “Specials Pharma Ltd will deliver all NHS essential services in accordance with the NHS Terms of Service, ensuring that they are accessible remotely to all persons in England without face-to-face interaction including:

1.9 (For a brief explanation see document "2. General statements of how the pharmacy will operate without face-to-face contact" attached as part of the application) [see 1.14 below]

1.9.1 Dispensing Medicines

1.9.2 Repeat Dispensing

1.9.3 Disposal of Unwanted Medicines

1.9.4 Public Health Promotion

1.9.5 Support for Self-Care

1.9.6 Clinical Governance and Audit

1.10 (a) Uninterrupted Provision of Essential Services Nationwide

1.11 Specials Pharma Ltd will ensure the uninterrupted provision of all NHS essential pharmaceutical services during our opening hours to any person in England who requests them. This will be achieved through the following procedures:

1.11.1 Electronic Prescription Service (EPS):

1.11.2 Workflow Automation:

1.11.3 Delivery Infrastructure:

1.11.4 Staffing and Shift Rota:

1.11.5 Business Continuity Plan:

1.12 (b) Safe and Effective Provision Without Face-to-Face Contact

1.13 We have implemented robust procedures to ensure safe and effective service provision without in-person contact:

1.13.1 Communication:

1.13.2 Clinical Checks:

1.13.3 Remote Consultations:

1.13.4 Medication Delivery:

1.13.5 Confidentiality & Data Protection:

1.13.6 No Access Premises Policy:

1.14 (c) Procedure If a Patient Attends the Premises

1.15 (d) Provision of Advanced Services Without Essential Services Onsite

1.16 Where applicable, Specials Pharma Ltd will provide Advanced Services (e.g., New Medicine Service) through remote consultation only, with no in-person element."

Document 2

1.17 "General statements of how the pharmacy will operate without face-to- face contact

1.18 Provision of Essential Services Without Face-to-Face Contact

1.19 Specials Pharma Ltd will deliver all NHS essential services in accordance with the NHS Terms of Service, ensuring that they are accessible remotely to all persons in England without face-to-face interaction.

1.20 **Dispensing Medicines**

1.20.1 Prescriptions will be received electronically via EPS or via secure postal methods.

1.20.2 All clinical and legal checks will be conducted by qualified pharmacists using our PMR system. Doctors Bona Fides checks with documents and record keeping kept securely on a shared drive. Documentation will include any Supplementary and Independent prescribers details.

1.20.3 Dispensed items will be packaged securely and delivered by a tracked, insured courier service to the patient's address.

1.20.4 Packages will be signed only and cannot be left "safe" as per contracted services. Delivery confirmation (e.g. signature, photo evidence, or GPS) will be logged securely.

1.20.5 Delivery information is kept with the dispatch records as proof.

1.21 **Repeat Dispensing**

1.21.1 Patients can nominate the pharmacy for EPS Repeat Dispensing.

1.21.2 Medication supply is automatically monitored and coordinated, with review reminders issued via text or email.

1.21.3 Medication reviews and reauthorisations will be arranged with prescribers and discussed with patients remotely.

1.22 **Disposal of Unwanted Medicines**

1.22.1 Patients can request prepaid, tamper-proof returns envelopes or book a courier pick-up (where appropriate).

1.22.2 Returned medicines will be disposed of according to waste management SOPs under pharmacist supervision.

1.22.3 Patients will be able to track all prescription on a app (In design) once new software is implemented.

1.23 **Public Health Promotion**

1.23.1 Health promotion materials will be delivered digitally (email, SMS, website), and printed leaflets may be included with deliveries.

1.23.2 Campaigns (e.g. smoking cessation, COVID-19 awareness) will be published on our website and shared directly with patients.

1.23.3 Additionally, information can be shared on the app (In design) directly into patients own login.

1.23.4 Additional support can be provided by phone for patients with low digital literacy.

1.24 **Support for Self-Care**

1.24.1 Patients may request advice on minor ailments or over-the-counter options by phone or secure online chat.

1.24.2 Our pharmacists are available during all core hours to provide personalised, clinically safe advice.

1.24.3 SOPs are in place for escalating red-flag symptoms and referrals to GP or NHS 111.

1.25 **Clinical Governance and Audit**

1.25.1 A full audit trail of communications, dispensing records, and patient interactions is maintained.

1.25.2 SOPs cover every step of the service from request to delivery and follow-up.

1.25.3 Monthly service audits and incident logs ensure continuous improvement.

1.26 **Key Safeguards**

1.26.1 No essential service is offered in person or at the pharmacy premises.

1.26.2 All essential services are accessible by telephone, secure website, email, and postal delivery, with language and disability access taken into account.

1.26.3 We ensure that any person in England can access the full range of essential services regardless of location, disability, or digital literacy.

1.27 Pharmacy procedures to ensure continuity of service:

1.28 **(a) Uninterrupted Provision of Essential Services Nationwide**

1.29 Specials Pharma Ltd will ensure the uninterrupted provision of all NHS essential pharmaceutical services during our opening hours to any person in England who requests them. This will be achieved through the following procedures:

1.29.1 Electronic Prescription Service (EPS): The pharmacy is fully EPS-enabled and integrated with NHS systems, allowing secure and continuous receipt of prescriptions nationwide.

1.29.2 Workflow Automation: Our pharmacy uses digital systems (PMR, barcode scanning, automated ordering) to maintain a streamlined and resilient dispensing process, reducing the risk of human error and delay.

1.29.3 Delivery Infrastructure: A contracted courier network with national reach ensures next-day or same-day of medicines across England and the rest of the UK. We also retain contingency arrangements with alternative couriers for business continuity.

1.29.4 Staffing and Shift Rota: Staff are scheduled to cover all core hours, with overlap periods and trained reserve staff to cover sickness, absence, or surges in demand. Staff are trained with a second pharmacist on hand.

1.29.5 Business Continuity Plan: In the event of system failure, staff illness, or supply chain disruption, documented contingency protocols ensure that all essential services continue without interruption.

1.30 **(b) Safe and Effective Provision Without Face-to-Face Contact**

1.31 We have implemented robust procedures to ensure safe and effective service provision without in-person contact:

1.31.1 Communication: All patient communication is carried out via secure digital platforms (email, SMS, and online portal) and telephone. A dedicated helpline is available during opening hours for clinical queries, medicine use support, and advice.

1.31.2 Clinical Checks: Pharmacists carry out clinical and accuracy checks via the PMR and EPS systems. Additional screening protocols are in place to identify high-risk prescriptions.

1.31.3 Remote Consultations: Clinical discussions for MUR-equivalent support or side-effect counselling are handled via video or phone consultation. (Webex allows both functions securely)

1.31.4 Medication Delivery: Medicines are dispatched in secure, tamper-proof packaging with full tracking and audit trails.

1.31.5 Confidentiality & Data Protection: All digital and phone communications comply with NHS IG Toolkit, UK GDPR, and DPA 2018. SOPs govern every stage of remote dispensing, from prescription handling to patient delivery confirmation.

1.31.6 No Access Premises Policy: Onsite security, access control systems, and staff training ensure that no member of the public can enter the pharmacy premises under any circumstance.

1.32 **(c) Procedure If a Patient Attends the Premises**

1.33 If a patient attempts (Highly unlikely due to security and access control) to attend the premises in person:

1.33.1 They are politely informed that the pharmacy does not provide any face-to-face services, in line with Regulation 25 requirements.

1.33.2 The patient will be directed to contact the pharmacy via telephone or email to receive remote support.

1.33.3 If they require urgent supply or help, they will be referred to the nearest community pharmacy or NHS 111 as appropriate.

1.34 **(d) Provision of Advanced Services Without Essential Services Onsite**

1.35 Where applicable, Specials Pharma Ltd will provide Advanced Services (e.g., New Medicine Service) through remote consultation only, with no in-person element:

1.35.1 NMS and Clinical Services will be offered via telephone or video call, fully documented in the PMR.

1.35.2 All follow-up and outcome tracking will also be conducted remotely.

1.35.3 These services will not involve physical access to the premises at any stage and will be clearly distinguished from essential services.

1.35.4 Patients will be informed in writing that no part of the service can be delivered in person."

1.36 [Other enclosures provided].

2 Comments to the Commissioner

On reviewing the paperwork provided by PCSE, it was noted that the comments made by the Applicant and 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 considering my application for inclusion to the pharmaceutical list. I would like to add and provide some clarity to the questions raised for those who made representations during the 45-day consultation

2.1.2 Specials Pharma Ltd has been operating as a direct-to-patient model pharmacy for over five years in the private sector and currently operate in line with regulation 25 in as far as it can for non-NHS patients. Those GAPs between our current operations and the needs of a Distant Selling Pharmacy have been risked assess [sic]. As we have been operating for 5 years we have been inspected by the GPhC twice as a distant selling pharmacy with all standards met.

2.1.3 I noted that there were some responses and questions that required further clarification.

2.1.4 We had a rolling lease. This has changed over the years as we expanded and a current 3 year lease signed in 2024 is in place. Please find attached Appendix 1 – SP lease.

