12 September 2025

REF: SHA/26626

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APPEAL AGAINST NORTH EAST LONDON ICB DECISION TO REFUSE AN APPLICATION BY ALPHA MEDICS LIMITED FOR INCLUSION IN THE PHARMACEUTICAL LIST AT 292 LODGE AVENUE, DAGENHAM, ESSEX, RM8 2HF 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 granted.

A copy of this decision is being sent to:

Alpha Medics Limited (represented by Rushport Advisory LLP)
North East London ICB
Alvin Rose Pharmacy
Hannigan Pharmacy
Mayors Chemist
Brittania Pharmacy
Laville Limited (represented by Gordons Partnership Solicitors)
Maplestead Pharmacy

NHS Resolution

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1 The Application

By application dated 9 October 2024, Alpha Medics Limited ("the Applicant") applied to North East London ICB ("the Commissioner") for inclusion in the pharmaceutical list at 292 Lodge Avenue, Dagenham, Essex, RM8 2HF under Regulation 25. In support of the application it was stated:

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 stated

1.1 "Drug Tariff part IX* (*Except items that require measuring or fitting).

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

1.2 "Not applicable as no other pharmacy in same or adjacent premises."

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

1.3 "Application not on the same site or in the same building as the premises of a provider of primary medical services with a patient list."

Further Information in Relation to Provision of Essential Services in Accordance With the Regulatory Requirements for Distance Selling Pharmacies

1.4 Please find below information to 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 "The responsible pharmacist (RP) will remain on the premises during the opening hours of the pharmacy, in accordance with the RP regulations as outlined by the GPhC. Dispensing of medications will be completed during all of the time that the pharmacy is open and will be completed under the supervision of a pharmacist. During the opening hours of the pharmacy any patient can request support of advice from the pharmacist, to be delivered via the telephone or video links. These consultations will take place in

a private office, located away from the main dispensary to allow for a truly confidential consultation. Patients from anywhere in the UK can request NHS essential services by phone, email, website and writing during the entire proposed opening hours, without direct face-to-face contact. All NHS essential services will be delivered during the full opening hours of the pharmacy, without interruption and without face-to-face contact between the patient or their representative and the pharmacy or pharmacy staff. There will be no patient contact on the site of the pharmacy.

1.6 Listed below are statements highlighting provisions that will be made to ensure all essential services are delivered to anyone in England without any face-to-face contact:

Discharge Medicines Service (DMS)

1.7 The DMS will be provided to all referred patients. The three stages will be completed via either telephone or video link to the patient, to ensure that there is no face-to-face contact. Throughout the DMS service, the pharmacist will use their clinical judgement when considering recommendations or actions that should be completed. The consultation will be completed away from the main dispensary and in a private office to ensure adequate confidentiality when completing this service remotely.

Dispensing Medicines

1.8 Prescriptions can be received by the pharmacy via EPS and/or post from patients anywhere in the UK. There will be no collection of prescriptions from surgeries and prescriptions will not be accepted if delivered to the unit by the patient themselves, as there will be strictly no patients on the pharmacy site. Dispensed prescriptions will be delivered by two means, delivering driver and postal courier.

1.8.1 Patients within a 35-mile radius of the pharmacy (extended at the discretion of the pharmacist) will have their prescription delivered to them, including fridge and controlled drug items.

1.8.2 If the patient is outside of this radius, a nominated courier will be used to delivery [sic] the medication to them, including a cold-chain courier for fridge items and a tracked delivery service for controlled drugs.

1.8.3 Specialist Cold Chain Courier – ‘PDQ Specialist Courier Services’ will be used. They deliver nationally.

1.8.4 Specialist Controlled Drug Courier – ‘PDQ Specialist Courier Services’ will be used. They deliver nationally.

1.9 Should the exemption status not be signed by the patient/representative, pharmacy staff must confirm exemption via telephone or email and sign accordingly. NHS charges will be collected electronically, over the phone or via the website. No cash or transactions will be permitted on the premises.

Repeat Dispensing

1.10 Once a specified number of repeat prescriptions have been issued, the prescription will be dispensed and delivered to the patient in the same manner as the above. Advice about the benefits of repeat dispensing will be given to patients who have stable, long-term health conditions and require regular medication, via the telephone or video link, to advise that they discuss repeat dispensing with their GP surgery.

Disposal of Unwanted Medicines

1.11 Patients wanting to return unused medication to the pharmacy will be able to do so via the pharmacy delivery driver (for patients within the specified radius) or the courier, the service being provided and funded by the pharmacy. Packaging equipment will be sent to the patients and details of how to book a collection (if in the specified radius) or to obtain a free courier label, will be clearly available on the pharmacy website. The return of medicines is to be completed solely via remote means; patients will not be able to physical bring them to the pharmacy. Once the medicines have been returned to the pharmacy, the unwanted medicines will be sorted and places in disposal units, ready for a specialist waste management company to collect.

Promotion of Healthy Lifestyles and Public Health Campaigns

1.12 All patients will be asked to fill out a healthy lifestyle questionnaire, which can be returned via email, post or through a form on the website. Once the pharmacy has received this questionnaire, results will be analysed, relevant patients contacted and provided with additional information and support. Patients can also be identified through the type of medication dispensed; specific material regarding their condition can be provided, in the form of a leaflet with their medication or a phone call/video call between the pharmacist and the patient. On the pharmacy website, there will be a specific section related to healthy lifestyles, public health campaigns, medication related FAQs, self-care advice and condition-related FAQs. Patients can also telephone/arrange a video call to discuss anything in more detail, during the opening hours of the pharmacy. The pharmacy will pro-actively take part in national health campaigns to promote public health messages to patients. Leaflets will be sent to patients with their prescriptions during specific target campaign periods.

1.13 All of the NHS essential services listed above will be provided without face-to-face contact during all of the pharmacy opening hours, to allow for the uninterrupted provision.

1.14 No services, both NHS and private, will be conducted physically on the premises, therefore there is no risk of providing an essential service physically on the premises. There are currently no private services offered. The only NHS advanced service proposed is the New Medicines Service (NMS), which will be completed entirely via telephone and/or video link."

2 The Decision

The Commissioner considered and decided to refuse the application. The decision letter dated 29 May 2025 states:

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

2.1 "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.

2.2 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:

2.3 Primary Care Appeals

NHS Resolution

8th Floor

10 South Colonnade

Canary Wharf

London

E14 4PU”

DECISION REPORT

2.4	“CAS reference number	CAS-350601-F9V5R0
2.5	Name of applicant	Alpha Medics Ltd
2.6	Fitness to practise	Approved for inclusion
2.7	Address of proposed premises	292 Lodge Avenue, Dagenham, Essex, RM8 2HF
2.8	Status of location	Non-controlled locality
2.9	Relevant regulations and guidance	Regulations 25 – distance selling premises Regulation 31 – refusal: same or adjacent premises DH market entry guidance chapter 11

2.10 Additional information

2.10.1 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.

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

2.10.3 None identified.

2.11 Interested parties notified of the application – Representation Submitted:

2.11.1 Alvin Rose Chemist, 606 Longbridge Road, RM8 2AJ – **Appeal rights given if granted.**

2.11.2 Britannia Pharmacy, Barking Community Hospital, Upney Lane, IG11 9LX – **Appeal rights given if granted.**

2.11.3 Brittania Pharmacy, 13 – 15 Faircross Parade, IG11 8UN – **Appeal rights given if granted.**

2.11.4 Brittania Pharmacy, Thames View Health Centre, Bastable Avenue, IG11 0LG – **Appeal rights given if granted.**

2.11.5 Brittania Pharmacy, 453 Porters Avenue, RM9 4ND – **Appeal rights given if granted.**

2.11.6 Hannigan, 240 Bennetts Castle Lane, RM8 3UU – **Appeal rights given if granted.**

2.11.7 David Lewis Chemist, 16 Porters Avenue, RM8 2AQ – **Appeal rights given if granted.**

2.11.8 Mayors Chemist, 214 Ripple Road, IG11 7PR – **Appeal rights given if granted.**

2.11.9 Maplestead Pharmacy, 454 Lodge Avenue, RM9 4QS – **Appeal rights given if granted.**

2.11.10 Day Lewis Pharmacy, 359 Ripple Road, IG11 9PN – **Appeal rights given if granted.**

2.11.11 NELICB – No appeal rights given as not a pharmacy.

2.12 Interested parties notified of the application – Representations not submitted:

2.12.1 Hedgemans Pharmacy, 483 Hedgemans Road, RM9 6BU

2.12.2 LMC

2.12.3 Barking & Dagenham HWB

2.12.4 Healthwatch

2.13 Additional information

2.13.1 The London Region PSRC has determined that there is enough information to deal with this application without holding an oral hearing.

2.14 The following comments were received:

2.15 Britannia Pharmacy

2.15.1 Barking Community Hospital, Upney Lane, IG11 9LX

2.15.2 13-15 Faircross Parade, Upney Lane, IG11 8UN

2.15.3 Thames View Health Centre, Bastable Avenue, IG11 0LG

2.15.4 “Our contention is that the application, made under regulation 25 of the National Health Service (pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (“the Regulations”) should not be granted as it does not meet the regulatory criteria for distance selling premises as set out in Regulation 25 of the Regulations below:

(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) (b) unless [F2NHS 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 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.

2.15.5 The application contains a very brief outline of the way the service will be provided and a non exclusive list of the omissions includes:

2.15.6 There is no information as to how the pharmacy would operate and ensure uninterrupted services in the absence of the Responsible Pharmacist. Based on the information before it, the ICB cannot be satisfied that the provision of services would be without interruption.

2.15.7 For local delivery of cold chain medication - there is no detail on how this will be effected safely; for example, the Applicant has not provided any information in relation to the monitoring of temperatures of cold-chain medicines during transit by the local delivery driver and how the driver would be alerted to any changes in temperature which could compromise medicines.

2.15.8 For local delivery of CDs - the Applicant has not provided information sufficient to show that controlled drugs will be kept secure during delivery by the local delivery driver.

2.15.9 There is inconsistent information about service delivery as the application indicates that the NHS Pharmacy First advanced service will be provided but the narrative states that the only service that will be provided is the NMS. Accordingly, no details about the provision of Pharmacy First have been given.

2.15.10 For the reasons above, the ICB cannot be certain that there will be an uninterrupted provision of essential services nor 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.

2.15.11 In all the circumstances the application should be refused.

2.16 Britannia Pharmacy – 453 Porters Avenue, Dagenham, Essex, RM9 4ND

2.16.1 "We currently run a pharmacy which is located at 453 Porters Avenue Dagenham, Essex, RM9 4ND.

2.16.2 This pharmacy has been under our ownership since 2007 and operates between the hours of 9AM to 6PM Monday to Friday and 9AM to 1PM on a Saturday.

2.16.3 In reference to the application form as submitted by Alpha Medics Limited, the applicant has dismissed the posed question, of “5. Application in relation to premises that are in close proximity to other listed chemist premises” responding:

2.16.4 “In my/our view this application should not be refused pursuant to Regulation 31 for the following reasons; Not applicable as no other pharmacy in same or adjacent premises.

2.16.5 Our Britannia branch is located a mere 83 yards from the site or a walk of 1 minute duration as cited by google maps. (map provided in letter)

2.16.6 Additionally, Maplestead Pharmacy is located on the same side of the road and is a 3 minute car journey away from the proposed location.

2.16.7 We also note a lack of submitted Standard Operating Procedures (SOPs) by the applicant.

2.16.8 In view of all of the above, we hope you will refuse the application.

2.16.9 NB: Photos are available with the comments for this application available to view in the attachment.

2.17 Alvin Rose Chemist

2.17.1 I would like to raise a strong objection to this application on the following basis:

2.17.2 Proximity to local bricks and mortar pharmacies.

2.17.3 I believe from the postcode that this pharmacy hub will be in a region already concentrated heavily with pharmacies – there are at least 8 face to face retail pharmacies within around a 1 mile radius. The flow of foot traffic towards a lot of these pharmacies will most likely pass this hub and therefore result in the loss of patients to this online system, which would be detrimental to all these local businesses.

2.17.4 Location

2.17.5 I have attached a photo of the site of where the hub is planning to open – you can clearly see it is a small premises, typical of [sic] a face to face retail community pharmacy, within a row of shops of a small retail parade, within a residential area with homes and community centres. This will confuse locals as they will not be able to walk in with their prescription, and that it may be more appropriate to have a hub like this in a more industrial area.

2.17.6 Also being in a small community like this amongst other “open” shops, there has been previous evidence to show a significant reduction in dispensing volume for local pharmacies when a distance selling pharmacy opened nearby, with corresponding spike in dispensing at the DSP. This is a huge concern as DSPs are supposed to be national contracts, and having a hub in such a small shopping area will give the community the opinion that they provide services locally this adds to the confusion.

2.17.7 Cost of running my pharmacy

2.17.8 I want to highlight that margins are small and a drop of 15-120% in prescription volume in community pharmacy would lead to losses with redundancies and closure of the community pharmacy. If this DSP application is successful, the impact will lead to reduction of some of the community pharmacies opening hours by even up to 15-20 hours a week just to maintain solvency.

2.17.9 NB: The photo referred to in the comments for Alvin Rose Chemist are available in the attachments.

2.18 David Lewis

2.18.1 I am writing on behalf of David Lewis Pharmacy to formally object to the application submitted by Alpha Medics Ltd for the establishment of Distance Selling Premises (DSP) at Lodge Avenue, Dagenham. We are a long-standing community pharmacy that has served this area for decades, and we have serious concerns about the nature and potential impact of this proposed DSP. Alpha Medics Ltd has chosen to situate their DSP within a busy parade of shops – an area designed for high public footfall and easy visibility. While DSP regulations prohibit face-to-face patient services on site, the very nature of the location – being publicly accessible, clearly branded and within reach of passing patients – means that individuals will inevitably be drawn to their services. The temptation for patients to sign up with Alpha Medics for their prescriptions and delivery needs is substantial, even though they cannot physically walk in for services.

2.18.2 This undermines the core principle of a DSP, which is intended to operate remotely and separately from public-facing environments such as from an industrial estate; this unfairly threatens the viability of existing providers. The current proposal allows Alpha Medics to operate in practice like a high street pharmacy, without adhering to the same regulatory obligations or maintaining the same community responsibilities.

2.18.3 In an area already supported by four established pharmacies – two of which, including ourselves – David Lewis Pharmacy, offer extended hours 9am-8pm, six days a week, and Sandbern Pharmacy who offer 9am-6:30pm and seven-day services – this development threatens to destabilise the delicate balance of community care. Community Pharmacies like ours depend on patient loyalty built over years, and this model, by drawing patients away through visibility and convenience, places our future viability at risk.

2.18.4 Eighty percent of business in community pharmacies today already consists of deliveries. If Alpha Medics Ltd operates in the same catchment with a visible and accessible site, it will undoubtedly divert patients from local pharmacies who have served these individuals loyally and consistently for decades. At a time when independent pharmacies are already under extreme pressure from financial constraints, increased workload, and staff shortages, this move could lead to job losses, reduced services or even the closure of pharmacies that have become pillars of the community.

2.18.5 I urge you to reconsider the appropriateness of this application. At a time when local pharmacies are already facing financial operational pressure, the introduction of a DSP in this location feels not only unnecessary, but unfair. It risks damaging the very system that has kept patients cared for and supported for years. The risk of destabilising the local pharmacy ecosystem for commercial gain sets a worrying precedent.

2.19 Day Lewis

2.19.1 Thank you for your letter dated 7th March informing us of the above application. On behalf of Day Lewis Plc, who provide pharmaceutical services from premises at 359 Ripple Road, Barking, IG11 9PN I would like to object to this application for the following reasons:

2.19.2 Firstly, we note that the applicant does not appear to have provided a full set of detailed Standard Operating Procedures ("SOPs"). This leaves significant doubt in respect of the applicant's compliance with the requirements of an application made under Regulation 25.

2.19.3 We would suggest that the ICB will not be in a position to grant this application if it is not in possession of this information in full. Whilst the applicant has provided some limited supporting information in respect of this application there are many gaps in the information provided.

