NHS Resolution

13 March 2026

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REF: SHA/ 26805

APPEAL AGAINST HERTFORDSHIRE AND WEST ESSEX ICB DECISION TO REFUSE AN APPLICATION BY PILLPORT LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT UNIT 6 WILLOW HOUSE STADIUM WAY HARLOW ESSEX CM18 6DX UNDER REGULATION 25

1 Outcome

1.1 The Pharmacy Appeals Committee ("Committee"), appointed by NHS Resolution, quashes the decision of the Commissioner and redetermines the application.

1.2 The Committee determined that the application should be refused.

A copy of this decision is being sent to:
Pharmaceutical Defence on behalf of Pillport Ltd
PCSE on behalf of Hertfordshire and West Essex ICB
Pharmacy Sales & Consultancy on behalf of Promising Healthcare Ltd t/a Greenway Pharmacy
Netteswell Pharmacy

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1 The Application

By application dated 11 June 2025, Pillport Ltd ("the Applicant") applied to Hertfordshire and West Essex ICB ("the Commissioner") for inclusion in the pharmaceutical list at UNIT 6 Willow House Stadium Way Harlow Essex CM18 6DX under Regulation 25. In support of the application it was stated:

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

1.1.1 "*NONE*".

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

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

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

1.3.1 "*Application 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*".

Pharmacy procedures

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

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

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

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

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

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

1.8 “Please see attached pharmacy procedures document.

1.9 Please see attached Draft SOPs.”

Pillport Limited- SOPs Pharmacy Procedures

1.10 Pillport Limited has prepared a draft of their initial Quality Management System and SOPs in preparation for securing the distance selling contract and to support this application. These DRAFT SOPs cover the essential services as required to be delivered by NHS pharmacy contractors and have been written to suit the Distance Selling model. The Superintendent Pharmacist will be responsible for the management of the SOPs and for training all staff on the SOPs according to their role within the pharmacy. After induction training, understanding of the SOPs will be validated by the Superintendent Pharmacist before new staff commence their shift.

1.11 The pharmacy will have SOPs in place for the provision of essential services. It is pertinent to know that only some of the SOPs have been provided to help facilitate the application, any specific SOP can be provided if requested.

1.12 Pillport Limited will have a website which facilitates the following:

1.12.1 Patient accesses website via a secure log-in procedure;

1.12.2 Patient provides details of prescription,

1.12.3 Patient will be contacted by the pharmacy and medical history assessed.

1.12.4 Patient posts prescription to pharmacy and/or prescription received via EPS.

1.12.5 Item is dispensed and details added to PMR.

1.12.6 The medication is delivered nationwide via a tracked delivery service. There will be no charge to the patient for delivery of medication dispensed against NHS prescriptions. Any costs incurred for delivery will be met by the pharmacy.

1.13 The website has been built by a company called web builder who are web developers that have experience within the pharmacy web development market. Each patient will have their own personal login account once registered which will include their own personalised password for added security. Upon

patient consent the pharmacy will then nominate them for EPS. This will then enable us to deliver a service safely and effectively to anyone in England without face to face contact.

1.14 Communication between the pharmacy and patients will be facilitated by phone, fax, email and webcam. Records of all patient interactions will be maintained on the PMR in use at the pharmacy. Pillport Limited has decided to use RxWeb as the software provider which will be a key tool in providing a safe and effective provision of service.

1.15 Pillport Limited is committed to having all staff trained by the National Pharmaceutical Association at a level suitable to their role. All training will need to be recognised and accredited by the GPhC and all staff will hold NVQ qualifications in Pharmacy Services. Staff and Responsible Pharmacists will also be provided with training on the SOPs relevant to their role. By following a set of SOPs, the pharmacy will be able to provide a safe and effective service that is patient-centric and outcome focussed.

1.16 The Superintendent Pharmacist will train all the staff members on the conditions of being a distance selling contractor. They will receive specific training on speaking to patients without face-to-face contact, an example being how to elicit a comprehensive medical history by telephone or webcam.

1.17 Pillport Limited is comprised of 1 director, [D P] who is the nominated superintendent and has suitable pharmacy experience. [D P] will act in overseeing the operations of the pharmacy and will maintain role of the Information Governance Lead, Clinical Governance Lead and Smartcard Sponsor. A full-time Responsible Pharmacist will be employed to be in attendance during the opening hours. He will be supported by a staff team of one full-time and one part-time dispenser. This level of staff will be able to cover initial trade levels once the pharmacy is open and will ensure an uninterrupted provision of essential services during the opening hours. The team is expected to grow with the business and new members will be added as and when required.