2.1.5 Regulation 25 does not require us to automatically submit Standard Operating Procedures (SOPs) with a market entry application as asserted. As such we did not so as to reduce the number of documents being sent. A summary of operation and a content of the SOPs were provided to provide the committee information as to explain how the pharmacy will meet the Regulation 25 conditions (eg. remote provision without face-to-face contact). Should the SOPs be required or as a pharmacist (and not a lawyer) I am incorrect in my interpretation, then the SOPs can be sent as further evidence. Please let us know if this is a requirement for this application and I will send our full SOPs. Please be aware that there are 12 Dispensing SOPs, 11 Quality Control SOPs and 11 QC Forms and 7 Patient Care Team SOPs and 6 Forms.

2.1.6 Whilst it is not envisaged that there will be many non-EPS prescription Specials Pharma currently uses the Royal Mail Free Post service (License no. RUHH-SATH-UZEG) and will be used for those patients that have non-EPS FP10s should the application be granted.

2.1.7 Within our current operations, all new patients undergo an “instillation” which provides checks on contact details (Addresses, DOB, Dr. details, email, mobile etc) but also to provide further information as to the service. After this call email information, leaflets and any forms to fill are sent to the patient so that they are fully informed both verbally and with documentation as to what to expect of the service. The patient is given all the pharmacy contact details including those for complaints etc. The final statement in the installation informs the patient that they can speak to a pharmacist at any time about their medication or health. Should the application be granted then this can be extended to include any further information both verbally and that emailed as an “opening pack” to

include all information ensuring that the conditions in regulation 25 are met.

2.1.8 NHS information such as prescription charges etc are not currently on our website but will be added if inclusion is granted. Currently the new website [to include relevant NHS information] is in draft and can be edited further prior to upload. This website will include links to NHS information, areas for health promotion, Nomination forms etc

2.1.9 Currently counselling is performed in a number of ways; Telephone counselling – before and/or after dispatch. Secure messaging – with IT support providing a high level of security provided by an external third-party IT support company based in the UK to include back-ups and software security. Printed patient information leaflets – always included in the parcel. Please find a draft leaflet including NHS information Appendix 2. Follow-up calls – for high-risk medicines, first-time use, or safeguarding cases. (Incident reporting forms and protocols for all staff to flag up potential concerns for the pharmacist). Currently we do not provide video calls but are looking at how to best achieve this. These are all outlined in the documents sent.

2.1.10 Currently medicines are sent via royal mail overnight (Click and Drop) and MUST be signed for and not left safe. These are contractual obligations that the service provider, Royal Mail, must adhere to. Staff check on a daily basis on the Royal Mail portal to ensure all deliveries are made and will flag any incidents for the supervisor to manage. Evidence of the patient's signature and a picture of the front door are provided as proof of delivery and remain for up to 6 months on the portal. Non-deliveries are returned back to the pharmacy. The Pharmacy also offers uplift should the patient wish product to be disposed of.

2.1.11 The General statements of how the pharmacy will operate without face-to-face contact does provide the information on how the pharmacy will, and in the majority cases currently where appropriate, does for private prescriptions, operate to ensure that essential services are met from a distance.

2.1.12 I hope that this addresses any concerns of those pharmacy owners that provided representation. We have been operating a direct-to-patient model for private clinics for the past five years and have many of the necessary systems in place, and with some changes, ensure that we meet regulation 25. We currently use Titan PMR which is validated for NHS prescriptions and are smart card ready. We have also been inspected by the GPhC twice and have met all standards. Again thank you for your consideration."

2.1.13 [Enclosures provided]

3 The Decision

The Commissioner considered and decided to refuse the application. The decision letter dated 20 October 2025 states:

3.1 “North East London 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 North East London 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 **“CAS reference number -** CAS-369582-R3W6G6

3.5 **Name of applicant -** Specials Pharma Ltd

3.6 **Fitness to practise -** Cleared for inclusion.

3.7 **Address of proposed premises -** TC1-32 The Cube Yewtree Avenue Dagenham Essex RM10 7FN

3.8 **Status of location** - Non-controlled locality.

3.9 **Relevant regulations and guidance** –

3.9.1 Regulations 25 – distance selling premises.

3.9.2 Regulation 31 – refusal: same or adjacent premises.

3.9.3 DH market entry guidance chapter 11.

3.10 **Additional information**

3.11 Consider impact of decision on those with protected characteristics under the Equalities Act 2010 and is this in accordance with NHS Public Sector Equality Duty.

3.12 Consider impact of decision on NHS duty on health inequality.

3.13 None identified.

Interested parties notified of the application – Representation Submitted			
Name	**Address**	**Postcode**	**Reason appeal rights – given or reason why not given**

Brittania Pharmacy	420 Wood Lane	RM10 7FP	Appeal rights given Objections received
Boots	17 The Mall, Heathway	RM10 8RE	No appeal rights given No objection made
North East London LPC			No appeal rights given Not a pharmacy

Interested Parties notified of the application – Representations not submitted		
Name	**Address**	**Postcode**
Day Lewis Pharmacy	7 Beadles Parade, Rainham Road South	RM10 8YL
Day Lewis Pharmacy	2 Royal Parade, Church Street	RM10 9XB
Oxlow Chemist	217 Oxlow Lane	RM10 7YA
Maylands Pharmacy	300 Upper Rainham Road	RM12 4EQ
Day Lewis Pharmacy	109 Mungo Park Road	RM13 7PP
Talati Chemist	282 Heathway	RM10 8QS
Waller Chemist	279 Heathway	RM9 5AQ
Orchard Village Pharmacy	Mick Fury House, Lowenhouse, Rainham	RM13 8HT
Day Lewis Pharmacy	6 Station Parade	RM12 5AB
Healthcare Pharmacy	2 Tadworth Parade	RM12 5AS
Elm Park Pharmacy	208-212 Elm Park Avenue	RM12 4SD
Asvacare Ltd	197 Rush Green Road	RM7 0JR
Heathway Pharmacy	149 Broad Street	RM10 9JA
Barking & Dagenham LMC		
Barking & Dagenham HWB		
Barking & Dagenham Healthwatch		
Havering LMC		
Havering HWB		
Havering Healthwatch		

3.14 **Additional information**

3.15 The PSRC are satisfied that there is enough information to deal with this application without holding an oral hearing.

3.16 Comments were received from Laville Ltd, Boots and North East London LPC. The applicant provided a response to these comments. See summary below:

3.17 <u>Laville Ltd</u>

3.18 Regulation 25

3.19 As NHS England will be aware, the application has been submitted pursuant to regulation 25 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 ("the Regulations"), being an excepted application for distance selling premises. It is therefore, incumbent upon the applicant to provide suitable and sufficient information to satisfy NHS England that the applicant has in place procedures which are likely to secure the uninterrupted, safe and effective provision of all essential pharmaceutical services without face-to-face contact and irrespective of where in England the patient may live.

3.20 Whilst an applicant need not repeat every element of the Terms of Service in its application documents, where compliance with a paragraph of the Terms of Service would ordinarily require face to face contact (and would be straightforward in that context), the applicant must explain how it is going to achieve compliance (and therefore safe and effective provision) in the distance selling context.

3.21 It is evident from the information provided by the applicant in its application form that NHS England cannot be satisfied that the application meets the requirements of regulation 25.

3.22 Regulation 25(2)(b) requires an applicant to provide details of the pharmacy's procedures; that is, the procedures that will be adopted by the applicant in its operation of the proposed pharmacy. At section 7 of the application form, the applicant refers to the document titled "General statements of how the pharmacy will operate without face-to-face contact" which is attached to the application form. The applicant has also provided a document titled "SOPs and Quality Management System". This appears to be an index of SOPs, but the SOPs themselves have not been provided and the index, itself, is of no assistance to NHS England in its determination of the application.

3.23 On behalf of my client, it is submitted that the information provided by the applicant is insufficient to satisfy NHS England that the relevant regulatory test will be met. By way of example:

3.24 In relation to dispensing services, the information provided by the applicant does not:

3.24.1 Explain how patients will be able to post prescriptions to the pharmacy without cost to the patient;

3.24.2 Detail the process for EPS registration (and, indeed, for patient registration with the pharmacy generally);

3.24.3 Include any information about prescription charges, owings, emergency supplies, etc.;

3.24.4 Provide any information in respect of appropriate patient counselling as required by the terms of service;

3.24.5 Explain how all classes of medication will be packaged and delivered safely, including dealing with failed deliveries.

3.25 No information is given in relation to the applicant's website or practice leaflet.

3.26 Whilst some of the essential pharmaceutical services are referred to (albeit in insufficient detail to explain how each service will be provided safely and effectively in the distance selling context), the applicant does not refer to some essential services at all.

3.27 The applicant's application form states that a number of advanced services will be provided. However, the information provided at section 7 (including the attached supporting information documents) only refer to one advanced service (NMS) and then only with limited detail which is insufficient to explain how the service will be provided safely and effectively in the distance selling context.