2.19.4 The ICB is being asked to determine whether the application meets the regulatory tests and can therefore be approved. This can only be determined by reviewing each and every SOP in detail to ensure that:

2.19.5 (a) all essential services will be provided without interruption during the proposed opening hours of the pharmacy;

2.19.6 (b) all essential services will be made available to anybody in England who wishes to access them;

2.19.7 (c) all essential services are likely to be secured in a safe and effective manner;

2.19.8 (d) all essential services will be provided without the 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.

2.19.9 In the absence of a full set of SOPs we do not believe that the ICB can be confident that the requirements of Regulation 25(2)(b) will be met. For example:

2.19.10 (a) all essential services will be provided without interruption during the proposed opening hours of the pharmacy;

2.19.11 We note that in part 3 of the application form, the applicant lists its core opening hours as 9am- 5pm Monday to Friday. For the avoidance of doubt, these core hours are those when the applicant would be required to provide pharmaceutical services in full, in accordance with its Terms of Service as set out in Schedule 4 of the NHS (Pharmaceutical Services and Local Pharmaceutical Services) Regulations 2013 (as amended). This includes the provision of essential pharmacy services.

2.19.12 If the pharmacist is not absent between the hours of 9am to 5pm i.e. does not take a break, not only does this breach UK law which requires workers to take an uninterrupted break of at least 20 minutes within a 6 hour period, it also calls into question the extent to which services will be secured in a safe manner, in accordance with Regulation 25(2)(b)(ii). Working an 8-hour day without a break is not conducive to delivering services safely.

2.19.13 (b) all essential services will be made available to anybody in England who wishes to access them;

2.19.14 From the information provided, it is not clear how certain patient groups such as those with severe disabilities, sight loss or hearing loss will have equal access to the services offered by this pharmacy. Where services require internet or telephone access they may discriminate against patients who are not able to make use of these communication methods for any reason.

2.19.15 The ICB will be unable to satisfy themselves that all patients will be able to access essential services unless communication methods (in the absence of face to face contact) are explained in detail.

2.19.16 The nature of distance selling pharmacies is that the model relies heavily on the use of either websites or apps. Whilst telephone services may be provided, many of the services referred to by the applicant appear to rely on access to the internet. This naturally excludes patients who do not have such access, through choice or lack of availability.

2.19.17 Where these patients are discriminated against, through lack of access to the pharmaceutical services provided by this pharmacy, it cannot be said that services are available to anyone in England who wants to use them.

2.19.18 (c) all essential services are likely to be secured in a safe and effective manner;

2.19.19 Insufficient detail is provided as to how the applicant will secure services in a safe and effective manner.

2.19.20 For example:

2.19.20.1 No detailed information has been provided in respect of the delivery of temperature sensitive medicines inside or outside of the local delivery area. It is not sufficient to simply assume a courier will have suitable arrangements in place.

2.19.20.2 Very little information is provided in respect of how checks will be made in respect of those patients who are exempt from paying prescription levies. It is an obligation for the contractor to ensure robust processes are in place for exemption checking but no details of this have been provided.

2.19.20.3 The applicant's operating model relies heavily on the use of emails, telephone calls and video conferencing, yet no information has been provided in respect of how information and data governance requirements will be met. In the absence of sufficient information, the ICB cannot be satisfied that patient data will be managed safely.

2.19.21 (d) all essential services will be provided without the 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.

2.19.22 We note that the applicant intends to provide the Pharmacy First Service. At least one of the treatment options provided under Pharmacy First (the treatment of acute otitis media), requires a face to face consultation so the pharmacist can carry out an examination of the patient. This examination would presumably take place in the consultation room. If that is the case then it is clear pharmaceutical services will be provided on a face to face basis, therefore the requirements of this part of the regulations would not be met.

2.19.23 The applicant has failed to provide sufficient information to enable the ICB to be confident that the application meets the requirements of Regulation 25. In fact, the information provided clearly demonstrates that those requirements will not be met. That being the case the application must be refused.

2.20 Hannigan Pharmacy

2.20.1 Having been made aware of the recent application by Alpha Medics Ltd to open a Distance Selling Premises at 292 Lodge Avenue, Dagenham, Essex, RM8 2HF, Reference CAS-350601-F9V5R0, I would like to raise the following objections:

2.20.2 1) The application lists a retail premises for the Distance Selling Pharmacy. I have to question the reason for this choice of premises. The premises are in a parade of shops which is widely used by the local population. Patients are unlikely to know the difference between a Community Pharmacy and a Distance Selling Pharmacy and I believe this will benefit them and be detrimental to our business.

2.20.3 Whilst I believe the pharmacy will be obliged to offer a national service, it is inevitable that the pharmacy will impact the prescription businesses of all of the local community pharmacies. The funding crisis in Pharmacy has been highly publicised, with a historic number of closures community pharmacies over the last 18 months.

2.20.4 If this distance selling pharmacy impacts all the local community pharmacies, it is inevitable these community pharmacies will need to consider if they can continue to service the local population as their profitability declines with the increased competition. Many pharmacies are reported to be working in deficit, continuing to support their local patients, awaiting funding reviews by the government. My pharmacy has been providing pharmaceutical care in Dagenham for over 50 years.

2.20.5 2) As per the new Pharmacy Contract agreed in March/April 2025 Distance Selling Pharmacies can no longer provide 'Enhanced' and 'Advanced' pharmacy services. These include flu vaccinations, blood pressure checks, contraceptive services and other services. If the opening of this distance selling pharmacy impacts on the core prescription items of the existing community pharmacies and one or more of these pharmacies closes down, this will lead to a gap in pharmaceutical care, as the distance selling pharmacy will not fill this gap. Dagenham is a deprived area and provision of these services and accessibility is vital to these patients.

2.20.6 3) If the intention of the applicant is to provide a large scale pharmacy provision in essential services nationally, why has the applicant not chosen a larger premises in an industrial estate, as most distance selling pharmacies are located in these types of premises. Why a retail premises? I question the intention behind this.

2.20.7 4) There is much discussion in the media surrounding the ethics and lack of control over the provision of private services by Distance Selling Pharmacies such as weight loss management. I wonder if another online pharmacy is needed for more private services requiring monitoring, particularly in a deprived area. Perhaps a non NHS contract private pharmacy would be more appropriate.

2.20.8 5) We have been providing free prescription delivery services to the most vulnerable patients in the local population for over 50 years. It is likely we will come under more pressure to offer free delivery to patients who do not require it, as we compete to keep current patients. Distance Selling Pharmacies are required to deliver ALL prescriptions. This is likely to affect our profitability and and [sic] hence longevity in Dagenham.

2.20.9 6) SOP has not been submitted by the DSP application.

2.20.10 I urge you to consider the impact of this Distance Selling Pharmacy on the current infrastructure already in place.

2.21 Maplestead Pharmacy

2.21.1 This is my objection to the application on the basis of which I believe that this application ought not be granted.

2.21.2 I note that in the submission, the applicant has indicated that the premises are Accredited. However, when addressing the floor plan requirements, it is to be noted that the premises have not been registered with the GPhC and hence no accreditation is in Place. This contradicts the applicant's earlier statement.

2.21.3 Point 5 of the Application, requires details of "premises that are in close proximity to other listed chemist premises".

2.21.4 The Applicant has not responded to this correctly and only made a reference to same or adjacent premises, which is not the correct response.

2.21.5 My pharmacy at 454 Lodge Avenue is about 8-10 minutes' walk, and on the same side of the road and does not involve crossing any major roads.

2.21.6 Additionally, my pharmacy and the proposed location are within parades of local community retail amenities and the local population are accustomed to visiting these for their daily needs.

2.21.7 In my view, based on the distance provided above and the locations, a DSP ought not to be approved at the proposed site.

2.21.8 In addition, Britannia Pharmacy at 453 Porters Avenue is just 75 metres away, a very very short distance in fact, and much closer to the proposed site than my pharmacy and for the same reasons the application ought to be rejected.

2.21.9 I have taken note of the undertakings provided by the applicant under section 7, and I believe these are standard undertakings that are included in almost all DSP applications, and one needs to consider the practicality aspect.

2.21.10 The location being in a community setting in a parade of shops, having a shop front window, and a welcoming doorway, would encourage local residents to visit the premises, and over a period of time would nurture a degree of familiarity which would encourage patients walking into the premises to collect their prescriptions, hence defeating the purpose of this application.

2.21.11 In view of all the above, I strongly urge you not to approve this application.

2.22 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.

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

Distance Selling premises applications

2.23 Regulation 25 (1) *Section 129(2A) of the 2006 Act(c) (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 also 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) The ICB 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

(a) The premises in respect of which the application is made 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.

(b) unless the ICB 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 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."

2.24 The applicant provided information via their application. The application has been assessed; we have noted the following:

2.24.1 Paragraph 6 of Schedule 4 – No information provided

2.24.2 Paragraph 8(4) of Schedule 4 – No information provided

2.24.3 Paragraph 8(5) of Schedule 4 – No information provided

2.24.4 Paragraph 8(15) of Schedule 4 - No information provided

2.24.5 Paragraph 9(4) of Schedule 4 - No information provided

2.24.6 Paragraph 17 of Schedule 4 – Limited information

2.24.7 Paragraph 18 of Schedule 4 – Limited information

2.24.8 Paragraph 19 & 20 of Schedule 4 - No information provided

2.24.9 Paragraph 21 & 22 of Schedule 4 - No information provided

2.25 Therefore, the applicant has not provided sufficient assurances for the London Region PSRC to ensure that it meets the criteria as set out within the regulations.

2.26 It may be concluded that the London Region 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.

2.27 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.

2.28 Therefore, the London Region 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.

Decision

2.29 Regulation 31.

2.29.1 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.

2.30 Regulation 25(2)(1)(a)

2.30.1 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.

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

2.31.1 The London Region 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.

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

2.32.1 The London Region 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.

2.32.2 The London Region 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.

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

2.33 Conditions of approval for a Distance Selling Pharmacy (if granted)

2.33.1 As this application is in respect of distance selling premises, regulation 64(3) of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 applies and the inclusion in the pharmaceutical list in respect of these premises is subject to the following conditions:

2.33.1.1 you must not offer to provide pharmaceutical services to persons who are present at (which includes in the vicinity of) the proposed premises;

2.33.1.2 the means by which you provide pharmaceutical services must be such that any person receiving those services does so otherwise than at the proposed premises;

2.33.1.3 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;

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

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

2.33.1.4.1.2 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 you or your staff; and

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

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

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

3 The Appeal

In a letter dated 2 June 2025, the Applicant (via its representative Rushport Advisory LLP) appealed against the Commissioner's decision. The grounds of appeal are:

3.1 "I act for Alpha Medics Limited in the above application and have been instructed by my client to submit this appeal against the decision of the Commissioner to refuse my client's application under regulation 25 for distance selling pharmacy premises.

3.2 My client acknowledges that the initial supporting information that was provided did not fully address each part of the legal test. My client has therefore instructed me to submit the attached SOPs that deal with all aspects of the legal test and which should satisfy the Committee that all relevant regulatory tests are met. These SOPs have been approved by my client for use in their pharmacy.

3.3 We also wish to take this opportunity to address some of the comments that have previously been made by objectors to this application as follows;

Britannia Pharmacy

3.4 The attached SOPs deal with all matters raised by Britannia Pharmacy.

3.5 There will be no absence of the Responsible Pharmacist ("RP") as a second pharmacist must sign in as RP in the event that the current RP wishes to leave the premises.

3.6 Full details of how controlled drugs and fridge lines will be delivered and handled are included within the attached SOPs.

3.7 To the extent that any Enhanced or Advanced service is provided, these services will only be offered where it is possible to provide the service remotely, i.e. without any patient visiting the premises.

3.8 Regulations 31 – regulation 31 only applies to the extent that any pharmacy is located at either the same or adjacent premises to that proposed by my client. There is no such pharmacy.

Alvin Rose and David Lewis

3.9 Both of these objectors highlight that the proposed premises is within a retail area. My client wishes to be clear that their premises will operate with a controlled entry system. Patients will not be able to walk into the pharmacy as there will be no public access to the premises. Only staff and delivery drivers will be permitted to enter the premises.

3.10 The attached floorplan shows the premises layout and the Committee will note that there is no retail area. The consultation room is available for staff to make phone and video calls with patients in private and will also not be used by patients.

Day Lewis

3.11 Day Lewis makes the following claim;

We note that in part 3 of the application form, the applicant lists its core opening hours as 9am- 5pm Monday to Friday. For the avoidance of doubt, these core hours are those when the applicant would be required to provide pharmaceutical services in full, in accordance with its Terms of Service as set out in Schedule 4 of the NHS (Pharmaceutical Services and Local Pharmaceutical Services) Regulations 2013 (as amended). This includes the provision of essential pharmacy services.

If the pharmacist is not absent between the hours of 9am to 5pm i.e. does not take a break, not only does this breach UK law which requires workers to take an uninterrupted break of at least 20 minutes within a 6 hour period, it also calls into question the extent to which services will be secured in a safe manner, in accordance with Regulation 25(2)(b)(ii). Working an 8-hour day without a break is not conducive to delivering services safely.

3.12 Firstly, we note that Day Lewis refers to a requirement in UK law that "which requires workers to take an uninterrupted break of at least 20 minutes within a 6 hour period". As the Committee will be aware, no such "law" exists. Day Lewis may be referring to the Working Time Directive but this Directive permits workers to opt out of rest breaks and allows for exceptions (notably in healthcare). In any event, this is not a relevant point as my client will have access to a second pharmacist who may cover not only breaks, but also share the work required over each day, with each signing in as RP as required.

3.13 Day Lewis also makes comments about patients with disabilities. As with any pharmacy, my client will communicate with patients in the manner that is most suitable for them, except that my client will not use face to face contact at the premises to provide essential services.

3.14 It must be remembered that the patient will have chosen to use a distance selling pharmacy and will therefore have considered that the communication methods available are appropriate for their needs.

3.15 Primary Care Appeals has dealt with this argument from Day Lewis in previous applications and found

"The Committee considered that having elected to use the distance selling pharmacy, people who would have difficulty in communicating with the pharmacy, would likely authorise another person to do so on their behalf."

3.16 The requirement under the Regulations is to provide essential services to any patient in England who requests those services and my client has shown how they the meet this requirement.

3.17 With respect to Pharmacy First, Day Lewis states;

We note that the applicant intends to provide the Pharmacy First Service. At least one of the treatment options provided under Pharmacy First (the treatment of acute otitis media), requires a face to face consultation so the pharmacist can carry out an examination of the patient. This examination would presumably take place in the consultation room.

3.18 As previously stated (and as confirmed within the SOPs), my client will only provide Advanced or Enhanced services where it is possible to do so remotely.

3.19 A distance selling pharmacy is not permitted to provide treatment for acute otitis media as part of the Pharmacy First service. It is simply not possible for a DSP to provide this service as it is specifically excluded from the service specification for DSPs. To quote Community Pharmacy England;

DSPs are limited to providing six of the seven clinical pathways consultations. The acute otitis media pathway is excluded as it requires otoscope examination of the patient's ear and DSPs cannot provide this type of consultation with the patient being present at the pharmacy premises.

3.20 Were a DSP to even attempt to provide an excluded service the NHS would not pay for it and the result would be that the service could not have been provided as an NHS service.

3.21 My client is fully aware of this restriction and will comply with it.

3.22 The remainder of the objections from Day Lewis are dealt with already above and within the SOPs.

Hannigan and Maplestead Pharmacy

3.23 These objectors repeat comments already dealt with above or raise issues that are not relevant to the determination of my client's application.

3.24 We look forward to hearing from you in due course."

4 Summary of Representations

This is a summary of representations received on the appeal.

4.1 THE COMMISSIONER

4.1.1 "I am writing in response to the above application where an appeal has been lodged against our decision to refuse the application.

4.1.2 We have reviewed the additional information received from the applicant in relation to the points raised in the decision report that were limited or missing. Had this additional information been available at the time of the decision, the London PSRC would have granted this DSP application.

4.1.3 We therefore have no objection to the application now being granted."

4.2 ALVIN ROSE PHARMACY

4.2.1 "I write in relation to the appeal SHA/26626 submitted by Alpha Medics Ltd for inclusion in the pharmaceutical list as a Distance Selling Pharmacy (DSP) at 292 Lodge Avenue, Dagenham, RM8 2HF (CAS-350601-F9V5R0).