1.18 The premises have been carefully chosen to prevent face to face contact for any person seeking the provision of essential services, in, or within the vicinity of the premises. No person who is seeking essential services under the NHS contract will be allowed entry to the premises. All entrances and exits will remain inaccessible to members of the public who are seeking the provision of essential services. An alarm system will cover the pharmacy premises which will notify the owner of unauthorised access when the premises are closed. All access routes will always be secured and kept locked when the premises not in use. Keys to the pharmacy premises will only be kept with authorised persons employed by the company. Schedule 1, 2 and relevant 3 drugs will always be stored in a locked CD cabinet. Security of premises will be reviewed regularly. A chosen member of staff will be available for emergency outcall in case of a breach.

1.19 **Essential Service - Dispensing**

1.20 Uninterrupted service

1.21 Provision of service through the opening hours of the pharmacy will be maintained by having a Responsible Pharmacist present at all times during the pharmacy opening hours and having sufficient support staff at all times. The pharmacy website will run throughout these hours together with a phone, fax, email and webcam service. If the responsible pharmacist is required to leave the premises, a further pharmacist will be on hand to ensure that there is no break in pharmacist cover during the opening hours.

1.22 **Persons anywhere in England**

1.23 Patients anywhere in England can access these services via our pharmacy website a direct phone line to the pharmacy, fax, email as well as webcam. Internet connections at the pharmacy will be provided by the NHS HSCN network via BT.

1.24 All prescriptions dispensed will be delivered using a dedicated courier service provided by City Sprint (www.citysprinthealth.co.uk). This will include the delivery of prescriptions received via post, fax and EPS. City Sprint will also be delivering cold chain items and CDs. This is addressed in the SOPs which have been included.

1.25 **Safe and effectively**

1.26 The service will be delivered safe and effectively by using SOPs to manage the process. Please see the attached SOPs provided to show examples of how the pharmacy will be managed safely and efficiently at all times.

1.27 We will have a suitable number of staff who will be trained to a minimum of an NVQ level 2 standards. This training will be undertaken by National Pharmaceutical Association (NPA) (www.npa.co.uk)

1.28 Requests from patients to show the Pharmacist visual symptoms of conditions will be done via a secure video link. All conversations will be recorded on the PMR in detail.

1.29 If patient counselling is required for any dispensed medication, the pharmacy will have procedures so this can be done via the telephone, videoconferencing or email before dispatch of medication. The pharmacy will require acknowledgment from the patient or another person that the counselling points have been understood. Patient interactions will be recorded on the PMR. A label will also be attached to the packaging asking the patient to contact the pharmacy for further details.

1.30 Prior to medication being delivered, staff will contact patient to confirm delivery address, date and time. Deliveries will be monitored with the online courier tracking service which will give real-time information and is also available as an app for smart phone and tablets.

1.31 All medication will be delivered in tamper-proof and seal-proof packaging. Several companies who produce packaging material have been researched with a view to order corrugated cardboard boxes and 5-panel wraps which are able to withstand a single trip. It will be packed so it is protected from the environment which may include using a double walled package design or using

waterproofing on the packaging material. This will also ensure that the delivery person is protected from cytotoxics and sharps.

1.32 **Without face-to-face contact**

1.33 This service will be delivered without face-to-face contact via the pharmacy website as a communication link as well as telephone post/email/fax/webcam. A courier service will provide a third-party delivery if this is required when it would not be practicable to use the in-house delivery service.

1.34 If needed, Controlled Drug (CD) deliveries will be undertaken by City Sprint who are accredited to handle and transport CDs. Their drivers will deliver to patients at a pre-determined time and the CD's must be signed for on receipt. Their drivers will only deliver the CD to the named recipient and they will ask for photographic proof of ID. In the instance of a failed delivery attempt, City Sprint will return any CDs to their overnight safe storage facility and the pharmacy will be contacted to arrange alternative delivery date to patient.

1.35 City Sprint is approved by the MHRA and has fully trained couriers to deal with all pharmacy deliveries including controlled drugs and fridge items. As well as collecting prescriptions from surgeries and collection of unwanted waste medication from patients. This will ensure there is no face to face contact.