3.28 **Conclusion**

3.29 Regulation 25(2)(b) requires the applicant to satisfy NHS England that the applicant will provide all NHS pharmaceutical services safely and effectively to patients anywhere in England who request those services.

3.30 NHS England must therefore consider Part 2 of schedule 4 to the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013. NHS England must have regard to each pharmaceutical service individually and consider whether the applicant has provided sufficient information to satisfy it that the requirements of regulation 25(2)(b) would be met for each service.

3.31 Having regard to regulation 25(2)(b) and Part 2 of schedule 4, it is evident that the applicant has failed to provide sufficient information in relation to each individual pharmaceutical service. This means that NHS England cannot know how, in fact, the applicant proposes to provide all pharmaceutical services in the distance selling context.

3.32 In conclusion, in the absence of suitable or sufficient information from the applicant regarding the procedures that it will have in place for the provision of all pharmaceutical services, NHS England cannot be satisfied that the requirements of regulation 25 are met.

3.33 <u>Boots</u>

3.34 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.

3.35 <u>North East London LPC</u>

3.36 North East London LPC have noted this application in respect of distance selling premises. We have a concern that the lease has expired and would like to see an updated lease or know the new address of an alternative lease.

3.37 Further Response from the Applicant [see section 2 above]

3.38 **PSRC Comments**

3.39 There is not a requirement for a valid lease to be in place ahead of approval of an application and whilst the representation have been reviewed this has not been considered as part of the approval process for this application.

3.40 The applicant is not required to submit the SOPs with the application; however, the applicant must demonstrate in their application that they meet the requirements of regulation 25.

3.41 The additional information provided by the applicant and the practice leaflet have been considered in making a decision for this application alongside the comments received from interested parties.

3.42 **With regard to Regulation 31 (Refusal: same or adjacent premises) and to the provisions of Schedule 2 to the Regulations: "Applications seeking the listing of premises that are already, or are in close proximity to, listed chemist premises.**

3.43 The proposed pharmacy is not on the same site or adjacent to any other pharmacy, therefore this regulation is not engaged.

3.44 **Distance Selling premises applications** [Regulation 25 quoted in full]

3.45 The applicant provided information via their application, response to the comments and the practice leaflet.

3.46 No information has been provided for the following regulations:

3.46.1 Paragraph 6 of Schedule 4

3.46.2 Paragraph 7(3) of Schedule 4

3.46.3 Paragraph 8(1) of Schedule 4

3.46.4 Paragraph 8(5) of Schedule 4

3.46.5 Paragraph 8(15) of Schedule 4

3.46.6 Paragraph 9(4) of Schedule 4

3.46.7 Paragraph 10(1) of Schedule 4

3.46.8 Paragraph 18 of Schedule 4

3.46.9 Paragraph 19 & 20 of Schedule 4 Paragraph 22B & 22C of Schedule 4

3.47 Limited information has been provided for the following regulations:

3.47.1 Paragraph 13 of Schedule 4

3.47.2 Paragraph 16 of Schedule 4

3.47.3 Paragraph 21 & 22 of Schedule 4

3.48 In additional there is in sufficient information provided for the responsible pharmacist role.

3.49 It may be concluded that the PSRC is not satisfied that pharmacy procedures for the pharmacy are likely to secure the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services.

3.50 It may also be concluded that the applicant is likely to not satisfy the criteria as set out in the Terms of Service of Pharmacists for the safe and effective provision of all essential services without face-to-face contact.

3.51 Therefore, the PSRC is not satisfied that the pharmacy procedures for the pharmacy premises are likely to secure 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.

3.52 **Decision**

3.53 Regulation 31.

3.54 There are no current pharmacies listed at the proposed premises or adjacent to the proposed premises. Therefore regulation 31 does not apply for this application.

3.55 Regulation 25(2)(1)(a)

3.56 The proposed site is not on the same site or in the same building as the premises of a provider of Primary Medical Services with a patient list. Therefore, this regulation does not apply for this application.

3.57 Regulation 25(2)(1)(b)(i)

3.58 The PSRC is not satisfied that pharmacy procedures for the pharmacy are likely to secure the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services.

3.59 Regulation 25(2)(1)(b)(ii)

3.60 The PSRC is not satisfied that the applicant is likely to satisfy the criteria as set out in the Terms of Service of Pharmacists for the provision of all essential services without face-to-face contact.

3.61 The PSRC is not satisfied that the pharmacy procedures for the pharmacy premises are likely to secure 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. Therefore, the application has been refused.

3.62 Determination made by London PSRC on behalf of NHS North East London ICB.

3.63 **Conditions of approval for a Distance Selling Pharmacy**

3.64 As this application is in respect of distance selling premises, by virtue of regulation 64(3) of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended, if the applicant is subsequently included in the pharmaceutical list for the area of Barking & Dagenham Health and Wellbeing board in respect of the premises included in the application, that inclusion will be subject to the following conditions:

3.64.1 The applicant must not offer to provide pharmaceutical services to persons who are present at (which includes in the vicinity of) the proposed premises.

3.64.2 The means by which the applicant provides pharmaceutical services must be such that any person receiving those services does so otherwise than at the proposed premises.

3.64.3 The proposed premises must not be on the same site or in the same building as the premises of a provider of primary medical services with a patient list.

3.65 The pharmacy procedures for the premises must be such as to secure:

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

3.65.2 the safe and effective provision of pharmaceutical services without face-to-face contact at the proposed 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; and

3.65.3 Nothing in the applicant's practice leaflet, in the applicant's publicity material in respect of the proposed premises, in material published on behalf of the applicant publicising services provided at or from the proposed premises or in any communication (written or oral) from the applicant or the applicant's staff to any person seeking the provision of essential services from the applicant must represent, either expressly or impliedly, that:

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

3.65.5 the applicant is likely to refuse, for reasons other than those provided for in the applicant's terms of service, to provide drugs or appliances ordered on prescription forms or repeatable prescription forms which are presented by particular categories of patients (eg because the

availability of essential services from the applicant is limited to other categories of patients)."

4 The Appeal

In a letter dated 18 November 2025, the Applicant appealed against the Commissioner's decision. The grounds of appeal are:

4.1 "We respectfully submit this appeal under Regulation 19 [sic] of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, on the grounds that the PSRC's decision was based on an incorrect or incomplete assessment of the evidence provided, and that the conclusions reached under Regulation 25(2)(1)(b)(i) and (ii) are not justified.

4.2 The PSRC stated that sharing SOPs were not required for the application but it seems that SOPs are integral to ensure that the application is approved as insufficient information had been provided is the reason for refusal in relation to a number of paragraphs of Schedule 4 by a summary. We would like to clarify and address each of these areas in turn, and to demonstrate that our proposed operating model, policies, and procedures do, in fact, meet all regulatory and professional standards required for a Distance Selling Pharmacy (DSP).

4.3 Furthermore, we would like to add that we have been operating as a Distant Selling Pharmacy for over 4 years providing dispensing services to patients from private clinics and have been operating nearly all (or similar) services as a NHS Distant Selling Pharmacy that are not face to face. This includes IT systems that provide customer relationships, ability to contact patients (and clinics) in an emergency and complaints policies. All are relevant with some above what is required for NHS services as currently the majority of what is dispensed is unlicensed. We have also been inspected twice by the GPhC and are found to have met all standards. Hence the reason proposed for refusal are not justified.

4.4 All of which you will find in our "Appeal Response to the refusal of Market Entry" and the attached appendixes as evidence."

"Appeal Response to the refusal of Market Entry"

4.5 "I am writing to formally appeal the decision made by the London Pharmaceutical Services Regulations Committee (PSRC) on behalf of NHS North East London ICB, dated 15.10.25 refusing our application for inclusion in the pharmaceutical list in respect of our proposed Distance Selling Pharmacy at Specials Pharma Ltd, TC1-32 The Cube, Dagenham RM10 7FN.

4.6 We respectfully submit this appeal under Regulation 19 [sic] of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, on the grounds that the PSRC's decision was based on an incorrect or incomplete assessment of the evidence provided, and that the conclusions reached under Regulation 25(2)(1)(b)(i) and (ii) are not justified.

4.7 The PSRC stated that sharing SOPs were not required for the application but it seems that SOPs are integral to ensure that the application is approved as insufficient information had been provided is the reason for refusal in relation

to a number of paragraphs of Schedule 4 by a summary. We would like to clarify and address each of these areas in turn, and to demonstrate that our proposed operating model, policies, and procedures do, in fact, meet all regulatory and professional standards required for a Distance Selling Pharmacy (DSP).

4.8 Furthermore, we would like to add that we have been operating as a Distant Selling Pharmacy for over 4 years providing dispensing services to patients from private clinics and have been operating nearly all (or similar) services as a NHS Distant Selling Pharmacy that are not face to face. This includes IT systems that provide customer relationships, ability to contact patients (and clinics) in an emergency and complaints policies. All are relevant with some above what is required for NHS services as currently the majority of what is dispensed is unlicensed. We have also been inspected twice by the GPhC and are found to have met all standards. Hence the reason proposed for refusal are not justified.