4.2.2 After a thorough review of the appeal and the proposed site, I respectfully submit that the appeal should be rejected in full. The appeal does not justify a departure from the original decision to refuse the application. The reasons are detailed below and are grounded in legislation, regulation, and well-established pharmacy market and public health considerations.

Regulation 25(2) Not Satisfied – Service Model Fails Critical Legal Requirements

4.2.3 Under the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, specifically Regulation 25(2), the Integrated Care Board (ICB) must refuse a DSP application unless it is satisfied that:

4.2.3.1 Essential services will be provided uninterrupted to patients anywhere in England, and

4.2.3.2 These services are delivered without face-to-face contact between patients and staff.

4.2.4 The ICB has correctly determined that the pharmacy procedures fail to ensure both uninterrupted service delivery and safe, remote-only interaction. The SOPs submitted in the appeal lack:

4.2.4.1 Adequate guarantees of Responsible Pharmacist (RP) continuity.

4.2.4.2 Clear systems for temperature controlled and secure delivery of cold chain and CD items.

4.2.4.3 Robust processes for accessible service to patients with disabilities, language barriers, or digital exclusion, in breach of the Equality Act 2010 and NHS Public Sector Equality Duty.

DSP Moratorium Introduced from 23 June 2025 – Applications No Longer Permitted

4.2.5 As of 23 June 2025, NHS England has ceased accepting or approving DSP applications following guidance aligned with the 2025 NHS Pharmacy Contract changes. The policy shift reflects:

4.2.5.1 Over proliferation of DSPs in densely populated regions.

4.2.5.2 Adverse impacts on local brick-and-mortar pharmacies.

4.2.5.3 Regulatory concerns about the misuse of high-street DSP premises to attract walk-in patients.

4.2.6 Permitting this application now would contradict the direction of travel in NHS policy and set a dangerous precedent post-moratorium. This appeal is clearly misaligned with the national strategy.

Unsuitable High Street Location – Inherent Risk of Public Confusion and Market Distortion

4.2.7 The proposed premises at 292 Lodge Avenue are part of a busy high-street retail parade with multiple community-facing shops. This location:

4.2.7.1 Creates visual cues that imply local accessibility.

4.2.7.2 Encourages walk-in behaviour, undermining the core non-patient-facing requirement of DSPs (per Regulation 64(3) of the 2013 Regulations).

4.2.7.3 Risks patients bypassing local pharmacies believing services can be accessed by Alpha Medics on site, leading to misrepresentation.

4.2.8 As per DHSC Market Entry Guidance, Chapter 11, DSPs should be located in non-public facing units, typically industrial or commercial premises, not retail outlets.

Documented Harm to Local Pharmaceutical Infrastructure – CCA and NHS data

4.2.9 The Company Chemists' Association (CCA) has recorded that in areas where a DSP has opened, an average of seven community pharmacies have closed within the same postcode. This is not theoretical; it is a demonstrable, quantifiable threat to local pharmaceutical infrastructure.

4.2.10 Approving a DSP in this case would:

4.2.10.1 Undermine multiple long-standing community pharmacies in Dagenham, many of whom serve vulnerable, elderly and deprived populations.

4.2.10.2 Accelerate the trend of closures, especially in health inequality hotspots such as Barking and Dagenham.

4.2.10.3 Contradict the NHS's core commitment to local access and continuity of case.

Contravention of NHS Contractual and Ethical Intent

4.2.11 The NHS Community Pharmacy Contractual Framework (2022-2025) stresses:

4.2.11.1 Integration of pharmacy services into primary care networks.

4.2.11.2 Local delivery of advanced and enhanced services to underserved populations.

4.2.11.3 Maintaining geographical spread and equitable access.

4.2.12 DSP's, by design, cannot deliver these outcomes. They are exempt from face-to-face services such as vaccinations, blood pressure checks, contraception, and Pharmacy First consultations (e.g. otitis media) – services that are vital in areas of deprivation like Dagenham.

4.2.13 Further, approval of this DSP would:

4.2.13.1 Breach the intent of the updated 2025 DSP service limitations, which exclude key advanced services from being delivered remotely.

4.2.13.2 Erode access to essential services for patients not equipped to use online pharmacies, including those with language, cognitive, or digital access barriers.

Surrounding Pharmacies at Risk – Density, Competition & Viability

4.2.14 There are more than eight established community pharmacies within a one-mile radius of the proposed DSP site, including:

4.2.14.1 Britannia Pharmacy

4.2.14.2 Maplestead Pharmacy

4.2.14.3 David Lewis Chemist

4.2.14.4 Hannigan Pharmacy

4.2.14.5 Alvin Rose Chemist

4.2.14.6 … and several others.

4.2.15 All these providers:

4.2.15.1 Already offer free delivery for vulnerable patients.

4.2.15.2 Operate in extended hours to meet local demand.

4.2.15.3 Are embedded in the community with decades of trust and continuity.

4.2.16 Introducing a high-street facing DSP would destabilise the local ecosystem, divert NHS funded dispensing away from community providers, and lead to workforce loss, job cuts, and pharmacy closures.

Conclusion and Formal Request

4.2.17 For the reasons above – legal, practical, ethical, and economic – we respectfully urge the Appeals Committee [sic] to:

4.2.18 Uphold the original refusal of the DSP application by Alpha Medics Ltd and confirm that the appeal is not justified under the relevant regulatory and policy frameworks.

4.2.19 Approving this DSP would directly contravene:

4.2.19.1 Regulations 25 and 64 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013

4.2.19.2 Chapter 11 of the DHSC Market Entry Guidance

4.2.19.3 The 2025 NHS Community Pharmacy Contract reforms

4.2.19.4 The NHS Public Sector Equality Duty

4.2.19.5 And the NHS Long Term Plan goals for localised, equitable access to care.

4.2.20 This application represents not only regulatory non-compliance, but also a clear threat to the sustainability and integrity of community-based pharmaceutical services in Dagenham.

4.2.21 Thank you for considering this submission."

4.3 HANNIGAN PHARMACY

4.3.1 "I am writing in response to the appeal SHA/26626 presented by Alpha Medics Ltd with regards to the Distance Selling Pharmacy (DSP) application, with the proposed location at 292 Lodge Avenue, Dagenham, Essex.

4.3.2 I do not believe Alpha Medics Ltd have addressed in their appeal, the elephant in the room – their proposed location on a busy High Street. In a document published by the CCA in 2023, they name DSPs such as this 'pseudo distance selling pharmacies'. I have attached the document for reference. These pharmacies operate under the name of a DSP, deriving the benefits of lower overheads and regulation; however, dispense a large proportion of their prescriptions within a 10-mile radius. Hence, they acutely affect the sustainability of the community pharmacies located in the area, many of which have supported the local community for many decades (including, I might add, during the pandemic) and have weathered years of funding shortfalls.

4.3.3 Any DSP located on a High Street, despite proposed measures implying the public will not be allowed access, is questionable. The entry and exit of staff members, the visibility of wholesalers delivering medication, the visibility of pharmacy drivers and pharmacy branded vehicles at the premises, would all draw the local population to see and understand a pharmacy to be present and available for them.

4.3.4 Patients' enquiries will need to be dealt with and inevitably, there will need to be some face-to-face contact between staff members and members of the public on occasion – something which would contravene DSP regulations.

4.3.5 Furthermore, I would like to highlight that SW Pharma, an existing distance selling pharmacy, location at Unit 9B, Sterling Industrial Estate, Dagenham,

RM10 8TX. They have already begun targeting our local area, leaflet enclosed [provided to Committee at Appendix A] and are advertising various services under the SW Pharma brand and approving another DSP, such as Alpha Medics, would only further erode the sustainability of existing community pharmacies.

4.3.6 As you will be aware, DSP applications have been closed from 23rd June 2025, recognising the lack of benefit, and potential risks associated with the approval of further licenses. Dagenham is one of the most socially deprived areas in London. Risking the pharmaceutical provision in the area through the approval of this DSP is not in the interests of the public.

4.3.7 I urge you to consider the true intention behind applying for approval in this particular location, as opposed to a remote business unit or industrial estate where the size of premises vs cost would have been far more favourable, had the true intention been to provide a national service, as opposed to a local one."

4.4 MAYORS CHEMIST

4.4.1 "I am writing to formally oppose and appeal the inclusion of Alpha Medics Ltd in the pharmaceutical list for a distance selling pharmacy at 292 Lodge Avenue, Dagenham (application reference CAS-350601-F9V5R0).

4.4.2 Having carefully reviewed both the original application and the supporting appeal documentation submitted by Alpha Medics Ltd, I submit this appeal on the basis that their application fails to meet critical regulatory standards and poses significant risks to patient safety, service integrity, and public confidence in distance selling pharmacy models.

4.4.3 I urge the Committee to give full weight to the following points, which I believe clearly justify refusal:

Failure to Satisfy Regulation 25 Requirements for Safe Service Provision

4.4.4 Despite the inclusion of generic SOPs, the applicant has not demonstrated robust and verifiable compliance with Regulation 25, particularly with regard to the provision of safe and effective services in a non-face-to-face model. Reliance solely on remote access cannot guarantee clinical adequacy or patient safety, especially for vulnerable populations.

Lack of Clear and Reliable Responsible Pharmacist (RP) Coverage

4.4.5 Alpha Medics Ltd.'s reference to a second pharmacist for cover during breaks is vague and operationally unconvincing. Without a precise, documented rota or contingency measures, there remains a real risk of non-compliance with RP requirements, potentially leading to unlawful dispensing or service disruption.

Exclusionary Access Model and Poor Consideration for Patient Needs

4.4.6 Delivering care solely through remote communication from a retail based environment fundamentally undermines equitable access to pharmaceutical services. This model disproportionately disadvantages patients with language barriers, disabilities, cognitive impairments, or those who need physical assistance or private consultation. Designing a healthcare service around remote only access – especially from an unsuitable retail context – creates

structural exclusion. A truly safe and patient centred service must be inclusive by design, not convenience.

Disregard for Workforce Welfare and Safety Standards

4.4.7 The response submitted by Alpha Medics Ltd appears to minimise or misinterpret working time regulations and rest break entitlements, which are critical to maintaining safe, alert staffing in healthcare environments. This cavalier attitude to staff welfare raises red flags about their capacity to sustain compliant service deliver [sic] over time.

Premises Unsuitable for Intended Purpose

4.4.8 The premises located at 292 Lodge Avenue are situated within a primarily retail environment. This location does not meet the expectations or regulatory intent of NHS Distance Selling Pharmaceutical Services, which require a setting that is clearly separate from walk-in or high street retail trade. The embedded retail nature of the site undermines the fundamental principle that such services should not encourage face-to-face access, making the location inherently unsuitable for its proposed use.

4.4.9 In summary, Alpha Medics Ltd.'s application is incomplete, operationally inadequate and potentially unsafe. It does not meet the standards required for approval and should be rejected to protect patients, uphold public trust, and ensure consistency with NHS pharmaceutical service expectations.

4.4.10 I respectfully request that the Primary Care Appeals Committee uphold the original refusal decision and prevent the inclusion of this premises in the pharmaceutical list.

4.4.11 Thank you for considering this appeal."

4.5 BRITTANIA PHARMACY

4.5.1 "Thank you for your letter of correspondence on the 26th of June 2025, with case reference and application as above.

4.5.2 Please see below my response to said appeal response.

4.5.3 I respectfully beg to differ in the response provided by Rushport Advisory LLP on page 2 of the response, copied and pasted as below;

Regulations 31 – regulation 31 only applies to the extent that any pharmacy is located at either the same or adjacent premises to that proposed by my client. There is no such pharmacy.

4.5.4 Regulation 31 clearly states that an application for Distance Selling Pharmacy (DSP) cannot be granted at the same or adjacent premises as an NHS pharmacy.

4.5.5 The Collins online dictionary defines adjacent as being near or close.

4.5.6 Our Pharmacy branch at 453 Porters Avenue is located a mere 83 yards away (30 second walk), and as such, Regulation 31 applies and so this application cannot be granted.

4.5.7 I also include below a Google street view of the two sites, compounding this statement. [provided for Committee at Appendix B]

4.5.8 I note the applicant has now included the SOPs in the appeal response from Rushport Advisory LLP; however, my concern still remains that members of the public will not be able to distinguish the premises from a conventional bricks and mortar pharmacy and in reality, the location is still that of a shop front and not in the ethos of a true DSP.

4.5.9 In relation to the floor plan of the proposed site, there will be nothing stopping patients from seeking to enter the premises and gain face to face advice and service. Additionally, the coat and wet area can be perceived as a reception point by members of the public.

4.5.10 In conclusion, I believe this application is not in line with a true application to be a Distance Selling Pharmacy and so the appeal should be dismissed on the above grounds."

4.6 LAVILLE LIMITED (represented by Gordons Partnership Solicitors)

4.6.1 "We act for Laville Limited, trading as Britannia Pharmacy. Representations made are on behalf of the following branches of Britannia Pharmacy:

4.6.1.1 Barking Community Hospital, Upney Lane, IG11 9LX

4.6.1.2 13-15 Faircross Parade, Upney Lane, IG11 8UN

4.6.1.3 Thames View Health Centre, Bastable Avenue, IG11 0LG

4.6.2 Our client wishes to make representations against the appeal by Alpha Medics Limited. The application for inclusion in a pharmaceutical list in respect of distance selling premises at 292 Lodge Avenue, Dagenham, Essex, RM8 2HF is made under Regulation 25 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 ("the Regulations").

4.6.3 Our client's case is that North East London ICB were correct to refuse the application and the appeal against that decision should be refused on the basis that it does not meet the regulatory requirements set out below:

Regulation 25(2) of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013

4.6.4 *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 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.

4.6.5 The basis on which our client says the Regulations are not met include the following:

SOPs

4.6.6 What are purported to be Alpha Medics Pharmacy Standard Operating Procedures are included with the appeal document dated 2 June 2025. Although presented as Alpha Medics SOPs they appear to be generic Rushport SOPs which do not represent procedures that the pharmacy has adapted to its own use. This is demonstrated by the sample delivery label on page 27 of the SOP which says

4.6.7 "*Please refer to the Product Information Leaflet Rushport sops enclosed with each product for further information about the product. Our Pharmacist is always available to answer any questions about your medicines and offer support and guidance. E-mail: services@xxxxxxxxxx.co.uk or Tel: 0845 xxxxxxxxxx"*

4.6.8 This not only does not make sense suggesting that the Superintendent Pharmacist of Alpha Medics Ltd has not reviewed each SOP but it also refers to Rushport SOPs rather than the pharmacy SOPs which suggests the SOPs have not been adopted as fully as suggested in the appeal. The committee therefore cannot be confident that these do represent the procedures that will actually be adopted in this pharmacy and according cannot be confident that the pharmacy will provide the safe and effective pharmacy services required by regulation 25.

Continuity and absence of the Responsible Pharmacist ("RP")

4.6.9 In the appeal letter it is said that there will not be any absence of the Responsible Pharmacist ("RP") as a second pharmacist is required to sign in as RP if the first leaves the premises. The SOPs attached to the appeal do not contain any provision for circumstances in which one of the two pharmacists is not available to work at the pharmacy for any length of time. The Pharmacy Business Continuity Plan states that if a member of staff is absent and no other employee is able to cover the role the Superintendent Pharmacist should 'Seek appropriate alternative staff to cover, e.g. from other branches or pharmacies where a mutual aid arrangement is in places.' Page 154 of the SOP document. It is unclear from the application whether Alpha Medics Limited has any other branches. However, on the GPhC's online register, the Superintendent Pharmacist listed on Alpha Medics Limited's application form is not listed as Superintendent Pharmacist which may indicate this is a stand-alone pharmacy. There also is not any evidence of the company having a mutual aid arrangement in place. The lack of provision for absence of a pharmacist demonstrates that that it is not certain that services can be provided without interruption.

4.6.10 There is a further difficulty in the provision of services without interruption. The appeal letter responds to the Day Lewis concerns in relation to the provision of pharmacist breaks by saying that there will be cover for pharmacist breaks as there will be access to a second pharmacist who "may" cover breaks. However this is inconsistent with the plan above but also the SOPs clearly foresee a time when only one member of staff will be working.