4.9 **Grounds for Appeal**

4.10 **Response to Regulation 31**

4.11 We note that the PSRC determined that Regulation 31 does not apply because there are no existing pharmacies at or adjacent to the proposed premises. We accept this outcome and raise no objection.

4.12 **Response to Regulation 25(2)(1)(a)**

4.13 We acknowledge and agree with the PSRC's findings that the proposed premises are not co-located with a primary medical services provider and therefore this regulation is not applicable.

4.14 **Response to Regulation 25(2)(1)(b)(i)**

4.15 The PSRC was not satisfied that our procedures demonstrated the uninterrupted provision of essential services throughout opening hours to persons anywhere in England. We respectfully submit that our SOPs address this fully. They include:

4.15.1 Guaranteed pharmacist presence during all operating hours. (Appendix 1 –Screenshot RP Register for last week)

4.15.2 A deputy (Second) pharmacist arrangement to ensure continued service if the RP is unavailable. (Appendix 1 – Screenshot RP Register for last week)

4.15.3 Business continuity plans for IT outages, staff absence, and supply chain disruptions.(Appendix 2 - 2. SOP/DSP12 Business Continuity Procedures)

4.15.4 National courier agreements with full tracking and contingency delivery options. We are contracted to Royal Mail click and drop service that is a signed for service and is contractually forbidden to leave packages safe (Must be to an adult at the address only). Currently we have changed our second courier from APC to DPD who require the patient

to provide a PIN that is SMS to them. We have always used two services, firstly as a business continuity back up but secondly to provide patient choice. (Appendix 3 – Royal Mail Latest Invoice, Appendix 4 – DPD contract)

4.16 These measures ensure that essential services will be provided without interruption nationwide and are currently operational.

4.17 **Response to Regulation 25(2)(1)(b)(ii)**

4.18 The PSRC concluded that it was not satisfied that we would meet the Terms of Service requirements for delivering essential services without face-to-face contact. Our DSP model is fully designed around remote provision. It includes:

4.18.1 Secure remote consultations via telephone, video link, and digital communication. Our communication system is powered by Cisco Webex which allows for phone, conference calls, and telemedicine. Webex provides a call history and recording as will email the patient care team with any messages left on the answer phone. We use Outlook as our email preferences.

4.18.2 Comprehensive clinical checking processes. This is performed by the pharmacist with the dispensary staff (See Appendix 5 - SOP_DSP01 Clinical and Legal Checks)

4.18.3 Secure identity confirmation for all patients. This is performed with all new patients and is incorporated into the Installation process (See Appendix 6 - SOP_PCT02 New Patient Installation)

4.18.4 Robust repeat prescription management and safe delivery systems all performed via a NHS-accredited pharmacy platform– Titan PMR (Appendix 7 –License Renewal 2023)

4.18.5 Proactive follow-up procedures for new medicines via our NHS-accredited pharmacy platform – Titan PMR (Appendix 8 – 8. Screenshot Titan PMR NMS Reporting Software). Titan PMR also allows us access to the NHS Summary Care Records via the pharmacist smart card. This is all operational with cared readers and software set up by local Registration Authority (RA).

4.19 We therefore meet all requirements for delivery of essential services without face-to-face interaction.

4.20 **Response to Concerns on Safe and Effective Remote Provision**

4.21 The PSRC expressed concerns about whether our pharmacy procedures were likely to secure the safe and effective provision of services without face-to-face contact. We confirm that:

4.21.1 No services will be delivered in person at the premises, a service that we have already provided for the past 5 years with our current patient base. In that time there has been no access granted to patients and this will remain. On top of which it would be near impossible for patients to

visit us. We are in a secure technical park with perimeter fencing, cameras linked to the security hut, 24/7 Security including access control of people and vehicles, (Without an email invitation sent by us there is no access. We have only provided access to suppliers and service contractors such as IT), Nighttime patrols, 3 Magna locked door to the floor that the pharmacy is on with all pharmacy rooms having locks, keypad locks and cameras facing all entrances. (Appendix 9 - Screenshot visitors log)

4.21.2 All interactions with patients occur remotely. This is done via email, phone and via Cisco Webex telemedicine service.

4.21.3 Our practice leaflet, website, and publicity strictly state that we serve patients anywhere in England with no geographical limitation. Currently our website does not hold any NHS details as we cannot provide NHS Services. The new website is in draft format and can be uploaded on with a touch of a button (Ready for upload) via our Ionos portal. We currently have a large patient base and to have our NHS web pages live prior to any contract would be confusing and lead to misunderstanding as many of them will want us to provide them NHS services as well as the current private ones. (Appendix 10 – Draft Practice Leaflet) (Appendix 11 – SP new site Home Page). This includes a new page for NHS patients (Appendix 12 - SP new NHS Web Page)

4.21.4 We do not target or restrict services to any specific patient group. (Appendix 12 -SP new NHS Web Page)

4.22 These measures fully comply with DSP regulatory obligations.

4.23 Further specific comments were made by the PSRC about Schedule 4 were made which our response was not felt adequate also requires us to comment on in this appeal to help provide further clarity.

4.24 Paragraph 6 – Opening hours and accessibility [sic]

4.25 Our Standard Operating Procedures (SOPs) and new NHS focused website include clear details of opening hours, emergency contact provisions, and arrangements to ensure uninterrupted access to services via telephone, email, and online platforms throughout those hours. We have implemented systems to ensure service continuity during staff absences and system downtime. (Appendix 2 - 2. SOP/DSP12 Business Continuity Procedures) (Appendix 9 – SP new site Home Page). (Appendix 11 - SP new NHS Web Page)

4.26 Paragraph 7(3) – Safe and effective service provision [sic]

4.27 Our procedures define clear lines of accountability for all staff involved in dispensing and clinical checks. The Responsible Pharmacist ensures compliance with the GPhC standards and NHS Terms of Service, including verification of prescriptions and clinical appropriateness checks. (Appendix 13 - SOP_DSP13 Responsibilities of an RP)

4.28 Paragraph 8(1), (5), (15) – Security, record-keeping, and confidentiality [sic]

4.29 We maintain electronic audit trails for all prescriptions handled, and all patient data are processed in compliance with UK GDPR and the Data Protection Act 2018 via our NHS-Accredited PMR, Titan PMR. Our systems are fully compliant with NHS Digital's Data Security and Protection Toolkit. We use a third-party IT company to ensure data security on our IT system and a standalone NHS Accredited PMR that is connected to the NHS ONLY. Confidential waste is securely destroyed, and the premises have restricted access for authorised personnel only. (Appendix 2 - SOP/DSP12 Business Continuity Procedures) (Appendix 7 –License Renewal 2023 NHS Accredited PMR) (Appendix 14 – Sweetbyte Contract Arrangement) (Appendix 15 - SOP_DSP11 - Safeguarding and Data Protection)

4.30 Paragraph 9(4) – Staff training and competence [sic]

4.31 All pharmacy team members receive structured induction and continuous professional development, including modules on distance dispensing, confidentiality, and patient counselling. The Responsible Pharmacist is responsible for overseeing competency assessments. All staff; dispensary and patient care team MUST undergo NVQ 2 Buttercup training with three staff due to complete their final exam once the tutor assessment has been passed. (Appendix 16 – Screenshot SOP Training Overview)

4.32 Paragraph 10(1) – Clinical governance [sic]

4.33 We have a documented Clinical Governance Framework, including procedures for incident reporting, audit cycles, and regular SOP reviews. Complaints are managed in line with NHS regulations and escalated appropriately. (Appendix 17 – SOP_ PCT06 – Handling Complaints) (Appendix 18 - SOP_PCT06-E Flow chart) (Appendix 19 - SOP_QCP04 Change Control) Appendix 20 - SOP_QCP05 CAPA and Quality Register) (Appendix 21 - Screenshot Near Misses November 2025) (Appendix 22 - Screenshot Dispensing errors last 3 months) (Appendix 23. Screenshot Expired and destroyed stock)

4.34 (Appendix 24 - Stericycle Contract)

4.35 Paragraphs 18, 19, 20 – Complaints, risk management, and audit [sic]

4.36 A robust complaints procedure is in place, accessible to patients through our practice leaflet and website. We have implemented risk assessments for remote operations, including contingency plans for delivery delays and system outages. Audits of dispensing accuracy, patient satisfaction, and delivery performance will be conducted quarterly. (Appendix 17 – SOP_ PCT06 – Handling Complaints) (Appendix 18 - SOP_PCT06-E Flow chart)

4.37 (Appendix 25 - QCP07 Risk Management) (Appendix 26 - DSP11-B Safeguarding Flow Diagram)

4.38 Paragraphs 22B & 22C – Distance selling obligations [sic]

4.39 Our practice leaflet and publicity material explicitly state that services are available to persons anywhere in England and not limited by geography. We do not provide services face-to-face at the premises, and all interactions occur

remotely (by telephone, email, or online consultation). (Appendix 2 - 2. SOP/DSP12 Business Continuity Procedures)

4.40 (Appendix 9 – SP new site Home Page) (Appendix 11 - SP new NHS Web Page)

4.41 **Responsible Pharmacist Role**

4.42 The Responsible Pharmacist (RP) has clearly defined duties, including oversight of all professional activities, verification of prescription authenticity, and ensuring compliance with the Medicines Act 1968 and Human Medicines Regulations 2012. The RP will be physically present during core hours, supported by a deputy pharmacist during absences to ensure uninterrupted service. (Appendix 1 – Screenshot RP Register for last week)

4.43 (Appendix 13 - SOP_DSP13 Responsibilities of an RP)

4.44 **Safe and Effective Provision Without Face-to-Face Contact**

4.45 Our operational model includes secure remote communication channels, confidential patient counselling via video or phone, and courier delivery with real-time tracking. We provide full accessibility to all patients in England without requiring in-person attendance, fully satisfying the intent of Regulation 25(2)(1)(b)(ii). We have already been operating for 5 years without face to face services and have been able to council patients, provide an instillation (To verify ID, get information and provide patients with a service overview including how to complain and sending an email providing the same information). We deal with two thousand plus patients per month as can be seen with our turnover of over £1,000,000 for every year for the last three years at a distance. (See Appendix 6 - SOP_PCT02 New Patient Installation) (Appendix 27 - 9011403 Pharmacy Notice of Entry)

4.46 Response to Conditions for Future Approval Under Regulation 64(3)

4.47 We confirm that we already comply with all DSP conditions, including:

4.47.1 No face-to-face service provision at or near the premises.

4.47.2 Exclusively remote service delivery.

4.47.3 The premises not being located on the same site as a GP provider.

4.47.4 Collaboration with prescribers to ensure seamless care continuity.

4.47.5 Systems ensuring uninterrupted and safe remote essential services.

4.47.6 Guaranteeing national availability with no implication of geographical restriction.

4.48 Our practice leaflet, publicity materials, and communication policies strictly adhere to these requirements.

4.49 **Conclusion**

4.50 We believe the concerns raised resulted from an incomplete interpretation of the comprehensive evidence we submitted. Our procedures and systems are fully aligned with the requirements of Regulation 25 and Schedule 4.

4.51 In light of the detailed evidence provided above and our commitment to upholding NHS standards for distance selling, we respectfully request that NHS Resolution overturn the PSRC's decision and grant approval for inclusion in the pharmaceutical list for the proposed Distance Selling Pharmacy.

4.52 We are fully committed to providing safe, effective, and accessible pharmaceutical services to patients across England in strict compliance with the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 and GPhC professional standards."

4.53 [Enclosures provided along with the NHS online appeal which included the same information as above].

5 Summary of Representations

NHS Resolution noted that despite the application being considered by the Commissioner on 15 October 2025, it appeared, from the PSRC report that the application was considered against the previous regulatory test. The Applicant was therefore given the opportunity to provide any comments it wished to make in support of its application in light of the amended Regulations.

This is a summary of representations received.

5.1 The Applicant

5.1.1 "Further to my responses on the 9 December 2025 and the 11 December 2025 [where the Applicant queried the opportunity it had been given to provide comments. To which NHS Resolution responded] I am still confused as to why there is a discussion about which rule should be used when testing the appeal. The original application was made on 13 June 2025 prior to any rule changes on 23 June 2025. The original application was tested against the rule prior to the change on 23 June 2025 and so should any subsequent appeal or further investigations regardless.

5.1.2 Specials Pharma's appealed against the decision of NHS England dated 20 October 2025 to refuse the Specials Pharma's application for inclusion in the NHS pharmaceutical list.

5.1.3 The application for inclusion was submitted on 13 June 2025. This appeal is brought within the prescribed time limit and in accordance with the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 ("the 2013 Regulations").

5.1.4 That Specials Pharma contends that the decision to test the appeal under a different to the application may be unlawful but definitely procedurally unfair and must be set aside.

5.1.5 On 13 June 2025, the Specials Pharma submitted an application to NHS England for inclusion in the pharmaceutical list under Regulation 25 of the 2013 Regulations, as then in force.

5.1.6 At the time the application was made:

5.1.6.1 Regulation 25(1)(a) permitted applications by persons not already included in a pharmaceutical list; and

5.1.6.2 The Specials Pharma satisfied the eligibility requirements under the regulatory framework then in force.

5.1.7 On 23 June 2025, amendments to the 2013 Regulations came into force which repealed Regulation 25(1)(a) and introduced a materially different legal framework for market entry applications. NHS England issued its decision on 10 October 2025 refusing the Specials Pharma's application.

5.1.8 The appeal must be determined by reference to the law in force at the date the application was made, namely the 2013 Regulations as they stood immediately prior to 23 June 2025. The amending regulations introduced express transitional provisions, which require that any application submitted before 23 June 2025:

5.1.8.1 "must be determined in accordance with the provisions of the 2013 Regulations as they had effect immediately before that date."

5.1.9 It follows that NHS England was required to assess the application under the pre-23 June 2025 legal framework; and the Appeal Panel must determine whether NHS England's decision was correct when tested against that same framework. Any reliance upon the amended regulations, post-June 2025 policy changes, or revised eligibility criteria is unlawful and impermissibly retrospective.

5.1.10 For the reasons set out above, the Specials Pharma respectfully submits that the decision of NHS England is unlawful and should be set aside.

5.1.11 The Specials Pharma invites the Appeal Panel to allow the appeal against the original test and look at the further evidence submitted for the appeal on 13 June 2025 and 18 November 2025 and to Quash NHS England's decision dated 20 October 2025 to direct NHS England to include the Specials Pharma in the pharmaceutical list; or remit the matter to NHS England for reconsideration strictly in accordance with the 2013 Regulations as in force immediately before 23 June 2025.

5.1.12 The Specials Pharma believes that the facts stated in this skeleton argument are true."

5.2 The Commissioner

5.2.1 "Please read this response in conjunction with the decision report.

5.2.2 Firstly, I would state that contrary to the applicant's comment in the appeal, SOPs are not required, however, the applicant would need to provide sufficient information in order to satisfy the PSRC that they are complying with the criteria within the regulations. What was provided originally by the applicant did not assure the PSRC which is why this was refused.

5.2.3 The application is assessed against the NHS regulations where there is specific criteria to adhere to, in order to provide essential NHS services and any advanced NHS services offered without face to face contact. These criteria will be different to private services.

5.2.4 Whilst the applicant has provided more information, which has been assessed, there is still missing information, this is detailed below:

5.2.5 All of the information missing is in relation to the terms of service, Schedule 4 of the regulations.

5.2.6 Paragraph 6 – Urgent Supply without a prescription - no information received.

5.2.7 Paragraph 7 (3) - patients' entitlement to exemption or remissions from NHS Charges - limited information received.

5.2.8 Paragraph 8(1) - how prescriptions will be delivered including cold chain and CDs. - limited information received

5.2.9 Paragraph 8(5) - SSP – no information provided.

5.2.10 Paragraph 8(15) - Suitable containers for prescriptions being delivered. – no information provided.

5.2.11 Paragraph 9(4) - Repeatable Prescription checks for second and further instalments. – no information provided.

5.2.12 Paragraph 10(1) - Advice about the benefits of repeat dispensing. – no information provided.

5.2.13 Paragraph 13 – Disposal of unwanted drugs – limited information provided.

5.2.14 Paragraph 16 – Healthy lifestyles – limited information provided.

5.2.15 Paragraph 17 – Prescription linked intervention – no information provided.

5.2.16 Paragraph 18 – Public Health Campaigns – no information provided.

5.2.17 Paragraph 19 & 20 – Signposting – no information provided.

5.2.18 Paragraph 21 & 22 – Support for self care – limited information provided.

5.2.19 Paragraph 22B & 22C – DMS – no information provided.

5.2.20 As we feel that the applicant has still not provided sufficient evidence to ensure compliance with the criteria for distance selling pharmacies being able to provide all essential services and any advanced services offered without face to face contact, we submit that this application should be refused."

6 Summary of Observations

This is a summary of observations received.

6.1 The Applicant

6.1.1 "Further to your letter dated 8 January 2026. I fully understand that with all the information sent on 10 June 2025, 12 November 2025 and 3 December 2025 information may have been missing. Please find a rebuttal to all the comments sent by representation. I would also like to take this opportunity to reiterate a number of facts.

6.1.2 That we have been providing pharmacy services since 2020 without face-to-face contact successfully for products that are controlled, unlicensed and refrigerated successfully. This includes handling complaints and dealing with returns, destructions, error and performance monitoring, staff training and complying with all pharmacy regulations. We are a learning organisation and ensure any gaps in service or compliance are dealt with. Unlike the majority of pharmacies, we have a quality management system.

6.1.3 I, [UC], the Superintendent Pharmacist have been qualified for over 35 years and have been a SI Pharmacist, MHRA Responsible Person and a Home Office CD witness for over 15 of these without any issues or concerns as to how I ensure compliance for any operations that I have run, including an internet pharmacy, a care home medication provider, a group of retail pharmacies, a wholesaler, a pharma importer, a specialist direct to patient compounding pharmacy and now Specials Pharma a distance selling pharmacy.