4.6.11 See Paragraph 1.4 page 15 of the SOPs “At least two members of staff **(unless fewer than two are working** at the pharmacy)…” emphasis added.

Signposting

4.6.12 It is said that the SOPs enclosed “demonstrate how essential services will be provided in a safe and effective manner without face-to-face contact with the patient”. It is important that patients are sign-posted to alternative providers if the pharmacy cannot provide a service. An example of this is at 7.9 page 33 and 24.14 (page 93 of the SOPs) regarding items requiring measuring and fitting. The SOP refers to a signposting SOP but there is no signposting SOP included.

Urgent Supply

4.6.13 The SOP fails to give a time frame for delivery. Page 58 of the SOPs says “For local deliveries the driver should be specially informed of the fact that the items are “URGENT” and for any items delivered by courier the company must be informed that items must be delivered ASAP by the quickest route possible.” There is no verification by the pharmacy that the supply will be delivered urgently, i.e.: within a certain number of hours or the courier’s understanding of the quickest route possible and whether this will be satisfactory and safe for the patient.

Pharmacy First

4.6.14 There is still insufficient information about the provision of the NHS Pharmacy First service. This is not dealt with within the appeal letter or within the appellant’s SOPs. It is unclear how appropriate consultations would take place for this, as there is not any confirmation of the format of the consultations. Without knowing this, Primary Care Appeals cannot be sure how and where the service would be provided, particularly ensuring patient safety and confidentiality.

4.6.15 In the circumstances, it appears that the PAC cannot be satisfied that the regulatory criteria for this application are met and we ask that this appeal is refused. If there is an oral hearing our client would want to attend and be represented.”

4.7 MAPLESTEAD PHARMACY

4.7.1 “Thank you for your letter of 26th June in relation to the above and please accept this as my letter of objection to this appeal.

4.7.2 I note that Primary Care Support England considered the original application and determined that the application did not meet the criteria for its approval.

4.7.3 The appeal documentation includes standard SOPs for a DSP and it is noted that these are not the Applicant’s own SOPs and simply used from an advisory service.

4.7.4 One therefore needs to consider how much reliance can be placed where it is evident that the operating procedures or their adherence/compliance have simply been deputised out to a third party.

4.7.5 It is also to be noted that this is not a DSP application where a prospective provider has made a determined effort to provide DSP services and then sought out an appropriate premises from within which to provide the service.

4.7.6 The application premises, 292 Lodge Avenue, is currently occupied by Alpha Dane Limited, which is a property development company and the property is owned by a related party, and please see attached a Google photograph of the premises. [provided for Committee at Appendix C]

4.7.7 The applicant's name is Alpha Medics Limited, with a very similar first name and this, therefore, leads me to believe that this is an opportunistic application, making use of a related party property ownership.

4.7.8 Furthermore, the location of 292 Lodge Avenue lends itself to be seen as a retail outlet and despite the assurances provided by the Applicant that there will be secured entrance, there is no assurance that this will be the case in reality. Again, the same photograph emphasises this point.

4.7.9 There have been known cases where DSPs have allowed people to walk into the premises simply because of where they are based. There are no policy arrangements, and even if there were any, they would be very expensive and difficult to pursue.

4.7.10 I also need to emphasise that the proposed premises is close to my pharmacy but EXTREMELY CLOSE to Brittania Pharmacy at 453 Porters Avenue.

4.7.11 This important aspect of the Application is as follows:

4.7.12 I would request that NHS Resolution consider Regulation 31 in this application. The applicant's premises are located in very close proximity to Brittania Pharmacy at 453 Porters Avenue, RM9 4ND and will be offering substantially the same services as provided by Brittania Pharmacy.

4.7.13 It is my view that the common sense meaning of "adjacent" would include a pharmacy located in this position in relation to Brittania Pharmacy. I am supported in this interpretation as a synonym of "adjacent" in the Collins English dictionary is "nearby" and it is clear that Brittania Pharmacy is nearby.

4.7.14 The listed chemist at 453 Porters Avenue is only 83 metres away, a walk of less than a minute and hence Regulation 31 will apply, and this Application cannot be granted.

4.7.15 I agree on the findings of PCSE that this subject premises are not on the same site or in the same building as the premises of a provider of primary medical services with a patient list, and hence Regulation 25 does not apply.

4.7.16 For ease of reference, I am attaching a Google map of Brittania Pharmacy and the proposed site, the distance being literally a stone's throw away.

4.7.17 In view of the above, I hope the NHS Resolution will agree with my proposals and refuse the application."

5 Amendments to Regulation 25

On 23 June 2025, amendments to Regulation 25 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 came into force, which affect this application. Given the amendments represent a new test the Applicant was given the opportunity to make

comments in support of its application and parties given the opportunity to provide comments in response, alongside any observations they wished to submit.

5.1 THE APPLICANT

5.1.1 “Thank you for your letter of 3 July 2025 seeking further representations in response to the changes made recently to Regulation 25 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (the Regulations).

5.1.2 The Committee will be aware of the meaning of “pharmaceutical services” and in the context of my client’s application has the meaning given in section 126(8) of the 2006 Health Act (arrangements for pharmaceutical services) which includes the provision of drugs and appliances as well as additional pharmaceutical services as many are subject to commissioning and in the context of appliances my client will only provide those that do not require measuring or fitting.

5.1.3 As a result of the changes made, the Committee will no longer consider the safe and effective provision of essential services and will instead consider the provision all NHS pharmaceutical services provided to patients.

5.1.4 In addition, the Committee will consider if the pharmaceutical services will be provided 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.

5.1.5 In addition to essential services my client applied to provide the following pharmaceutical services:

5.1.5.1 NMS – new SOP attached with updated SOPs.

5.1.5.2 CPCS – this service is no longer commissioned and therefore not relevant to the application.

5.1.5.3 Home Delivery Service – there is no commissioned home delivery service that my client would provide and this was added to the list of services by my client simply to show that they intended to deliver medicines to patients. Full details of how medicines will be delivered are contained within the attached SOPs.

5.1.5.4 Pharmacy First – new SOP attached with updated SOPs.

5.1.6 My client has updated their SOPs to reflect the new legal test. The updates make the following changes:

5.1.7 Clarify that no NHS pharmaceutical services will be provided to patients at the premises. See SOP 3 – Procedures for NHS Pharmaceutical Services.

5.1.8 Include SOPs for the remote provision of both NMS and Pharmacy First – See SOPs 7 and 8. NOTE Each service will only be provided where it is approved by the Commissioner.

5.1.9 Remove references to essential services and replace those with references to pharmaceutical services.

5.1.10 Other small minor and typographical changes.

5.1.11 These changes ensure that my client's application meets the updated legal test and I look forward to hearing from you in due course."

6 Summary of Observations

This is summary of observations received.

6.1 THE APPLICANT

6.1.1 "Thank you for your letter of 1 August 2025 seeking further representations in response to comments made by interested parties on my client's appeal.

Alvin Rose Chemist

6.1.2 The updated SOPs properly specify how continuity of service will be maintained (see SOPs 34.9) and the delivery of cold chain and CD items (SOPs 20.16 and 24 respectively). We note that the objector cannot identify and [sic] specific deficiencies in these (or any other) SOPs.

6.1.3 With respect to access for patients for any sort of disability/language barrier, or digital exclusion, it would be up to each patient to request services from a pharmacy that suits their own needs best or to ask a carer of [sic] relative to do so on their behalf. My client's service will remain available to any patient in England who requests it.

6.1.4 With respect to the recent change in the regulatory test, my client has made appropriate amendments to their SOPs to reflect these changes.

6.1.5 With respect to premises, the SOPs provided make it clear that no services will be provided at the premises and a controlled entry system will mean that no patient can access the premises. Further, the floorplan already provided shows that the pharmacy does not cater for walk in patients or have any sort of retail area.

6.1.6 Points 4, 5, and 6 of the objector's letter does not address the legal test and we do not comment on these points save to say that they are not accepted as correct.

Hannigan Pharmacy

6.1.7 The comments from Hannigan Pharmacy are either already dealt with above or have no relevance to my client or the legal test.

Mayors Chemist

6.1.8 The comments from Mayors Chemist are either already dealt with above or have no relevance to my client or the legal test.

Brittania Pharmacy

6.1.9 As the Committee will be aware, regulation 31 relates to premises that are either the same or adjacent premises. The word adjacent in this context is interpreted as meaning next to or touching. Regulation 31 therefore does not apply in this case.

6.1.10 The comments regarding patient access to the premises are already dealt with above and in the relevant SOPs.

Laville Limited

6.1.11 As the Committee will be aware, the legal test set out by Gordons Solicitors ("Gordons") is no longer correct and my client's SOPs address the updated legal test.

6.1.12 In relation to the specific points raised by Gordons we respond as follows.

6.1.13 SOPs

6.1.13.1 My client has approved the SOPs for use in their pharmacy and it is commonplace for pharmacies to use SOPs written and produced by third parties.

6.1.13.2 The inclusion of the words 'Rushport sops' in the same delivery label is a typo and we apologise for this.

6.1.14 RP absence

6.1.14.1 Gordons chooses to ignore the content of the SOPs and focus instead on hypothetical situations. In response to their comment regarding 1 pharmacist not being available, my client would still have the first pharmacist working and would have access to locums in the same way as any other pharmacy does.

6.1.15 Business Continuity Plan

6.1.15.1 The Business Continuity Plan is adapted from the plan recommended by Community Pharmacy England and used by many pharmacies. The use of the term "e.g." means that the plan gives examples of where a pharmacy may attempt to source other staff from, which may, or may not, be applicable at any time.

6.1.16 Signposting

6.1.16.1 The Signposting SOP can be found at 27.12 in the SOP bundle.

6.1.17 Urgent Supply

6.1.17.1 Gordon's comments regarding urgent supply are incorrect. SOP 17.11 deals with the delivery of urgent medicines to ensure that the quickest supply method is used. The same SOP refers the reader to the delivery SOP. The Order Delivery SOP specifically states at 20.8 part 4, that the patient will be provided with an estimated delivery time.

6.1.18 Pharmacy First

6.1.18.1 Having read the comment regarding Pharmacy First, it is not clear what objection is being made. The SOP is clear that the most appropriate method of contacting the patient will be used.

Maplestead Pharmacy

6.1.19 The comments from Maplestead Pharmacy are either already dealt with above or have no relevance to my client or the legal test.

6.1.20 I look forward to hearing from you in due course."

6.2 BRITTANIA PHARMACY

6.2.1 “Thank you for giving me the opportunity to reply to your letter dated the 1st of August 2025.

6.2.2 Firstly, I note, I do not have a copy of your letter dated the 3rd of July 2025, to which Rushport Advisory LLP has referred to in their response dated the 3rd of July 2025. Please can this be shared for full transparency.

6.2.3 With regards [sic] to the letter dated 3rd of July 2025 from Rushport Advisory LLP; my main concerns are on the following lines as indicated in earlier correspondence:

6.2.4 Without any doubt, the application site is in a retail shopping parade with a retail shop front and this cannot be overlooked.

6.2.5 The Standard Operating Procedures (SOPs), now provided by Rushport LLP [sic], were not in the original application and are simply a tick box exercise and thus no reliance can be placed on these.

6.2.6 Other than the SOPs, there are no adherence procedures in practical terms to ensure compliance with the regulations, i.e. preventing face to face consultations or patients walking onto the premises.

6.2.7 All the above factors are evidence that this is not a true DSP application and therefore the application should be refused.”

6.3 GORDONS PARTNERSHIP SOLICITORS (on behalf of Laville Limited)

6.3.1 “Thank you for your letter of 1 August 2025 with enclosures. We are instructed by our client to make comments on the representations received as follows:

6.3.2 Firstly, we apologise for the incorrect recital of the regulation 25 test: it is acknowledged that paragraph 25(2)(a)(ii) of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 now reads:

> *“(2) NHS England must refuse an application to which paragraph (1) applies –*
>
> *(a) unless NHS England is satisfied that the pharmacy procedures for the pharmacy premises are likely to secure –*
>
> > *(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.”*

6.3.3 The submissions in our letter of 25 July 2025 remain the same.

Letter from Rushport Advisory LLP dated 3 July 2025

6.3.4 The letter from Rushport Advisory encloses a new set of SOPs which we have reviewed and inserted new page numbers for the concerns raised in our previous representations. We have also reviewed the entirely new SOPs and

consider they do not give assurance that a safe and effective service will be provided.

Capacity assessment

6.3.5 An overall omission in the new set of SOPs relates to capacity assessment. Given the change in the legalisation, the applicant has to establish that is securing safe and effective provision of all pharmaceutical services without face-to-face contact. It is concerning that there is no indication in the SOPs that capacity will be assessed before undertaking remote consultations about complex health and medication issues and if it is to be assessed, how the assessment will be carried out. Without clarity on this issue, the provision of services such as Pharmacy First and NMS cannot be safe or effective.

SOPs

6.3.6 Our client's concerns remain about whether to SOPs are in fact Alpha Medics SOPs when some references within the SOPs suggest that they are generic Rushport SOPs which do not represent procedures that the pharmacy has adapted to its own use. It is noted that despite many changes being made to the SOPs the generic label delivery label [sic] (still on page 27 of the SOPs) has not been amended.

Continuity and absence of the Responsible Pharmacist ("RP")

6.3.7 Our client's concerns about continuity remain. We note that the passage referred to in the Pharmacy Business Continuity Plan, "if a member of staff is absent and no other employee is able to cover the role the Superintendent Pharmacist should 'Seek appropriate alternative staff to cover, e.g. from other branches or pharmacies where a mutual aid arrangement is in place' is now at page 174 of the SOP document.

SOP's referred to but not evidenced

6.3.8 Reference has been to a missing SOP on signposting. The new page number where that is mentioned are now at 10.9 of the new SOP (page 53), 24.14 (page 113 of the SOPs) regarding items requiring measuring and fitting and also Promotion of Healthy Living, Lifestyle & Health Campaigns paragraph 28.7 (page 117). To clarify, although reference is made to Signposting, the process is included in the Support for Self-Care, Signposting and Health Promotion SOP (SOP 27, page 110 of the new SOPs). It appears that this passage on signposting is intended to ensure the pharmacy provides 'guidance for the provision of self-care to patients and their families, including signposting to appropriate supporting organisations and promotion of a healthy lifestyle including health campaigns' (see introductory comment on page 110). It does not function as a standalone SOP providing guidance whenever signposting is required. Accordingly, NHSR cannot be satisfied that patients will be appropriately signposted to services they need.

6.3.9 Other examples of where SOPs are referred to but not included are:

6.3.9.1 Medicines Sales SOP – referred to on page 116.

6.3.9.2 SOP on confirming identity - referred to on page 123.

6.3.9.3 It is unclear whether the SOP referred to as ‘Dealing with complaints’ (referred to on page 135) is the same as the included SOP entitled ‘Customer Complaints’.

6.3.10 If the SOP is important enough to be referred to in what are identified as key SOPs, then they should be included in the SOP document so that NHS Resolution can be confident that the SOP exists and provides an effective process.

Urgent supply

6.3.11 Our client’s concerns about urgent supply remain. The SOP fails to give a time frame for delivery – the revised page number for this is page 78. The SOP also says ‘Refer to relevant delivery SOP for further information on the delivery process’. There is no further information in the delivery SOP on urgent supplies. Accordingly, there is no verification by the pharmacy that the supply will be delivered urgently, or what ‘urgently’ means for this pharmacy. There is no cut-off time after which it will be deemed that a supply cannot be made urgently, and the patient should be signposted elsewhere. The flaws in this SOP mean that NHSR cannot be satisfied that an urgent supply will be made safely.

NMS

6.3.12 This new SOP lacks detail and is missing a number of essential particulars including the following:

6.3.12.1 At the engagement stage the pharmacy should be offering initial advice and opportunistic advice on healthy living and or public health topics.

6.3.12.2 Specific records of interventions should be made for patients who are not registered with a GP.

6.3.12.3 At the intervention stage (and others) checks should be made with the patient that they are in place here they cannot be overheard unless by someone who the patient wants to hear the conversation. The SOP only covers privacy at the pharmacy end of the appointment.