6.1.4 That Specials Pharma has operated within all safety guidelines and has been inspected a number of times by the GPhC with all standards being met.

6.1.5 We currently use a NHS approved Patient Medication Record Titan PMR that allows for the management of Repeat Dispensing Services. Pharmsmart that allows us to electronically record Control Drug Register, Dispensing Errors, Near Misses, SOP training and staff training records. Our data is managed by a third-party IT company, Sweetbytes, that ensures data security infrastructure to the highest levels. We also have access to the NHS and can adopt many systems such as summary care records and pharma outcome (OCS code required) that help in the provision of services.

6.1.6 A new website and prescription portal are in development and with a specialist company Chirac to ensure that all distant selling requirements are met by the software. (They currently provide for a number of DSP and were selected for their experience.

6.1.7 I would like to point out that some of the observations were not previously offered. We have provided no new evidence but a rebuttal of the information as requested. Please note we are a learning organisation and as such are looking at ways to continually improve ourselves."

6.1.8 [Enclosure 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").

7.5 As a preliminary matter, the Committee noted the comments by the Applicant on the amendments to the Regulations that occurred on 23 June 2025 [paragraphs 5.1.1 to 5.1.12 above]. The Committee noted that the amendments created the following wording for Regulation 25(2)(b):

> *(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*

7.6 The Applicant contends that as it made its application before this date, its application should be considered against the previous Regulations. The Applicant states that "*The amending regulations introduced express transitional provisions, which require that any application submitted before 23 June 2025: "must be determined in accordance with the provisions of the 2013 Regulations as they had effect immediately before that date."* The Committee considered that the Applicant is referring to Regulation 25A.

7.7 Regulation 25A states that:

> *"In the case of an application made before 23rd June 2025 to which regulation 25(1)(a) applied (applications for inclusion in a*

pharmaceutical list by a person not already included), notwithstanding the repeal of regulation 25(1)(a), that application is to be determined in accordance with regulation 25(1) as it had effect on 22nd June 2025."

7.8 The Committee noted that in addition to the amendments outlined at 7.5 above, the market entry route for distance selling applications lapsed on 23 June 2025. The Committee considered that Regulation 25A applies insofar as it is making clear that any applications that were received before 23 June 2025 but determined after this date, should still be determined as if market entry for distance selling applications are open. The Committee therefore considered the Applicant's interpretation to be incorrect.

Regulation 31

7.9 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).

7.10 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. This was supported by the Applicant's comment in its appeal that "*We note that the PSRC determined that Regulation 31 does not apply because there are no existing pharmacies at or adjacent to the proposed premises. We accept this outcome and raise no objection".*

7.11 The Committee noted that the Commissioner in its decision report had concluded that "*The proposed pharmacy is not on the same site or adjacent to*

any other pharmacy, therefore this regulation is not engaged" and that no party had sought to dispute this finding.

7.12 The Committee therefore determined that it was not required to refuse the application under the provisions of Regulation 31.

Regulation 25

7.13 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."

7.14 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)

7.15 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)

7.16 As far as Regulation 25(2)(a) is concerned, 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. This was supported by the Applicant's comment in its appeal "*We acknowledge and agree with the PSRC's findings that the proposed premises are not collocated with a primary medical services provider and therefore this regulation is not applicable".*

7.17 The Commissioner it is decision report stated that "*The proposed site is not on the same site or in the same building as the premises of a provider of Primary Medical Services with a patient list. Therefore, this regulation does not apply for this application*" and no party had sought to dispute this finding.

7.18 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)

7.19 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.

7.20 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.

7.21 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.

7.22 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.

7.23 The Committee has sought evidence within the application, appeal, representations and observations in order to satisfy itself that it is appropriate to grant the application, the absence of which would require it to reject it. The Committee noted the Applicant's comments that it currently provides private services remotely but considered this has no bearing on the merits of this application and it would be unfair to treat the Applicant differently to any other applicant.

7.24 The Committee considered how the Applicant would provide essential services without interruption.

7.25 The Commissioner was "*not satisfied that pharmacy procedures for the pharmacy are likely to secure the uninterrupted provision of essential services".*

7.26 In its appeal, the Applicant states that "*Guaranteed pharmacist presence during all operating hours…A deputy (Second) pharmacist arrangement to ensure continued service if the RP is unavailable…Responsible Pharmacist Role…The RP will be physically present during core hours, supported by a deputy pharmacist during absences to ensure uninterrupted service".* The Committee also noted that "SOP_DSP12" and "SOP_DSP13" state that "*Staff Shortages…Activate relief/locum staff from pre-approved list. Contact second pharmacist".*

7.27 With regard to services being available to persons anywhere in England, the Commissioner was not satisfied that they would.

7.28 In its appeal, the Applicant states that it has measures to "*ensure that essential services will be provided…nationwide*". The Committee also noted that the screenshot titled "SP new NHS Web Page" states that "*We are regulated by the General Pharmaceutical Council (GPhC) and commissioned by NHS North East London Integrated Care Board (ICB) to provide NHS pharmaceutical services to patients across England".*

7.29 The Committee considered how the Applicant would provide pharmaceutical services without face to face contact.

7.30 The Commissioner was not satisfied that "*the applicant is likely to satisfy the criteria as set out in the Terms of Service of Pharmacists for the provision of all essential services* [sic] *without face-to-face contact".*

7.31 In its appeal, the Applicant states that "*Our DSP model is fully designed around remote provision. It includes: Secure remote consultations via telephone, video link, and digital communication. Our communication system is powered by Cisco Webex which allows for phone, conference calls, and telemedicine. Webex provides a call history and recording as will email the patient care team with any messages left on the answer phone. We use Outlook as our email preferences…No services will be delivered in person at the premises".*

7.32 The Committee also noted the Applicant's "Draft practice leaflet" states that "*We do not offer walk-in services. All services are provided remotely in line with GPhC regulations*".

7.33 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.

7.34 In its application, which the Committee acknowledged was completed before the regulatory amendments came into force, the Applicant had stated that it intended to provide:

7.34.1 "*New Medicines Service*

NHS Community Pharmacy Smoking Cessation Advanced Service

NHS Pharmacy Contraception Service – Ongoing Supply and Initiation of Oral Contraception

Lateral Flow Device (LFD) Tests Supply Service

Home Delivery Service

Stop Smoking Service

Emergency Supply Service."

7.35 The Committee noted that some of these services are not Directed services.

7.36 The Committee noted that the Applicant had stated "*Where applicable, Specials Pharma Ltd will provide Advanced Services (e.g., New Medicine Service) through remote consultation only, with no in-person element*". As a result of the amendment, the Committee noted that the Applicant would not be able to provide any pharmaceutical services at its premises.

7.37 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.

7.38 The Committee was satisfied that the provision of essential services would be without interruption, 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.

7.39 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.

7.40 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:

7.40.1 Dispensing of drugs and appliances

7.40.2 Urgent supply without a prescription

7.40.3 Preliminary matters before providing ordered drugs or appliances

7.40.4 Providing ordered drugs or appliances

7.40.5 Refusal to provide drugs or appliances ordered

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

7.40.7 Disposal service in respect of unwanted drugs

7.40.8 Promotion of healthy lifestyles

7.40.9 Prescription linked intervention

7.40.10 Health campaigns

7.40.11 Signposting

7.40.12 Support for self-care

7.40.13 Discharge medicines service

7.40.14 Websites and health promotion zones

7.41 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

7.42 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.

7.43 The Commissioner found that "*No information has been provided for the following regulations:…Paragraph 7(3) of Schedule 4".*

7.44 In its observations, the Applicant states that "*Paragraph 7(3) – Patients' Entitlement to Exemption or Remission from NHS Charges Regulatory Requirement: Arrangements to advise patients regarding NHS prescription charges, exemptions, and remission schemes. This will be automated at the point of any transaction via a patient portal and information provided during a patient instillation both by phone and with documents sent via email as per appeal documents sent 12 November 2025 6. PCT02 New Patient Installation and on the patient portal.*

Pharmacy Arrangements:

Patients are provided with information on NHS prescription charges at the instillation, via the website, on the patient portal and the point of ordering.

Exemption categories are explained where relevant.

Patients are signposted to the NHS Low Income Scheme when appropriate.

Declarations are obtained and recorded in accordance with NHS requirements".

7.45 The Committee had regard to the "6. PCT02 New Patient Installation" document provided with the Applicant's appeal however it found no specific reference to how evidence will be sought and provided about the patients' entitlement to exemption or remissions from NHS Charges.

7.46 The Committee 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.

Providing ordered drugs or appliances

7.47 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).

7.48 The Commissioner found that "*No information has been provided for the following regulations:…Paragraph 8(1) of Schedule 4".*

7.49 In its observations, the Applicant states that "*Paragraph 8(1) – Delivery of Prescriptions (including Cold Chain and Controlled Drugs) Regulatory Requirement: Safe and secure delivery of NHS medicines to patients, including temperature sensitive medicines and Controlled Drugs. This has been answered. We use 2 courier services (Primary and back up for each other), both of whom are tasked with the safe custody of the medicines (i.e. end to end audit of the product to show who, or where and when product was handled, no safe storage and only with a PIN or ID) as outlined Initial Application on 10 June 2025 General Statement 1. Dispensing Medicines and further information given in appeal documents sent 12 November 2025 3. Royal mail latest Invoice, 4. DPDLocal-Terms-and-Conditions. All packaging is validated (to ensure that they can do what the company says they can. Ie keep products at label temperature) prior to good being sent and both services offer a "Medication Service". Thus far without any issue.*

Pharmacy Arrangements:

Medicines are delivered using secure, tracked delivery services.

Patient identification is needed and delivery is only to a named patient in their hands and not delivered to a "safe" location.

Cold chain products are packed in validated temperature-controlled packaging.

Temperature monitoring processes are in place.

Controlled Drugs are supplied and delivered in accordance with Misuse of Drugs legislation.

Procedures are in place to manage failed or returned deliveries".

7.50 The Committee had regard to the documents highlighted by the Applicant along with the other information provided with its application and appeal.

7.51 The Committee noted that the "General statements of how the pharmacy will operate without face-to face contact" document provided with its application states that "*Dispensed items will be packaged securely and delivered by a tracked, insured courier service to the patient's address. Packages will be signed only and cannot be left "safe" as per contracted services. Delivery confirmation (e.g. signature, photo evidence, or GPS) will be logged securely. Delivery information is kept with the dispatch records as proof".*

7.52 Further, "SOP_DSP12" states that:

"*Power Outage…Cold-chain items monitored using battery-powered thermometers (Monitors have back up batteries). (Do not use or open fridge until such time as power back on)."*

Courier or Delivery Disruption…Switch to alternative contracted courier (e.g., from Royal Mail to secondary parcel service, APC, DPD, Polar Speed and vice versa).

For local urgent deliveries, use pharmacy-owned vehicle or staff courier.

Notify patients via SMS/email of delays and rescheduled deliveries. Document all temporary changes for audit trail."

7.53 The "*QCP07 Risk Management"* document states that *"HIGH RISK from GDP partners High Importance to GDP and High risks.*

This could include MIA and distributors and some WDA whose operation may be extensive.

Transport arrangement if cold chain

Temperature control/Mapping

Safe storage arrangement for CDs

Export arrangements."

7.54 Further, in the Applicant's 14 days comments to the Commissioner, it states that "*Currently medicines are sent via royal mail overnight (Click and Drop) and MUST be signed for and not left safe. These are contractual obligations that the service provider, Royal Mail, must adhere to. Staff check on a daily basis on the Royal Mail portal to ensure all deliveries are made and will flag any incidents for the supervisor to manage. Evidence of the patient's signature and a picture of the front door are provided as proof of delivery and remain for up to 6 months on the portal. Non-deliveries are returned back to the pharmacy. The Pharmacy also offers uplift should the patient wish product to be disposed of".*

7.55 Whilst appreciating that the information had been provided in relation to "courier or delivery disruption", the Committee could not ignore the Applicant's reference to use of a pharmacy-owned vehicle or staff courier. The Committee noted that no information had been provided to demonstrate how the cold chain would be maintained or monitored in this instance, for example, if there was a breach in the cold chain, how they would become aware of this and what the process would be for the return of any medication where the integrity of the cold chain had been breached. The Committee considered the reference to a power outage to be in relation to the fridge at the pharmacy's premises and not a refrigeration unit in the pharmacy owned vehicle.

7.56 The Committee further noted that whilst the Applicant had provided some information in relation to the tracking service available for Royal Mail, it had not provided information to demonstrate what would happen in the event of a failed or missed delivery of a controlled drug, whether by courier or by the pharmacy's own driver or staff courier. The Committee noted there was no information regarding a tracking system and an explanation given as to how this would

allow the Applicant to ensure that it is aware on a regular basis of the safe progress of the dispensed items to the patient sent via courier. The Committee also noted that no assurance had been provided to outline the measures that will be in place to ensure controlled drugs are kept secure when out for delivery for example if the items will be stored in a locked delivery vehicle and not left unattended.

7.57 The Committee was therefore not satisfied that the Applicant had provided information sufficient to show that there would be compliance with paragraph 8(1) of Schedule 4.

7.58 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.

7.59 In the application, the Committee noted that in response to the question as to whether they were undertaking to provide appliances, the Applicant had left this box blank and had not provided any information on this point in its appeal.

7.60 In the "Draft Practice Leaflet" provided with the appeal, it states that "*Our Services includes …Dispensing of NHS and private prescriptions for medicines and appliances…".* However, the Committee noted that no information had been provided to explain how a registered pharmacist would measure / fit any appliances which required measuring / fitting, in a distance selling setting.

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

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

7.63 The Commissioner found that "*No information has been provided for the following regulations: …Paragraph 8(15) of Schedule 4".*

7.64 In its observations, the Applicant states that "*Paragraph 8(15) – Suitable Containers for Delivered Prescriptions Regulatory Requirement: Medicines must be supplied in containers suitable to protect the contents during delivery. All packaging will be either original or in pharmacy validated containers as in line with current practices. Patient confidentiality will be maintained in appeal documents sent 12 November 2025 SOP_DSP11 - Safeguarding and Data Protection.*

> *Pharmacy Arrangements:*
>
> *All delivered medicines are packaged in tamper-evident, protective containers.*
>
> *Packaging maintains confidentiality of patient information.*
>
> *Materials are selected to minimise damage, contamination, and temperature exposure*."

7.65 The Committee was of the view that the Applicant had not provided sufficient information to demonstrate what outer packaging it would be using and how this would be suitable for posted/delivered items to ensure that the integrity of the medication would be maintained. There was no explanation as to what constitutes a 'protective container'.

7.66 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.

Disposal service in respect of unwanted drugs

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

7.68 The Commissioner found that *"Limited information has been provided for the following regulations: Paragraph 13 of Schedule 4".*

7.69 In its observations, the Applicant states "*Paragraph 13 – Disposal of Unwanted Drugs Regulatory Requirement: Arrangements for safe disposal of unwanted medicines. This is a service currently provided and has been asked and answered with Initial Application on 10 June 2025 3. Disposal of Unwanted Medicines. This was the further answered in the appeal documents sent 12 November 2025 24. Stericycle Contract and 23. Screenshot Expired and destroyed stock.*

> *Pharmacy Arrangements:*
>
> > *Patients are able to return unwanted or expired medicines for safe disposal which currently happens*
> >
> > *Controlled Drugs are handled and destroyed in accordance with legal requirements.*
> >
> > *Waste contractors are authorised and audited".*

7.70 In the "Draft Practice Leaflet" and the "SP new NHS Web Page", it lists the services the pharmacy will provide and both state that "*Our Services includes… Disposal of unwanted medicines (free of charge – return by post or courier)*" and "*Our Services… Safe disposal of unwanted medicines (on request and in accordance with regulations)*" respectively.

7.71 The "General statements of how the pharmacy will operate without face to face contact" document provided with the application states that "*Disposal of Unwanted Medicines*

> *Patients can request prepaid, tamper-proof returns envelopes or book a courier pick-up (where appropriate).*
>
> *Returned medicines will be disposed of according to waste management SOPs under pharmacist supervision.*

Patients will be able to track all prescription on a app (In design) once new software is implemented".

7.72 However, the Committee noted that whist the Applicant had explained how medication could be delivered to the pharmacy and had provided a copy of waste management agreement, it had not provided a copy of the waste management SOP it had referred to or explained how it would safely dispose of any returned medication.

7.73 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 paragraphs 13-15 of Schedule 4.

Prescription linked intervention

7.74 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.

7.75 The Commissioner did not provide a conclusion in relation to paragraph 17 of Schedule 4 in its decision. However, in its observations, it states that "*Paragraph 17 – Prescription linked intervention – no information provided*".

7.76 In response, the Applicant states that "*Paragraph 17 – Prescription-Linked Interventions Regulatory Requirement: Provision of interventions linked to the supply of prescriptions. This has not been answered however the pharmacy uses Titan PMR which allows for recording and management of interactions*

Pharmacy Arrangements:

Pharmacists provide counselling on new and existing medicines.

Adherence support and side-effect management advice is offered.

Interventions are recorded as part of the dispensing process".

7.77 However, the Committee noted that the Applicant had not explained how it would specifically assess whether persons require prescription linked intervention advice because they have diabetes, are at risk of coronary heart disease, smoke or are overweight and therefore, the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 17 of Schedule 4.

Signposting

7.78 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.

7.79 The Commissioner found that "*No information has been provided for the following regulations: …Paragraph 19 & 20 of Schedule 4".*

7.80 In its observations, the Applicant states that "*Paragraphs 19 & 20 – Signposting Regulatory Requirement: Signposting patients to other NHS or local services where appropriate. A general statement sent with the Initial Application on 10 June 2025 5. Support for Self-Care provided a statement as to Sign posting.*

Pharmacy Arrangements:

Patients are directed to GP, urgent care, or specialist services as needed.