6.3.12.4 Record keeping for this service is particularly important and the SOP does not describe the extent of record keeping required or the time for which these records should be kept. For example, records should be made of opportunistic advice given and if the patient does not take part in the intervention stage a record of the reason why, for example the prescriber has stopped the new medicine, should be made. The SOP created by Rushport merely states for the intervention stage that the pharmacist should ‘Record the follow-up call details and provide an appointment reminder to the patient’.

Pharmacy First

6.3.13 Again, the SOP lacks some significant details. For example, for an urgent supply of medicine the pharmacist should, where appropriate, advise the patient or their representative on the importance of ordering prescriptions in a timely manner from their GP practice and prevent the future need for emergency supplies. This obligation is not present in the SOP and thus reduces the effectiveness of this service.

6.3.14 Some parts of the SOP do not make sense – process 16 on SOP page 43 say 'the pharmacist will ensure the patient is able to

6.3.14.1 Referring the patient to their own GP.

6.3.14.2 Contacting the local Out of Hours provider.'

6.3.15 In addition, it is mandatory to include the service in the business continuity plan and there is no reference to Pharmacy First in the business continuity plan for this pharmacy.

Letter from NHS North East London dated 25 July 2025

6.3.16 This letter does not disclose a detailed review of the new material and accordingly should be given little weight.

6.3.17 In relation to the remaining representations, our client has no specific comments on the representations from Alvin Rose, Brittania Pharmacy's branch at 453 Porters Avenue, Dagenham Essex, RM9 4ND, Hannigan Pharmacy, Maplestead Pharmacy or Mayor's Chemist. However we note that many of the representations refer to the High Street location of the proposed premises and it is noted that the applicant has made no adjustments in terms of signage or security to ensure that patients and opportunistic users of pharmacy services do not enter the premises. For this reason, the committee cannot be confident that the services will be provided without face-to-face contact.

6.3.18 In the circumstances, it appears that NHS Resolution cannot be satisfied that the regulatory criteria for this application are met and we ask that this appeal is refused. Our client has been sent two DSP applications in the vicinity of their pharmacy and if both are granted this places extreme pressure on the viability of the face-to-face service that they offer. Accordingly, we would urge NHS Resolution to interpret the regulations strictly to ensure that only those which provide clear evidence that they meet the regulatory criteria are granted. If there is an oral hearing our client would want to attend and be represented."

6.4 DAVID LEWIS PHARMACY

6.4.1 "Thank you for your letter of 1st August.

6.4.2 We note that your letter included an attachment from NHS Commissioning Hub, regarding their view on this application and we must reiterate that the Primary Care Appeals Authority [sic] is required to make a decision on all the matters put forward to them, rather than be influenced by the Commissioning Hub/ Market Entry personnel.

6.4.3 This appeal cannot be allowed as it will directly contradict the principles set out in the NHS Pharmaceutical Services Regulations 2013 which clearly state under Schedule 2, paragraph 25 that a DSP must "provide pharmaceutical services anywhere in England". Alpha Medics Ltd has failed to demonstrate this nationwide scope in spirit or practice, instead positioning itself on a high street within a densely populated pharmacy area, without sufficient justification, without operational clarity, and without any compelling evidence of intent or infrastructure to provide a true nationwide service.

6.4.4 Please see attached the VOA, i.e. the government backed commercial property rates valuation report for 292 Lodge Avenue, Dagenham. This

indicates the entire property providing 42.8m i.e. 430 sq. ft of floor space and this is hardly sufficient for providing a nationwide service.

6.4.5 A lock up garage is also included in this valuation and this has not been included by the applicants as being used for pharmacy purposes and this garage needs to be disregarded.

6.4.6 The Lodge Avenue location is part of a visible, accessible retail parage, not a remote or light-industrial site.

6.4.7 Historically, NHS Resolution has consistently refused DSP applications where applicants have:

6.4.8 Failed to show clear intent to operate from an appropriate industrial or remote location.

6.4.9 Provided only generic Standard Operating Procedures (SOPs) with no supporting detail on how a nationwide service would be implemented.

6.4.10 Situated themselves in close proximity to multiple existing community pharmacies without adequate justification.

6.4.11 No detailed evidence of premises layout, scale, or capacity to handle a national volume of prescriptions.

6.4.12 Lack of proof of intent to operate nationwide, aside from generalised SOPs.

6.4.13 No evidence that the premises is suited for DSP operation, particularly when regulations imply a remote or non-retail setting.

6.4.14 The applicant's physical positioning within a highly competitive local area, with clear potential to attract footfall and act as a pseudo-community pharmacy, rather than serving distance patients as the DSP model intends.

6.4.15 It is becoming increasingly evidence [sic] that certain DSP applications are exploiting regulatory loopholes – setting up pseudo-DSPs on high street, offering minimal compliance on paper, while diverting patients and destabilising existing services. This is not the purposes for which DSPs were designed.

6.4.16 The decision to refuse this appeal is appropriate because there are still many high street based DSP applications in the pipeline – submitted just before the June 23rd cut off. By approving this application, NHS England risks setting a dangerous and damaging precedent that could lead to a wave of similar approvals, even though such models have now been formally recognised as detrimental to the community pharmacy sector. This is exactly the kind of outcome the new regulations were designed to prevent.

6.4.17 We respectfully urge NHS Primary Care Appeals [sic] and relevant decision makers to fully consider this application and evaluate the consequences of allowing DSPs to establish themselves in such surroundings, where they are not a true nationwide DSP provider. NHS has a duty of care to both patients and long-established pharmacies, and it is imperative that it protects the infrastructure which has supported communities for years.

6.4.18 It is simply not enough to offer template SOPs or claim remote intent while functioning locally in all but name. A DSP approval must be earned through

demonstrated scope, capability, and location, not awarded through tick-box compliance.

6.4.19 Lastly, NHS England has a fundamental duty to ensure that public funds are used wisely and responsibly. Supporting applications that do not meet the national service criteria – and that have clear potential to destabilise established, trusted providers – risks squandering taxpayers money and eroding public trust in the fairness and sustainability of the system.

6.4.20 We respectfully request that the Appeal outcome after careful consideration of all the facts will be a refusal of this appeal."

6.5 ALVIN ROSE PHARMACY

6.5.1 "We act for Alvinrose [sic] Pharmacy and write in response to your letter dated 1 August 2025 concerning the appeal lodged by Alpha Medics Ltd. This submission constitutes a formal objection under the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 ("the 2013 Regulations") to the proposed inclusion of Alpha Medics Ltd in the pharmaceutical list for a Distance Selling Premises ("DSP").

6.5.2 Our objection is grounded in demonstrable non-compliance with statutory requirements, deficiencies in operational readiness, public interest considerations, and clear precedent from NHS Resolution determinations.

1. Regulatory Non-Compliance – Regulation 25(2)(b) (Prohibition of Face-to-Face Provision)

6.5.3 Regulation 25(2)(b) of the 2013 Regulations mandates that:

"*Essential services must be provided at or from the premises only by means of the provision of those services otherwise than face to face*."

6.5.4 The proposed site at 292 Lodge Avenue is located in a high-footfall, mixed-use area with direct street access.

6.5.5 Further, according to the Valuation Office Agency, the premises measure only 42.8 m²—a space consistent with a small retail outlet rather than a national dispensing hub. This size is inherently insufficient for:

6.5.6 Secure segregation of goods and workflow,

6.5.7 Storage of medicines (including cold chain and controlled drugs),

6.5.8 Packing and dispatch functions for nationwide coverage.

6.5.9 In our view, this evidences:

6.5.10 A physical inability to operate in compliance with Regulation 25(2)(b) and (c).

6.5.11 A strong likelihood & crystal clear that the premises will operate as a pseudo-DSP, primarily servicing a local population already served by approx. 8 community pharmacy [sic], contrary to the statutory DSP model.

6.5.12 A deliberate choice of a high street location to divert trade from local community pharmacies, undermining Regulation 13 market protection principles.

6.5.13 This Premises must be in the Industrial area not on the high street to be able to serve nationwide.

6.5.14 This profile matches multiple NHS Resolution refusals, including SHA/20784, where premises location and public accessibility rendered compliance with Regulation 25(2)(b) impracticable.

2. Inability to Comply with Regulation 25(2)(c) – Nationwide Service Requirement

6.5.15 Regulation 25(2)(c) requires a DSP to:

6.5.16 "*Provide essential services to any person in England who requests them, regardless of where in England they live*."

6.5.17 The application fails to demonstrate:

6.5.17.1 Nationwide logistics capability (absence of partnerships with national couriers or guaranteed delivery timelines).

6.5.17.2 Cold chain compliance under the Human Medicines Regulations 2012, which require maintenance of 2–8°C for refrigerated products and ≤25°C for ambient medicines, with validated temperature logging at every stage. This omission of evidance [sic] is critical given UK temperature trends and legal obligations under the Medicines and Healthcare products Regulatory Agency (MHRA) guidelines.

6.5.17.3 Procedures for urgent supply or exemptions for vulnerable patients in remote locations.

6.5.17.4 End-to-end digital governance for clinical records, real-time prescription tracking, and complaints management in accordance with GPhC Standards for Registered Pharmacies

6.5.17.5 (Standard 1: Governance and Standard 2: Staff competence).

6.5.18 Without these, there is no assurance of uninterrupted, safe, and equitable service to all patients in England.

3. Defective and Generic Standard Operating Procedures (SOPs)

6.5.19 We note that Alpha Medics' SOPs are identical to those submitted by another DSP applicant. This duplication suggests they were purchased or downloaded without adaptation, contrary to:

6.5.19.1 GPhC Standards for Registered Pharmacies (requirement for SOPs to be tailored to the specific premises and services), and Regulation 26(3)(b) of the 2013 Regulations (obligation to ensure adequate procedures for service provision).

6.5.20 These SOPs lack bespoke risk assessment for:

6.5.20.1 Controlled drug security, Contingency planning for system or courier failure,

6.5.20.2 Temperature excursions in delivery transit.

6.5.20.3 Generic documentation is inadequate to meet statutory DSP obligations.

4. Failure to Demonstrate Public Interest or Need – Regulation 13

6.5.21 While Regulation 13's "necessary or expedient" test applies differently to DSPs, NHS Resolution has consistently considered local service duplication and destabilisation of existing providers as relevant factors.

6.5.22 The Dagenham area is already well-served by both DSPs and community pharmacies— many providing free delivery, remote consultations, and NHS clinical services. Approving this application would:

6.5.22.1 Create unnecessary duplication,

6.5.22.2 Risk closures of community pharmacies (potentially up to 50% locally),

6.5.22.3 Reduce face-to-face service availability for the elderly, vulnerable, and digitally excluded contrary to NHS Long Term Plan integration goals.

5. Precedent from NHS Resolution and Regulatory Changes (June 2025)

6.5.23 Multiple NHS Resolution decisions (including SHA/20784, SHA/19862, and SHA/19241) have refused DSP applications where:

6.5.23.1 The premises were in walk-in accessible locations,

6.5.23.2 Nationwide service capability was unproven,

6.5.23.3 SOPs were generic and non-site-specific.

6.5.24 Furthermore, as of 23 June 2025, amendments to the 2013 Regulations preclude new DSP applications altogether—a policy change arising directly from the systemic risks this application exemplifies.

6. Conclusion

6.5.25 Alpha Medics Ltd has failed to demonstrate compliance with:

6.5.25.1 Regulation 25(2)(b) – prohibition of on-site access,

6.5.25.2 Regulation 25(2)(c) – nationwide service provision,

6.5.25.3 Regulation 26 – operational governance,

6.5.25.4 GPhC Standards – premises suitability and SOP adequacy,

6.5.25.5 Human Medicines Regulations 2012 – storage and delivery conditions.

6.5.26 Approval would undermine local pharmaceutical provision, breach statutory obligations, and contradict established appeal precedent.

6.5.27 We therefore respectfully request that the Pharmacy Appeals Committee reject this application in full in order to safeguard patient safety, NHS equity objectives, and regulatory integrity.

Formal Legal Objection Letter

6.5.28 We act for Alvinrose [sic] Pharmacy and write in response to your letter dated 1 August 2025 concerning the appeal lodged by Alpha Medics Ltd. This submission constitutes a formal objection under the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 to the proposed inclusion of Alpha Medics Ltd in the pharmaceutical list for a Distance Selling Premises ("DSP"). Our objection is based on demonstrable non-compliance with statutory requirements, deficiencies in operational readiness, public interest considerations, and precedent from NHS Resolution determinations.

1. Regulatory Non-Compliance – Regulation 25(2)(b)

6.5.29 The proposed premises is located in a high-footfall retail area with direct public access and inadequate physical barriers to prevent walk-in services, contrary to Regulation 25(2)(b). The VOA confirms the premises is 42.8 m²—insufficient for a compliant nationwide DSP operation. The location indicates a commercial intent to target local patients, undermining the statutory model.

2. Inability to Comply with Regulation 25(2)(c) – Nationwide Service

6.5.30 The application fails to evidence infrastructure for nationwide service delivery, including courier partnerships, urgent supply protocols, or cold chain compliance as required by the Human Medicines Regulations 2012 and MHRA GDP guidelines.

3. Defective and Generic SOPs

6.5.31 The SOPs are identical to another DSP applicant's, suggesting they are generic and not tailored to the premises. This breaches GPhC Standards requiring site-specific procedures.

4. Failure to Demonstrate Public Interest or Need – Regulation 13

6.5.32 The Dagenham area is already served by multiple DSPs and community pharmacies, many offering free delivery and remote consultations. Approval risks destabilising local provision.

6.5.33 5. Precedent and June 2025 Regulatory Changes Past NHS Resolution refusals have been issued for similar premises and deficiencies. As of 23 June 2025, new DSP applications are prohibited under amended regulation.

Annex – Statutory Breaches and Supporting Evidence

No.	Breach/Concern	Relevant Law/ Regulation	Evidence from Objection	Precent/ Guidance
1	Prohibition of face-to-face provision breach	NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations	Premises in high footfall high street area; no access control; high risk of walk in patients	SHA/20784 – DSP refused due to inability to prevent local walk ins.

		2013, Reg 25(2)(b): "Essential services must be provided… otherwise than face to face."	receiving services.	
2	Premises too small to support nationwide DSP operations	GPhC standards for Registered Pharmacies – Standard 3: "Premises are safe and suitable for the services provided."	VOA records: 42.8 m^2; inadequate for storage, packing, dispatch, segregation of stock; more akin to local retail footprint.	SHA/19862 – refusal where premises lacked capacity for national service.
3	Pseudo DSP model likely	Reg 25(2)(c) – obligation to provide essential services to "any person in England".	Premises location and scale indicate intent to serve local patients, not nationwide audience; >70% DSPs in similar profile fail national coverage in practice.	Multiple NHSR determinations; GPhC inspection findings on DSP compliance failures.
5	Nationwide delivery infrastructure unproven	Reg 25(2)(c)	No evidence of courier agreements, urgent supply protocols, or remote service equality.	SHA/19421 – refusal where delivery coverage and contingency arrangements were inadequate.
6	Generic SOPs	Reg 26(3)(b); GPhC Standards – tailored procedures required.	SOPs identical to another DSP applicant; no site specific adaptation; inadequate risk management for controlled drugs, urgent supply, cold chain.	GPhC guidance – "off the shelf" SOPs not acceptable for compliance.

7	Destabilisation of existing services	Reg 13; NHS Long Term Plan objectives.	Area already well served by DSPs and community pharmacies offering delivery; approval risk closures and harms access for vulnerable patients.	NHSR determinations considering local duplication in DSP appeals.
8	Contrary to post-23 June 2025 policy change	NHS (Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2025.	New DSP applications prohibited due to systemic risk to local services; this application exemplifies identified harms.	Parliamentary statement and DHSC policy rationale for change.

6.5.34 Submission notes:

6.5.34.1 All legal citations are drawn from the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, the Human Medicines Regulations 2012, GPhC Standards, MHRA GDP Guidelines, and NHS Resolution appeal precedent.

6.5.34.2 This bundle is submitted in accordance with NHS Resolution guidance on documentary evidence for appeals and objections."

6.6 HANNIGAN PHARMACY

6.6.1 "Further to your latest communication on 1st August 2025 regarding the application by Alpha Medics to open a distance selling pharmacy at 292 Lodge Avenue, Dagenham, please find below our final observations which we hope you will consider with some seriousness.

Location and size of premises

6.6.2 The premises listed as the location for this pharmacy is that of a retail premises in a busy footfall location. Alpha Medics have put in an application for a DSP, as an application for a bricks and mortar pharmacy would be refused based on the Pharmaceutical Needs Assessment (PNA) and current density of pharmacies in this area. The application is for a DSP, yet the local and size of the premises do not align with this.

Approval or rejection – the precedent

6.6.3 We have received a further notification for a second distance selling pharmacy applying for approval in this area. The NHS has previously refused applications if it is clear the aim of the application and the purpose of the pharmacy is to open as a bricks and mortar pharmacy under the guise of a DSP. We would urge you to consider the potential damage to the current pharmacies in the area who have supported the local community for decades with well known

underfunding by the government. If any current pharmacies close (as many have done nationally) due to a decline in items, the local population will have a reduction of service providers, as DSPs cannot offer many services offered by bricks and mortar pharmacies such as covid vaccinations, flu vaccinations, face to face consultations for urinary tract infections, shingles and so on. We are concerned that a wrongful approval of this application, which is not a true nationwide DSP application, may set a precedent for further such wrongful approvals. It is, therefore, imperative that this application is refused.

Standard Operating Procedures (SOPs) submitted by Alpha Medics

6.6.4 Inadequate procedures was raised previously in the objections. There was a question regarding Alpha Medics have carefully and thoroughly prepared for the opening of this pharmacy and whether they had procedures in place to safeguard various concerns raised such as uninterrupted care and delivery of controlled drugs. Whilst SOPs may have been provided following this, there is still concerns – particularly since we have come to realise the SOPs provided are identical to the second DSP applying for approval.

6.6.5 This highlights the lack of thought, risk management and adaption from the 'off the shelf' SOPs that will simply have been purchases online or downloaded. In all fairness, this application is not a true DSP application.

Cost of approval to tax payers

6.6.6 Whilst pharmacies must generate their own income through the prescription services they provide, there are NHS funds split between current pharmacies nationally for training and so on. Could this unnecessary pharmacy be considered a good use of taxpayers money when the NHS budget is already deeply stretched?

6.6.7 DSPs are only able to deliver medication – patients cannot collect. This will therefore reduce the number of interactions between patients and healthcare professionals (pharmacists) thus reducing safety netting currently in place.

6.6.8 Finally, I would like to also highlight, that should this pharmacy genuinely wish to offer a national service (something that has not been the case for 70% of DSPs), this pharmacy will in no way benefit the local population. Hence, there is no benefit to the local council, nor to North East London ICB in approving this application."

7 Consideration

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

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

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

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

Regulation 31

7.5 The Committee first considered Regulation 31 of the Regulations which states:

(1) A routine or excepted application, other than a consolidation application, must be refused where paragraph (2) applies.

(2) This paragraph applies where -

(a) a person on the pharmaceutical list (which may or may not be the applicant) is providing or has undertaken to provide pharmaceutical services ("the existing services") from -

(i) the premises to which the application relates, or

(ii) adjacent premises; and

(b) NHS England is satisfied that it is reasonable to treat the services that the applicant proposes to provide as part of the same service as the existing services (and so the premises to which the application relates and the existing listed chemist premises should be treated as the same site).

7.6 The Committee had regard to the application form in which the Applicant states "*Not applicable as no other pharmacy in same or adjacent premises"*. The Committee noted that the Commissioner concluded in its decision letter that "*the proposed pharmacy is not on the same site or adjacent to any other pharmacy*" and did not see fit to refuse the application under Regulation 31.

7.7 The Committee noted the comments from numerous parties that the proposed premises are within close proximity to existing brick-and-mortar pharmacies and the subsequent requests to refuse the application pursuant to this. However, the Committee had regard to NHS Resolution's Guidance Note in relation to Regulation 31 which states:

7.7.1 "*The Committee has previously determined that the applicant's premises are to be treated as:*

Part of the existing premises – if the applicant's premises share any part of their 'footprint' or (though predominantly detached from the existing premises) the applicant's premises are in some other way physically connected to the existing premises; and

Adjacent premises – if the two sets of premises share a boundary whether to the front, side or rear via which access between the two sets of premises could be achieved (whether or not such access currently exists)."

7.8 The Committee noted the images provided by Brittania Pharmacy and Maplestead Pharmacy to demonstrate the close proximity between the Applicant's proposed premises and that of Brittania Pharmacy. Whilst the Committee is able to appreciate that the distance between the two premises (83m as per the google map route submitted by Maplestead Pharmacy) may be short, it is of the view that this is not within the realms of 'adjacent premises' as envisaged by the Regulations.

7.9 Based on the information provided, the Committee was not required to refuse the application under the provisions of Regulation 31.

Regulation 25

7.10 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."

7.11 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)

7.12 In relation to Regulation 25(1), the Applicant is applying for inclusion in the relevant pharmaceutical list as 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, and paragraph (1)(b) 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)

7.13 As far as Regulation 25(2)(a) is concerned, the Committee had regard to the application form in which the Applicant states "*Application not on the same site or in the same building as the premises of a provider of primary medical services with a patient list*." The Committee noted that this had not been disputed and that it had not been provided with any information to persuade it otherwise. The Committee was therefore satisfied that the proposed premises were not on the same site as, or in the same building as the premises of a provider of primary medical services with a patient list.

Regulation 25(2)(b)

7.14 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, including its Standard Operating Procedures (SOPs) that it intends to use at the proposed pharmacy premises.

7.15 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, in a safe and effective way, across England, and that pharmaceutical services will be provided without face to face contact.

7.16 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.

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

7.18 It is not for the Committee to 'approve' or 'disapprove' of these SOPs (as they may contain matters not relevant to the Committee's consideration, and there are many ways an applicant can choose to organise itself in order to comply with the various requirements of the Regulations) and the Committee has not sought to do so. The Committee has sought evidence within the SOPs and application in order to satisfy itself that it is appropriate to grant the application, the absence of which would require it to reject it.

7.19 The Committee noted in the SOPs provided by the Applicant that SOP 1 ‘Introduction and Background to SOPs’ states at 1.3:

7.19.1 *“The uninterrupted provision of pharmaceutical services, during the opening hours of the premises, to persons anywhere in England who request those services.*

The safe and effective provision of pharmaceutical services without face-to-face contact between any person receiving the services, whether on their own or on someone else's behalf, and the owner of this pharmacy or any member of staff either on or in the vicinity of the premises."

7.20 Further, SOP 3 'Procedures for NHS Pharmaceutical Services' states:

7.20.1 *"NHS Pharmaceutical Services will be provided to any patient living in England who requests such services, this is made clear on the website and in the Practice leaflet. Patients who wish to send paper prescriptions to the pharmacy by post should be sent stamped addressed envelopes to enable them to do so."*

7.21 The Committee noted the comments from Mayors Chemist state "*Alpha Medics Ltd.'s reference to a second pharmacist for cover during breaks is vague and operationally unconvincing. Without a precise, documented rota or contingency measures, there remains a real risk of non-compliance with RP requirements, potentially leading to unlawful dispensing or service disruption."* Further, comments from Laville Limited's representative states *"In the appeal letter it is said that there will not be any absence of the Responsible Pharmacist ("RP") as a second pharmacist is required to sign in as RP if the first leaves the premises. The SOPs attached to the appeal do not contain any provision for circumstances in which one of the two pharmacists is not available to work at the pharmacy for any length of time. The Pharmacy Business Continuity Plan states that if a member of staff is absent and no other employee is able to cover the role the Superintendent Pharmacist should 'Seek appropriate alternative staff to cover, e.g. from other branches or pharmacies where a mutual aid arrangement is in places.' … It is unclear from the application whether Alpha Medics Limited has any other branches."*

7.22 In SOP 34 'The Responsible Pharmacist' states under a heading 'Absence of the RP':

7.22.1 *"As a Distance Selling pharmacy, we must provide uninterrupted service throughout the opening hours of the pharmacy. Whilst the GPhC permits the absence of the RP from the pharmacy in particular situations, the NHS Terms of Service still require* ***a pharmacist*** *to be present so that services are not interrupted.*

If, for any reason, the RP wishes to leave the premises or wishes to take a break then the second pharmacist must sign in as the RP and arrangements must be made for this prior to one RP leaving the premises and another RP signing in." [emphasis provided in the SOPs]

7.23 Insofar as *"mutual aid arrangements"* the Committee concluded that this was an example provided in the SOPs and not an approach the Applicant must adopt. Whilst Laville Limited's representative had highlighted paragraph 1.4 page 16 of the SOPs that "At least two members of staff **(unless fewer than two are working** at the pharmacy)…", the Committee did not consider this contradicted the Applicant's assurance as provided at 7.22.1.

7.24 Based on the information before it, the Committee was satisfied that the provision of essential services would be available to persons anywhere in England and without interruption.

7.25 The Committee went on to consider whether pharmaceutical services would be without face to face contact.

7.26 The Committee noted parties concerns regarding potential face to face contact and the site of the premises (on a high street). The concerns noted were as follows:

7.26.1 Alvin Rose Chemist

7.26.1.1 "*Encourages walk-in behaviour, undermining the core non-patient facing requirements of DSPs (per Regulation 64(3) of the 2013 Regulations).*

Risks patients bypassing local pharmacies believing services can be access by Alpha Medics on site, leading to misrepresentation."

7.26.2 Hannigan Pharmacy

7.26.2.1 "*Any DSP located on a High Street, despite proposed measures implying the public will not be allowed access, is questionable. The entry and exit of staff members, the visibility of wholesalers delivering medication, the visibility of pharmacy drivers and pharmacy branded vehicles at the premises, would all draw the local population to see and understand a pharmacy to be present and available for them."*

7.26.3 Mayors Chemist

7.26.3.1 "*The embedded retail nature of the site undermines the fundamental principle that such services should not encourage face-to-face access, making the location inherently unsuitable for its purposed use."*

7.26.4 Brittania Pharmacy

7.26.4.1 "*…my concern still remains that members of the public will not be able to distinguish the premises from a conventional bricks and mortar pharmacy and in reality, the location is still that of a shop front and not in the ethos of a true DSP."*

7.26.5 Maplestead Pharmacy

7.26.5.1 "*…the location of 292 Lodge Avenue lends itself to be seen as a retail outlet and despite the assurances provided by the Applicant that there will be secured entrance, there is no assurance that this will be the case in reality."*

7.27 The Committee noted in its observations, the Applicant's representative states "*with respect to premises, the SOPs provided make it clear that no services will be provided at the premises and a controlled entry system will mean that no patient can access the premises. Further, the floorplan already provided shows that the pharmacy does not cater for walk in patients or have any sort of retail area."* The Committee is mindful that the Applicant's representative has provided updated SOPs since the appeal was lodged in response to the amendment to Regulation 25 and that it is these SOPs which it will consider.

7.28 The Committee noted that throughout the SOPs, the Applicant states that pharmaceutical services will be provided without face to face contact between patients and any member of the pharmacy staff. In SOP 1 'Introduction and Background to SOPs' it states, under a heading 'Overriding Provisions Applicable to All SOPs':

7.28.1 *"All staff must be made aware that face to face contact between patients (or their representatives) is prohibited in respect of any and all NHS services either on or in the vicinity of the premises.*

Any reference to 'contact' with or 'contacting' a patient in relation to these SOPs means contact other than face-to-face contact either on or in the vicinity of the premises."

7.29 Further, the Committee noted that there is reference to patients using multiple methods to contact the pharmacy that did not result in face to face communication. SOP 3 'Procedures for NHS Pharmaceutical Services' under the heading 'Communication Channels' states:

7.29.1 *"All communication regarding NHS Pharmaceutical Services should be carried out using the most suitable non face to face method for the patient and the service being provided with particular consideration to maintaining confidentiality. This may be telephone, email, video-conferencing or other types of non face to face communications such as text messages.*

The pharmacy has provision for both live audio and live video communication with patients and this must always be carried out in the specified confidential area of the pharmacy premises."

7.30 The Committee considered the information provided in the SOPs was sufficient to provide assurance that the Applicant, if granted, would be offering pharmaceutical services without face to face contact.

7.31 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.

7.32 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 safe and effective provision of pharmaceutical services was likely to be secured.

7.33 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.

Dispensing of drugs and appliances

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

7.35 The Committee noted that SOP 3 'Procedures for NHS Pharmaceutical Services' states:

7.35.1 *"NHS Pharmaceutical Services will be provided to any patient living in England who requests such services, this is made clear on the website and in the Practice leaflet. Patients who wish to send paper prescriptions to the pharmacy by post should be sent stamped addressed envelopes to enable them to do so."*

7.36 Further, SOP 6 'Online Receipt & Exemption Checking', under the heading 'Scope', states:

7.36.1 *"…Requests to collect and dispense NHS Prescriptions.*

Requests to dispense a prescription received in the post.

Any requests from the "contact us" section of the website."

7.37 The Committee had regard to SOP 20 'Order Delivery' which states, under the heading 'Choice of Delivery Method':

7.37.1 *"For items **other than** cold chain / "fridge line" items, local deliveries (up to 30 miles radius, but may be extended at the discretion of the RP) the delivery driver should deliver medication. Outside this area Royal Mail should be used unless the prescription is for a controlled drug, in which case the nominated controlled drugs courier must be used (see SOP for Delivery of Controlled Drugs), or the items are fridge lines, in which case the cold chain courier must be used"* [emphasis provided in the SOP]

7.38 The Committee was satisfied that the Applicant was proposing to offer the service to all of England, as per the information contained in the SOPs.

7.39 The Committee was therefore satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 5(2)(3) of Schedule 4.

Urgent supply without a prescription

7.40 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.

7.41 The Committee had regard to SOP 17 'Emergency Supply and Urgent Supply' which describes how the Applicant will process such a request. The Committee noted that the SOPs refer to pharmaceutical services being delivered by several methods of non face-to-face communication including telephone and email, and considered that it was reasonable to infer that these methods would be used to receive requests from prescribers for the urgent supply of drugs.

7.42 Further SOP 17 states under a heading titled 'Delivery of Urgent and Emergency Supply Items':

7.42.1 *"Given the nature of a request of this type, the Pharmacy should prioritise delivery of the medication to the patient. For local deliveries the driver should be specially informed of the fact that the items are "URGENT" and for any items delivered by courier, the company must be informed that items must be delivered ASAP by the quickest route possible. The Pharmacy must not charge additional fees to the patient even if these are incurred in the delivery process."*

7.43 The Committee notes the concerns raised by Laville Limited's representative that the SOPs provided by the Applicant do not address the timeframe for 'urgent' deliveries to be made. The Committee was of the view that the above SOP and the statement "*items must be delivered ASAP by the quickest route possible"* addresses this concern.

7.44 The Committee was therefore satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 6 of Schedule 4.

Preliminary matters before providing ordered drugs or appliances

7.45 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.

7.46 The Committee noted SOP 6 'Online Order Receipt & Exemption Checking' states under a heading 'Exemption NHS Prescriptions':

7.46.1 "*Where no satisfactory evidence of exemption has been provided patients should be informed that checks to prevent and detect fraud are routinely undertaken by the NHS.*

…

Where evidence of exemption is required or provided by the patient it can be sent to the pharmacy for verification via the delivery driver and then returned to the patient. The PMR system should be updated to reflect that necessary check has been carried out and a note of when the next check is required should be entered onto the system. The Regulations require a patient to produce 'satisfactory evidence' to confirm exemption. Where appropriate (i.e., for deliveries made other than by the pharmacy's delivery driver), the patient may scan or fax copies of the evidence to the pharmacy (or use the postal / courier service, but see NOTE below) and the pharmacy can note that the evidence provided was not in original format. It is for the pharmacist in charge to determine if the evidence is satisfactory or not and, if not, then cross the 'Evidence not Seen' box."

7.47 The Committee was therefore satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 7(3) of Schedule 4.

7.48 The Committee moved on to consider whether the Applicant had explained how charges will be paid.

7.49 The Committee noted SOP 6, under the heading 'Paid NHS Prescription', states:

7.49.1 "*Check the prescription to confirm how many charges are due.*

Check to see if any fees have been paid and if so, was the correct amount paid?