Contact details and access routes are provided clearly".

7.81 The "General statements of how the pharmacy will operate without face-to face contact" document provided with the application states that "*Support for Self-Care*

Patients may request advice on minor ailments or over-the-counter options by phone or secure online chat.

Our pharmacists are available during all core hours to provide personalised, clinically safe advice.

SOPs are in place for escalating red-flag symptoms and referrals to GP or NHS 111".

7.82 However, the Committee did not consider that these statements satisfy the requirements of paragraph 19 – 20 of Schedule 4. No further information had been provided with regard to how the Applicant was proposing to provide information to users about other health and social care providers and support organisations. 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

7.83 The Committee considered whether the Applicant had explained how it will provide advice and support to people caring for their families.

7.84 The Commissioner found that *"Limited information has been provided for the following regulations: …Paragraph 21 & 22 of Schedule 4".*

7.85 In its observations, the Applicant states that "*Paragraphs 21 & 22 – Support for Self-Care Regulatory Requirement: Support for patients to self-care and self-manage conditions. This is on the new website which has not been published on the internet as it includes NHS services not currently being offered and would therefore be irresponsible as it will cause confusion. Patient will also get all this information during "first contact" as we provide an instillation followed by back up information. PCT02 New Patient Installation included in appeal documents sent 12 November 2025.*

Pharmacy Arrangements:

Advice is provided for minor ailments and appropriate OTC use.

Patients are advised on when to seek further medical attention.

Patients have access to a pharmacist".

7.86 The Committee had regard to the "PCT02 New Patient Installation" document highlighted by the Applicant, however it found no information that demonstrates compliance with paragraphs 21 – 22 of Schedule 4 within the context of patient interactions beyond first contact. The Committee noted that no further information had been provided to demonstrate how the Applicant would be providing information about advice and support to people caring for their families.

7.87 The Committee was therefore not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 21 – 22 of Schedule 4.

Other considerations

7.88 The Committee noted that the Commissioner had refused the application on the basis that they were not satisfied that the Applicant had provided information to show that there would be compliance with certain Terms of Service. The Committee, taking into account the additional information provided by the Applicant on appeal considered these areas of the Terms of Service in more detail.

Urgent supply without a prescription

7.89 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.

7.90 The Commissioner found that "*No information has been provided for the following regulations: Paragraph 6 of Schedule 4*".

7.91 In its observations, the Applicant states that: *"Paragraph 6 – Urgent Supply without a Prescription Regulatory Requirement: Provision of emergency supplies at the request of a patient or prescriber in accordance with the Human Medicines Regulations…All pharmacist are trained to provide best judgement and ensure that assessments are made. Patient identity verification is provided via a patient instillation for all new patients as evidenced appeal documents sent 12 November 2025 6. PCT02 New Patient Installation.*

Pharmacy Arrangements:

Emergency supplies are provided following a pharmacist-led clinical assessment.

Identity of the patient is verified prior to supply.

Quantity supplied complies with legal limits.

Full records are maintained, including reason for supply and prescriber details where applicable.

Patients are advised to obtain a prescription as soon as practicable."

7.92 Based on the information provided, the Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 6 of Schedule 4.

Refusal to provide drugs or appliances ordered

7.93 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 regime 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.

7.94 The Commissioner found that "*No information has been provided for the following regulations: … Paragraph 9(4) of Schedule 4".*

7.95 In its observations, the Applicant states that "*Paragraph 9(4) – Repeatable Prescription Checks (Second and Further Instalments) Regulatory Requirement: Appropriate checks prior to dispensing repeat instalments of repeatable prescriptions. This has been answered with the Initial Application on 10 June 2025 2. Repeat Dispensing. Titan PMR has a repeat dispensing functionality with the patient portal providing information and reminders directly to the patient. Furthermore Titan PMR will provide all the management services required including messaging as in appeal documents sent 12 November 2025 7. Titan License Renewal 2023*

Pharmacy Arrangements:

Before each repeat supply, patients are contacted to confirm continued need.

Changes to medicines, health status, or adverse effects are assessed.

Pharmacist approval is required prior to release of further instalments".

7.96 The Committee noted that the "General statements of how the pharmacy will operate without face-to face contact" document provided with the application states that:

"*Repeat Dispensing*

Patients can nominate the pharmacy for EPS Repeat Dispensing.

Medication supply is automatically monitored and coordinated, with review reminders issued via text or email.

Medication reviews and reauthorisations will be arranged with prescribers and discussed with patients remotely".

7.97 Further, the "Draft patient leaflet" provided with the appeal states that "*Our Services includes…Advice on medicines, side effects, and interactions".*

7.98 The Committee was therefore 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

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

7.100 The Commissioner found that *"No information has been provided for the following regulations: …Paragraph 10(1) of Schedule 4".*

7.101 In its observations, the Applicant states that "*Paragraph 10(1) – Advice on the Benefits of Repeat Dispensing Regulatory Requirement: Provision of advice to patients regarding repeat dispensing. Information is provide [sic] by our patient instillation and on the website and portal as appeal documents sent 12 November 2025 6. PCT02 New Patient Installation*

Pharmacy Arrangements:

Patients are informed about repeat dispensing during onboarding (Instillation) and reviews.

Benefits such as convenience, continuity of care, and reduced GP visits are explained.

Information is provided via digital and written communications at instillation but also on website and patient portal."

7.102 The Committee was therefore satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 10(1) of Schedule 4.

Promotion of healthy lifestyles

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

7.104 The Commissioner found that "*No information has been provided for the following regulations: … Paragraph 18 of Schedule 4"* and *"Limited information has been provided for the following regulations: … Paragraph 16 of Schedule 4".*

7.105 In its observations, the Applicant states that "*Paragraph 16 – Healthy Lifestyles Regulatory Requirement: Promotion of healthy lifestyle choices. This has been answered with the Initial Application on 10 June 2025 4. Public Health Promotion*

Pharmacy Arrangements:

Patients are provided with advice on smoking cessation, diet, exercise, and alcohol consumption.

Health promotion information is shared digitally.

Patients are signposted to relevant NHS services where appropriate".

7.106 The "General statements of how the pharmacy will operate without face-to face contact" document provided with the application states that "*Public Health Promotion*

Health promotion materials will be delivered digitally (email, SMS, website), and printed leaflets may be included with deliveries.

Campaigns (e.g. smoking cessation, COVID-19 awareness) will be published on our website and shared directly with patients.

Additionally, information can be shared on the app (In design) directly into patients own login.

Additional support can be provided by phone for patients with low digital literacy".

7.107 The Committee was therefore satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 16 – 18 of Schedule 4.

Health campaigns

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

7.109 The Commissioner found that "*No information has been provided for the following regulations: … Paragraph 18 of Schedule 4".*

7.110 In its observations, the Applicant states that "*Paragraph 18 – Public Health Campaigns Regulatory Requirement: Participation in NHS public health campaigns. This has been answered with the Initial Application on 10 June 2025 4. Public Health Promotion.*

Pharmacy Arrangements:

The pharmacy supports national and local NHS public health campaigns.

Campaign materials are shared with patients through digital channels".

7.111 The "General statements of how the pharmacy will operate without face-to face contact" document provided with the application states that "*Public Health Promotion*

Health promotion materials will be delivered digitally (email, SMS, website), and printed leaflets may be included with deliveries.

Campaigns (e.g. smoking cessation, COVID-19 awareness) will be published on our website and shared directly with patients.

Additionally, information can be shared on the app (In design) directly into patients own login.

Additional support can be provided by phone for patients with low digital literacy".

7.112 The Committee was therefore satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 18 of Schedule 4.

Discharge medicines service

7.113 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.

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

7.115 The Commissioner found that "*No information has been provided for the following regulations: … Paragraph 22B & 22C of Schedule 4".*

7.116 In its observations, the Applicant states that "*Paragraphs 22B & 22C – Discharge Medicines Service (DMS) Regulatory Requirement: Provision of the Discharge Medicines Service where the pharmacy is opted in. Whilst this question has not been answered specifically, it has been indirectly with appeal documents sent 12 November 2025. We cannot currently access many of the services as we will require access to NHS mail, Pharma Outcomes Refer-to-Pharmacy which can only be done with an OCS code. Whilst access to Summary Care Records is available vis Titan PMR. Titan PMR also offers a DMS feature allowing tracking, management and recording of Discharge Medication of service. (Titan PMR contracted provided with appeal documents sent 12 November 2025)*

Pharmacy Arrangements:

The pharmacy accepts and processes DMS referrals from NHS Trusts.

Medicines reconciliation is undertaken by a pharmacist.

Patients are contacted post-discharge to provide counselling and resolve issues".

7.117 Based on the information provided, the Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 22B and 22C of Schedule 4.

7.118 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

7.119 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).

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

7.120.1 confirm the Commissioner's decision;

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

7.120.3 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.

7.121 In those circumstances, given that the Committee had additional information before it, which was not available to the Commissioner, the Committee determined that the decision of the Commissioner must be quashed.

7.122 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.

7.123 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.

7.124 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 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