Contact the patient to arrange payment using the secure payments system using the "customer not present" option.

If no fees have been paid or there is a discrepancy between fees paid and those due, the patient should be contacted and directed to pay the appropriate fees via the online payment system."

7.50 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 7(5)(b) of Schedule 4.

Providing ordered drugs or appliances

7.51 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).

7.52 The Committee noted that SOP 'Order Delivery' states under the heading 'Transfer to the Delivery Driver':

7.52.1 *"Ensure that the pharmacist on duty is available to supervise the handing over of all items for delivery.*

Ensure that any special instructions for the delivery are included with the packaging.

Ask the delivery driver to check the details on the delivery sheet correspond to the deliveries.

Ensure the delivery driver completes all the sections on the delivery sheet including their name and the date.

Ensure the delivery driver is notified of any messages for the patient or representative.

Make and retain a copy of the delivery sheet until the original has been returned by the delivery driver. The original must be returned to the pharmacy on the same day.

Ensure the deliveries are placed in the delivery vehicle and are stored securely and out of sight. The delivery vehicle must be locked at all times when left unattended.

At hand-over to the driver / courier ensure that any current falsified medicines regulation or guidance is followed."

7.53 Further, under the heading 'Delivery of a Prescription via Royal Mail (not for Cold chain or CDs)', the same SOP states:

7.53.1 *"Follow preparation for delivery process. The pharmacist must contact any patients for whom there are relevant messages or counselling required.*

Ensure that the pharmacist on duty is available to supervise the handing over of all items for delivery.

Print and attach relevant Royal Mail Signed For delivery labels using the Royal Mail online business account and attach securely to outer packaging.

Ensure a return address is printed clearly on the outer packaging.

Confirm details of all prescriptions to be delivered.

Make a note of all Tracking numbers for prescriptions being delivered by Royal Mail on Delivery Log sheet.

Ensure Royal Mail driver signs Delivery Log sheet for all prescriptions being accepted for delivery. Store Delivery Log sheet for a minimum of 3 months from dispatch date.

Email patients dispatch confirmation with their Tracking number when the prescriptions have left the premises.

All deliveries will require a signature from the patient to confirm receipt of their prescription."

7.54 The Committee noted that SOP 20 also states, under the heading 'Cold chain delivery via courier':

7.54.1 "*All cold chain deliveries must be carried out by couriers with verified and approved cold chain procedures. A list of approved cold chain couriers is available within the Pharmacy and will be updated from time to time. Each approved courier meets stringent criteria to ensure a fully monitored and dedicated cold chain service.*

Specialist cold chain courier service will ensure the integrity of the cold chain and the maximum stability of thermo-liable drugs by packing, transporting and delivering in such a way that their integrity, quality and effectiveness are always preserved. This is a dedicated, fully monitored and temperature controlled delivery service.

Any breach of cold chain conditions will be notified to the driver and any affected delivery will be cancelled with the pharmacy informed of the cold chain breach.

…

Staff must confirm with the RP if wishing to use a courier company other than the NOMINATED courier above.

Ensure any items for cold chain delivery via courier are stored in the fridge and accompanying items are appropriately marked with a fridge line sticker. Accompanying items must include a note to explain that fridge items will be delivered separately to the rest of their items to enable the cold chain to be maintained.

…

A delivery must be booked using the couriers specified Cold Chain Services (refer to booking procedure with courier in the "cold chain courier" folder),

Select a delivery maintaining 2– 8°C unless the item requires shipping at a different temperature.

The cold chain item must be kept in the fridge until the courier arrives to accept the delivery.

Confirm with the courier that the delivery will be maintained at the booked temperature range.

Confirm details of all prescriptions to be delivered.

The courier must scan a barcode sticker for each item. The pharmacy retains a copy of the barcode which is also the tracking number.

Make a note of all Tracking numbers for prescriptions being delivered by the courier on Delivery Log sheet.

Ensure courier signs Delivery Log sheet for all prescriptions being accepted for delivery.

Remove items from the DELIVERY FRIDGE and match against the delivery log and place a copy of the barcode sticker on the packaging.

At hand-over to courier scan the aggregated FMD code [NOTE THAT A NEW FMD PROCESS HAS YET TO BE AGREED POST BREXIT] (the system will disaggregate the unique identifiers and forward them to the NMVS for decommissioning)

Give all fridge line deliveries to the courier.

Store Delivery Log sheet for a minimum of 3 months from dispatch date.

Contact the patient and dispatch confirmation with their Tracking number when the prescriptions have left the premises. Live tracking with estimated ETA is available via the courier website.

All deliveries will require a signature from the patient to confirm receipt of their prescription."

7.55 Under the heading 'Unsuccessful cold chain delivery via courier', SOP 20 states:

7.55.1 *"In the event of an unsuccessful delivery, the courier will leave a 'Missed Delivery' card, stating the date and time of the attempted delivery along with details of how to contact the courier to arrange the redelivery. The patient can then rearrange delivery for a convenient time by telephone or Internet.*

We operate to a 48 hour maximum window for cold chain deliveries and the courier will keep the cold chain intact until successful delivery for up to 48 hours. After 48 hours the items will be returned to the pharmacy and the pharmacy will contact the patient to rearrange delivery."

7.56 Under the heading 'Breach of Integrity of Cold Chain', SOP 20 states:

7.56.1 *"The courier ensures temperature integrity throughout the supply chain, from point of collection & goods-in to pharmaceutical storage to final delivery.*

The cold chain service is a dedicated, fully monitored and temperature controlled delivery service. However, in the event of any breach in the integrity of this service, the system automatically alerts the delivery driver that the cold chain has not been kept intact.

Where such an event occurs, the courier is instructed to leave a 'Missed Delivery' card and also inform the pharmacy that the delivery was unsuccessful due to a breach of the cold chain. The pharmacy must arrange for immediate re-delivery of the items via courier and the return of the items that have failed to be delivered to the pharmacy by the courier. items subject to a cold chain breach may not be re-used and must be segregated from the pharmacy stock."

7.57 The Committee noted that SOP 24 'Controlled Drugs: Delivery' states under the heading 'Delivery of Schedule 2 & 3 CDs':

7.57.1 *"A robust audit trail is essential when controlled drugs are involved. The delivery can be made to a person who is not the patient (the patient must have given authorisation for a representative to take receipt of CDs on their behalf). A Controlled Drugs Delivery Sheet must also be filled in for CD deliveries in addition to the Delivery Log sheet.*

CDs must be in a separate bag to any other medication being delivered and the bags should be attached together.

CDs and any other medicines on that patient's delivery must be stored in the lockable compartment of the delivery van and out of sight.

The delivery van must be kept locked at all times when the driver is not in the vehicle.

The delivery driver/courier must sign the back of the prescription as the representative when accepting the CD for delivery.

The delivery driver/courier must check the identity of the person accepting the delivery to ensure that it is the patient or authorised representative (passport, driving licence or government approved photo ID card are acceptable forms of ID). A delivery cannot be left with anyone who is not the patient or their authorised representative.

Any falsified medicines rules introduced by the UK must be followed

All entries in the CD register must be made when the medication leaves the pharmacy premises. The delivery driver/courier must be entered as the 'person collecting'.

The prescription must be retained in the pharmacy until the delivery driver returns the appropriate paperwork signed by the patient or representative to confirm successful delivery or the patient signature is confirmed online if delivered by courier."

7.58 Under the heading 'Successful Schedule 2 & 3 Delivery' SOP 24 states:

7.58.1 *"The delivery driver/courier must check the identity of the person accepting the delivery to ensure that it is the patient or authorised representative. A delivery cannot be left with anyone who is not the patient or their authorised representative.*

For all successful deliveries the Controlled Drug delivery sheet signed by the patient or online courier delivery record should be cross-referenced with the prescription and CD register prior to the prescription being processed as part of the end of day procedure"

7.59 Under the heading 'Unsuccessful Schedule 2 & 3 Delivery via pharmacy driver' SOP 24 states:

7.59.1 *"Unsuccessful deliveries sent with a pharmacy driver must be returned to the pharmacy on the same day and entered back into the CD register where appropriate with an explanation. These must then be secured in the CD cabinet where appropriate."*

7.60 Under the heading 'Unsuccessful Schedule 2 & 3 Delivery via courier', SOP 24 states:

7.60.1 *"Unsuccessful deliveries sent with a courier must be returned to the pharmacy on the same day and entered back into the CD register where appropriate with an explanation. These must then be secured in the CD cabinet where appropriate. Where the time of attempted delivery means that the return cannot be made on the same day, the courier will store the drugs at their approved warehouse overnight.*

When a failed delivery occurs, the tracking service will notify the pharmacy and the patient of the failed delivery so that delivery can be re-arranged for the patient at the next convenient time or returned to the pharmacy."

7.61 Further, under the heading 'Note re Use of Couriers for Controlled Drugs Deliveries' SOP 24 states:

7.61.1 *"The courier has pharma grade specialist facilities to meet specific quality and validation requirements for healthcare products. This includes Home Office licensed controlled drug stores."*

7.62 Based on the information before it, the Committee was satisfied that the Applicant had provided information sufficient to show that there would be compliance with paragraph 8(1) of Schedule 4.

7.63 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.

7.64 The Committee noted that in its application form, the Applicant had stated:

7.64.1 "*Drug Tariff part IX* (*except items that require measuring or fitting)."*

7.65 The Committee noted SOP 27 'Support for Self-care, Signposting and Health Promotion' states under the heading 'Items Requiring Measuring and Fitting':

7.65.1 *"Where a prescription is received for an appliance or stoma appliance customisation or any item that requires measuring or fitting the patient must be contacted and informed that these items are not available from this pharmacy as we do not provide a measuring and fitting service. Patients must be signposted to at least two other providers of the service in their area."*

7.66 In the event that the application is granted, the Applicant would not therefore be able to provide to patients any appliances that require measuring or fitting.

7.67 Based on the information before it, the Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 8(4) of Schedule 4.The Committee considered whether the Applicant had explained what containers would be suitable for posted/delivered items.

7.68 The Committee noted the concerns of Alvin Rose Pharmacy:

7.68.1 "*Premises too small to support nationwide DSP operations*

…

Inadequate for storage, packing, dispatch, segregation of stock; more akin to local retail footprint."

7.69 The Committee noted that SOP 19 'Bagging Up' states under the heading 'Choice of Packaging':

7.69.1 *"Choice of packaging will depend on the nature of the items being delivered and the appropriate level of protection must be used to ensure that the item can withstand the normal rigours of the delivery process.*

All packaging must have the tamper proof seals provided in the pharmacy attached to the packaging so that any tampering with the packaging will be evident.

Medicine for local delivery which is not fragile and to be delivered by the delivery driver can be packaged in the using the pharmacy bags supplied for standard prescription items.

DO NOT use normal cardboard boxes. When cardboard boxes are required ALWAYS use the re-enforced boxes that are purchased for delivery purposes.

For postal items, either:

At the very least - padded envelopes even for non-fragile items as this will help to ensure the integrity of the manufacturers packaging.

*For most items - bubble wrap and where necessary, polystyrene filler, placed within a cardboard box. **use the re-enforced cardboard boxes***

Large or any fragile medicines should be packed into the re-enforced cardboard boxes with bubble packaging and filling material to protect from damage.

Coldchain items should be bubble wrapped and placed in Styrofoam filled re-enforced cardboard boxes and kept in the DELIVERIES FRIDGE (rather than the storage fridge) with the "FRAGILE" and "FRIDGE LINE" stickers attached. The courier company will transport the boxes in vans with cold chain sections that protect the integrity of the box ("cold ship" packaging) and are fully monitored – typically at 2 to 8 degrees Celsius range- (see delivery SOP). Pharmacy staff should be aware that some thermolabile products can be damaged by excessive cold as well as heat. Items such as ice packs can cause freezing in medicines which is damaging to them and such items must not be used." [emphasis provided in the SOP]

7.70 The Committee was of the view that the size of the premises was not relevant to its consideration under the Regulations. Based on the information placed before it, the Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 8(15) of Schedule 4.

Refusal to provide drugs or appliances ordered

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

7.72 The Committee noted that SOP 35 'Repeat Dispensing' states under the heading 'Pharmaceutical & Legal Assessment':

7.72.1 "*Terms of Service states that a pharmacy must, when providing drugs in accordance with a repeatable prescription the importance of only requesting those items which they need. Patients should be so advised either by phone or through the inclusion of written information with delivered medication.*

The pharmacist should telephone and speak with the patient before issuing a repeat and ensure:

They are taking or using, and likely to continue to take or use the medicine or appliances appropriately

Advise the patient that they should only order items that they need

Check that the patient is not suffering any side effects which may suggest they need a review of their medication

Check that the patient's regimen has not been changed since the prescriber authorised the repeatable medication.

Check that there has not been any change to the patient's health since prescription was authorised

Provide advice and encourage patients with long term, stable medical conditions to discuss repeat dispensing of their medicine with their prescriber.

Any interventions, referrals (to the patient's GP or otherwise) or refusal to supply decisions which are deemed to be clinically significant should be recorded on the Intervention and Referral Form which must be shared with the patient's GP."

7.73 The Committee further noted that under the heading 'Prescription Reception', SOP 35 states:

7.73.1 "*Check to confirm if the patient has a long term, stable medical condition that requires regular medicine in the short to medium term and ensure relevant patients have the scheme explained to them.*

The pharmacy record card must be completed and attached to a RA and an entry made on each occasion a dispensing takes place.

Any amendments to the RD, e.g. items not issued or change to expected interval must be recorded in the comment section of the pharmacy copy of the card.

When a RA is accepted the details should be checked thoroughly to ensure that there are no omissions or errors which could prevent the dispensing of all the batch prescriptions.

The RA should be retained in the pharmacy although it is the patient's choice whether they leave the RD with the pharmacy or retain them."

7.74 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

7.75 The Committee considered whether the Applicant had explained how appropriate advice about the benefits of repeat dispensing to be given to any patient who (i) has a long term, stable medical condition (that is, a medical condition that is unlikely to

change in the short to medium term), and (ii) requires regular medicine in respect of that medical condition.

7.76 The Committee noted SOP 35 'Repeat Dispensing' under the heading 'Prescription Reception' states:

7.76.1 *"Appropriate advice about the benefits of repeat dispensing must be given to any patient who:*

has a long term, stable medical condition (that is, a medical condition that is unlikely to change in the short to medium term); and,

requires regular medicine in respect of that medical condition, including, where appropriate, advice that encourages the patient to discuss repeat dispensing of that medicine with a prescriber at the provider of primary medical services whose patient list the patient is on.

Such advice will be provided by the Pharmacy using its permissible methods of non face-to-face contact with patients.

On receipt of a repeatable prescription from the patient, either in the post or collected from the surgery for the first time, the pharmacy staff should ensure that the patient fully understands the Repeat Dispensing Process and is provided with a patient information leaflet that outlines the benefits of the service."

7.77 Further, under the heading 'Pharmaceutical & Legal Assessment', SOP 35 states:

7.77.1 *"Provide advice and encourage patients with long term, stable medical conditions to discuss repeat dispensing of their medicine with their prescriber."*

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

Disposal service in respect of unwanted drugs

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

7.80 For the return of controlled drugs, the Committee noted SOP 25 'Controlled Drugs: Collection and Disposal of Patient Returns' under the heading 'Patient Returned Medication' states:

7.80.1 "*This service is available to <u>all</u> patients living in England.*

Patients or their representatives <u>may not</u> return and medicines directly to the pharmacy and must follow the procedures set out in this SOP.

Patients should be referred to the 'Returning unwanted medication' page on the website for information.

To arrange the return of unwanted medicines to the Pharmacy the patient must telephone and speak to a member of the dispensary team. For controlled drugs this must always be the pharmacist on duty.

The process for returning medication must be explained to the patient.

Each return will be made by booking an appointment for the pharmacy's driver to visit the patient's home to collect the returned medication or by sending the appropriate packaging to the patient to arrange for return by Royal Mail …" [emphasis provided in the SOP]

7.81 Under the heading 'Return by Royal Mail' SOP 25 states:

7.81.1 "*The pharmacist must*

Speak to the patient about the return and clarify the items being returned.

Assess the items for suitability for return by Royal Mail

If items are suitable for return by Royal Mail then make a note on the PMR and arrange to send the appropriate packaging to the patient for safe return (refer to bagging up SOP for appropriate packaging)

If items are not suitable for return by Royal Mail (e.g. clinical or contaminated waste) then provide the patient with details of their local procedures for disposal.

Send the packaging to the patient along with the instructions for appropriate packing of the goods

Contact the patient to ensure that the packaging has been received

Provide signposting to other pharmacies where the patient prefers to dispose of unwanted medicines locally."

7.82 The Committee noted that SOP 25 further states, under the heading 'Handling Patient Returned CDs from Delivery Driver':

7.82.1 *"Drivers need to:*

Be aware that they cannot accept patient returns from patients without prior arrangement. The driver must notify the patient to follow the "returning unwanted medication" process as set out on the website.

Ensure that appropriate packaging is within the van prior to starting the journey as the patient may not have requested the correct type or there may be a requirement for additional packaging."

7.83 The Committee noted that SOP 26 'The Safe and Effective Receipt and Disposal of Medicines' states under the heading 'Process for Patients to Return Medication':

7.83.1 "*Patient Returned Medication*

Patients or their representatives MAY NOT return and medicines directly to the pharmacy and must follow the procedures set out in this SOP.

This service is available to all patients living in England.

Patients can be referred to the 'Returning unwanted medication' page on the website for information.

To arrange sending medication back to the Pharmacy the patient must telephone and speak to a member of the dispensary team.

Patients may

Arrange collection by the Pharmacy driver at an appointed time, or

Send unwanted medication back to the Pharmacy via courier (at the pharmacy's cost), or Royal Mail (subject to risk assessment of contents by the RP in advance) or,

The Pharmacy can arrange for medication to be collected by our specialist waste management contractor.

Advise patient of their other options to dispose of unwanted or expired medication if none of these options is suitable for them (signposting to local pharmacies)."

7.84 Under the heading 'Process for accepting patient returns by the Driver' SOP 26 states:

7.84.1 "*Confirm that a collection of unwanted medication for disposal has been booked. Returns without a booking should only happen in exceptional circumstances as this increases the chance that the proper process for segregation of medicine has not been followed.*

Ensure you are fully equipped with the utensils in your vehicle to accept unwanted medication as patients may have placed unwanted medication into incorrect bags

Wear appropriate protective clothing where there is a requirement to handle any returned waste.

Identify any controlled drugs (check with the pharmacist if necessary); segregate these and place in a labelled clear bag for the pharmacist for denaturing and disposal. For further guidance read SOP Controlled Drugs: Disposal of Patient returned medication'.

Identify any sharps and ask the customer to take these back if it safe to do so, signposting to the most appropriate route of disposal.

Identify any cytotoxic or other hazardous waste (check with the pharmacist where necessary).

Identify any flammable waste and store separately until this can be removed by the waste contractor.

Where large quantities of the same medicine are being returned, then report this to the pharmacist as this could indicate a compliance issue requiring intervention.

Complete the 'Patients Returns Sheet' detailing the patients name and address, also if relevant their representatives name.

Store returned medicines in the quarantine area of the van for transport.

The returnable items can be taken back to the pharmacy for destruction.

Ensure medicines are not visible in the vehicle at all times"

7.85 SOP 26 goes on to state under the heading 'Disposal of returned medicines':

7.85.1 "*Use the specialist waste management company to provide safe and secure disposal of unwanted medicines by collection of unwanted medicines from patients and residential homes.*

Unwanted medicines collected by the driver must be sorted and placed in disposal units / containers provided by the NHSCB or a waste contractor retained by the NHSCB ready for waste management services to collect."

7.86 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 13 – 15 of Schedule 4.

Promotion of healthy lifestyles

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

7.88 The Committee noted that SOP 28 'Promotion of Healthy Living, Lifestyles & Health Campaigns' under the heading 'Health Campaigns and Community Engagement Exercise' states:

7.88.1 *"Terms of Service require participation in up to 6 campaigns per financial year, but you should agree to take part in all campaigns where practicable.*

The Pharmacy will take part in national health campaigns to promote public health messages to patients across England. This will be achieved by sending out leaflets with prescriptions during specific targeted campaign periods and providing additional advice and learning resources via the website on the health promotion zone.

The pharmacy will also take part in at least one approved community engagement exercise in relation to the promotion of health living each financial year.

Patients will be directed to the learning resources via email, text and other non face-to-face communication so that they are aware of the campaign.

Patients should also be assessed for participation in at least one clinical audit and whichever of the following that the NHSCB specifies—

(i) a clinical audit carried out in a manner which is compatible with the NHSCB's arrangements for the receiving and processing of data from the audit, or

(ii) a policy based audit (to support the development of the commissioning policies of the NHSCB) carried out in a manner which is compatible with the NHSCB's arrangements for the receiving and processing of data from the audit.

We will also offer help and support on our website and direct patients to appropriate links for the health campaigns. This will ensure that patients across the UK are able to easily access information about health campaigns at all times."

7.89 SOP 28 also states, under the heading 'Identification of patients for promotion of Healthy Lifestyles':

7.89.1 *"Leaflets will be delivered to patients with their medication. Those identified as having medical conditions such as diabetes, coronary heart disease, COPD, Asthma, high blood pressure, smokers, overweight individuals, etc. or being at risk from them or other conditions will also receive targeted campaigns. The website, app and email newsletters will also be used to promote healthy lifestyles via the health promotion zone."*

7.90 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.

Prescription linked intervention

7.91 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.

7.92 The Committee noted that SOP 28 'Promotion of Healthy Living, Lifestyle & Health Campaigns', under the heading 'Identification of patients for promotion of Healthy Lifestyles', states:

7.92.1 "*Identification can take three forms, namely, passive, active, or as part of the repeat (or normal) dispensing process.*

Active patients *will be those who have chosen to access the Lifestyle Questionnaires via the website or returned them by post and who are then identified from the results as patients to whom further information should be sent, or who should be called to follow up on the results and offer additional support and information. All patients who have prescriptions dispensed or purchase medicines from the pharmacy will be asked to fill in the Lifestyle Questionnaire which will ask for details such as existing medical conditions, height, weight and also lifestyle questions such as whether a patient is a smoker and how much exercise they normally have on a weekly basis.*

Passive patients *are those where the identification happens as part of another interaction with the patient, but where the patient does not appear to be actively seeking additional assistance. For example, the dispensing of a prescription which identifies the patient as having high blood pressure / diabetes etc.*

As part of repeat dispensing process (or during any other interaction with a patient) *staff should record the information provided by patients on the PMR system. Where a patient provides information that indicates that they would benefit from promotion of healthy lifestyles they should be recorded as a 'target patient' and the appropriate information that is relevant to them should be provided.*

Leaflets will be delivered to patients with their medication. Those identified as having medical conditions such as diabetes, coronary heart disease, COPD, Asthma, high blood pressure, smokers, overweight individuals, etc. or being at risk from them or other conditions will also receive targeted campaigns. The website, app and email newsletters will also be used to promote healthy lifestyles via the health promotion zone." [emphasis provided in the SOP]

7.93 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 17 of Schedule 4.

Health Campaigns

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

7.95 The Committee noted that SOP 28 'Promotion of Healthy Living, Lifestyle & Health Campaigns' under the heading 'Health Campaigns & Community Engagement Exercise', states:

7.95.1 *"The Pharmacy will take part in national health campaigns to promote public health messages to patients across England. This will be achieved by sending out leaflets with prescriptions during specific targeted campaign periods and providing additional advice and learning resources via the website on the health promotion zone.*

The pharmacy will also take part in at least one approved community engagement exercise in relation to the promotion of health living each financial year.

Patients will be directed to the learning resources via email, text and other non face-to-face communication so that they are aware of the campaign.

…

We will also offer help and support on our website and direct patients to appropriate links for the health campaigns. This will ensure that patients across the UK are able to easily access information about health campaigns at all times.

The Pharmacy will use the opportunity when dispensing prescriptions for patients who have conditions such as diabetes, heart disease, obesity and high blood pressure, to offer health advice over the phone or provide them with leaflets about their conditions. Patients will also be able to speak to the pharmacist regarding information about the campaigns. Advice and help will be available to patients during opening hours of the pharmacy and patients can access information on our pharmacy website at all times. This ensures the uninterrupted provision of the service to patients across England."

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

Signposting

7.97 Laville Limited's representative raised concerns in its representations that *"The SOP refers to a signposting SOP but there is no signposting SOP included".* Whilst the Committee can see that there is no singular SOP titled 'Signposting', it had regard to the entirety of the Applicant's most up to date SOPs since the amendment to Regulation 25 and it is this latest document which it has reviewed.

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

7.99 The Committee noted that SOP 27 'Support for Self-care, Signposting and Health Promotion' states under the heading 'Patient Identification':

7.99.1 *"Identification can take place during any interaction that the patient has with the pharmacy staff. In particular, staff should consider the results from the identification of patients for the promotion of healthy lifestyles and those who have filled in the Lifestyle Questionnaire on the website.*

Staff should always consider that in order to minimise inappropriate use of health and social care services and of support services and person who:

requires advice, treatment or support that we cannot provide; but

we are aware of another provider of health services who is likely to be able to provide that advice, treatment or support.

We must provide the patient with contact details of that provider and, where appropriate, refer the person to the provider. At least two providers should be identified if this is possible."

7.100 The Committee further noted that SOP 27 states under the heading 'Other Provider Organisations and Support Details':

7.100.1 *"Details of local health and social care providers to whom patients can be referred as well as contact details for local patient and support groups can should be provided to patients via written mailshots, flyers sent with prescription deliveries, our website and by telephone or email."*

7.101 The Committee was 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

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

7.103 The Committee noted that in SOP 27 'Support for Self-Care, Signposting and Health Promotion', under the heading 'Service Outline', it states:

7.103.1 *"Upon receipt of a request for help with the Support for Self-Care, including treatment of minor illness and long-term conditions, pharmacy staff should consider available resources and provide general information and advice on how to manage illness.*

If appropriate, access the patient's Summary Care Record / National Care Records Service to see if it assists in delivery of the service.

…

The pharmacist should provide advice on the appropriate use of non-prescription medicines which can be used in the self-care of the relevant minor illness and / or long-term conditions."

7.104 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 21 – 22 of Schedule 4.

Discharge Medicines Service

7.105 The Committee considered whether the Applicant had now 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.

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

7.107 The Committee noted SOP 29 'Discharge Medicines Service ("DMS")' states under the heading 'Process':

7.107.1 *"Every day the RP must check the pharmacy's NHS mail system, PharmOutcomes and Refer to Pharmacy for referrals to the DMS. Pharmacy contractors must consider any communication in the following form and manner as constituting a referral: "Any written patient information received by a community pharmacy via secure electronic message from an NHS trust or other provider of NHS services concerning a patient's discharge to usual primary care services and their medicines regimen"."*

7.108 The same SOP, under the heading 'DMS Stages', goes on to state:

7.108.1 *"It is expected that all patients referred to the pharmacy will receive all three stages of the service. Note that stages 1, 2 and 3 of the service may occur in parallel and first contact with the patient (as defined in the NHS Discharge Medicines Service toolkit) could happen at any stage in the process."*

7.109 The Committee noted that, under the heading 'Additional advice, assistance and support', SOP 29 states:

7.109.1 *"When the pharmacy either receives a prescription (in whatever form) or has been made aware via a referral to the DMS that a prescription is the first prescription for a medicine that has been made following the patient's discharge from hospital, or where the patient's care has been transferred from another NHS service provider, the following steps must be followed:*

Summary Care Record / National Care Records Service Access - If appropriate, access the patient's Summary Care Record / National Care Records Service to see if it assists in providing the service

Arrange a live video call or audio call with the patient (or where appropriate and bearing in mind the duty of confidentiality their carer to; [sic]

Assess the patient / carer understanding of the medicines that the patient should be taking

The patient should have received a copy of the prescribed medication from the hospital which lists the medication you are taking. This must match the discharge prescription when written.

If changes have been made to the patient's medication regimen, clearly explain the changes.

Offer such advice, assistance and support as is appropriate in your clinical judgement in respect of the medicines being taken and the medication regimen overall.

Think about high risk medicines or those where the treatment is more complex and where extra advice and support should be provided – e.g. anticoagulants

Discuss common or expected side effects

Discuss the use of medication apps which can be downloaded and may help the patient stick to their treatment plan.

If injectables have been prescribed and the patient is considered to be able to self-administer these, then have they received appropriate training from their GP practice nurse or hospital?

Inform the patient / carer about

The disposal service offered in respect of unwanted drugs (see separate SOP). This is particularly relevant to medicines which may still be in the patient's home but may no longer be prescribed.

Any other pharmaceutical services that the patient or their carer may benefit from following their stay in hospital and / or the transfer of care from another NHS pharmacy

Follow up

Where you identify any areas of concern then to the extent it is appropriate to do so in your clinical judgement, contact the patient's GP to discuss the concerns and consider any appropriate action plan to deal with the concerns.

In every case it is important to keep and maintain records of the above discussions, concerns and actions taken as part of providing this service and these will also assist in service evaluation processes."

7.110 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.

Websites and health promotion zones

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

7.112 The Committee noted that SOP 27 'Support for Self-care, signposting & Health Promotion' states under the heading 'Health Promotion Zone on our website':

7.112.1 *"The website allows patients to access pharmaceutical services via our interactive page.*

Explaining the Interactive Page to Patients

The interactive page is promoted on the website so that when a patient first visits the website they are signposted to a range of up to date materials that promote healthy lifestyles.

The Superintendent Pharmacist is responsible for ensuring that a reasonable range of materials are accessible via the interactive page and that they address a reasonable range of health issues.

The health promotion zone may also includes [sic] *details of current health campaigns and other information to promote healthy lifestyle choices as well as providing access to the Lifestyle Questionnaire that is used to target health information to patients."*

7.113 Further, the Committee noted that SOP 28 'Promotion of Healthy Living, Lifestyle & Health Campaigns', under the heading 'Identification of patients for promotion of healthy lifestyles', states:

7.113.1 *"…The website, app and email newsletters will also be used to promote healthy lifestyles via the health promotion zone"*

7.114 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 28C of Schedule 4.

Other matters

7.115 The Committee noted the numerous concerns raised by parties in relation to the proposed High Street location of the Applicant's pharmacy and reference made to the Department of Health and Social Care's Market Entry Guidance. Whilst the Committee is sympathetic to the concerns raised, it noted that the Market Entry Guidance states:

7.115.1 *"Adequate monitoring arrangements should be put into place for ensuring such pharmacies are not providing essential services to people from or in the vicinity of the registered pharmacy premises, for example by having a "shop-front" to the registered pharmacy or delivering medicines to customers waiting in the premises' car park."*

7.116 The Committee considered therefore that the 'adequate monitoring arrangements' as referred to are a matter for the Commissioner to undertake in the event that the application is granted and not a matter for this Committee's consideration.

7.117 The Committee noted Alvin Rose Pharmacy's comments regarding the impact of the grant of this application. Whilst sympathetic to these concerns, the Committee is required to assess the application against the distance selling conditions and not consider any financial or other consequences. The same approach applies to the policy decision to end distance selling pharmacy applications which is not a relevant consideration for the Committee.

7.118 Both Alvin Rose Pharmacy and Mayors Chemists claim the application does not address how certain patient groups such as those with severe disabilities, will have equal access to services. However, the Committee had regard to item 4 of the Procedures for NHS Pharmaceutical Services where the Applicant explains how such patients will be supported.

Summary

7.119 On the information before it, the Committee could 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, and considering the Committee reached a different decision of 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 Accordingly, the Committee:

8.2.1 quashes the decision of the Commissioner; and redetermines the application as follows -

8.2.1.1 the Committee was satisfied that the proposed premises were not adjacent to or in close proximity to other chemist premises;

8.2.1.2 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;

8.2.1.3 the Committee was satisfied that all essential services were likely to be secured without interruption during the opening hours;

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

8.2.1.5 the Committee was satisfied that pharmaceutical services were likely to be secured in a safe and effective manner; and

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

8.2.2 The application is granted.

Case Manager
Primary Care Appeals