1.36 Delivery of Refrigerated Medicinal Products - For cold chain products, delivery times will always be pre-arranged with the patient to minimise the risk of failed delivery. The patient's contact number will be given to the City Sprint delivery driver so they can again call the patient approximately 15-30 minutes prior to so they can check that somebody will be at the address to receive the medication. Cold chain products will be packed in such a way as to ensure that the required temperatures are maintained throughout the journey and the medicines are transported in accordance with their labelling requirements to maintain product integrity.

1.37 For delivery of medication with short journey times of less than 3 hours, validated medical cool boxes will be used as recommended by the MHRA. For extended journeys, gels/ ice packs will be added to the packaging to maintain appropriate temperatures throughout. Extra caution will be taken with regards to the positioning of these packs within the consignments as this would be deemed extremely important as they must not be allowed to come into direct contact with the medicines being delivered. Temperatures will be strictly controlled and monitored with calibrated temperature probes to provide temperature data for the entire journey. This will be done by the courier driver. Temperatures will be recorded at the beginning of the journey and again at the point of delivery to ensure it stays between 2-8°C. If the temperature is outside of the required range, then the product will be deemed unsafe to deliver, marked as waste and returned to the pharmacy for destruction. Thermometer(s) will be calibrated annually against a certified standard to ensure safe and effective use. When used to deliver medication, the City Sprint delivery driver must only remove the item from cold storage once the patient has answered the door and verified their identity. In the event of failed delivery, the cold storage item must be returned to the pharmacy as soon as possible, with the maximum and minimum temperatures again being recorded at the

point of return. Once again, if temperature monitoring suggests that the medication may have been transported outside of the required range, then the product will be destroyed by the pharmacy and then item will be re-dispensed by the pharmacy. Once again, a new delivery will be agreed with the patient prior to redelivery.

1.38 Acute or Urgent Dispensing Requests – Any acute, urgent medication received by ETP or directly via courier from a surgery for patients anywhere in England can be dispensed and dispatched the same day using City Sprint who offer a 24 hour, 365 day service for any type of delivery.

1.39 If a prescription is received for an appliance which requires measuring and fitting, the patient will be telephoned and emailed to state that the pharmacy cannot provide this service because the pharmacy must operate without face to face contact. The patient will then be advised that they would need to have the prescription dispensed by a pharmacy where a pharmacist would be able to measure and fit the appliance. We would facilitate this by gaining the permission of the patient to contact their nominated pharmacy and explaining the situation. We would then return the prescription to the patient or to the NHS spine so that the prescription can be dispensed.

1.40 **Essential Service - Disposal of Unwanted Medication**

1.41 **Uninterrupted Service**

1.42 Provision for disposal of unwanted medications can be requested by any patients during the core opening hours of the pharmacy. This can be requested via telephone, fax, email or webcam. All staff will be trained to deal with such enquiries.

1.43 **Persons anywhere in England**

1.44 Patients anywhere in England can request for safe disposal of their unwanted medication from our pharmacy via phone, fax, email, post or webcam.

1.45 **Safe and Effectively**

1.46 Patients, anywhere in England, can contact the pharmacy for collection of their unwanted medicines. We will take details of medication being returned by patients and assess if we are allowed to take them. We would provide patients with adequate packaging so medication can be returned securely via City Sprint couriers at no charge to the patient. All legal records will be kept and we would have procedures in place to comply with Hazardous Waste Regulations and we would keep any additional legal records such as those required for Controlled Drugs. Returned medication can be collected from patients' homes and residential homes but we will not be accepting from nursing homes. Returned medication will be stored in UN type containers provided by PHS.

1.47 Returned medication will be stored in UN type containers provided by PHS. Returned solid medicines/ ampoules, liquids and aerosols will be separated. Schedule 2 and 3 Controlled Drugs that are subject to safe custody regulations which are returned by patients will be segregated from other returned medicines and stored in compliance with the Safe Custody Regulations until

they have been rendered irretrievable. As the Environment Agency has suggested that the denaturing of CDs is likely to constitute a waste treatment, the pharmacy will hold a waste management license. We will ensure that the courier collecting returned medication is registered as a waste carrier with each local environmental agency office that it operates in. We will keep full records of any waste collected and disposed of for at least three years.

1.48 **Without face-to-face contact**

1.49 Disposal of unwanted medication will be delivered without face-to-face contact via City Sprint couriers or, for local requests, out in-house delivery service. This courier service will provide a third party delivery. Patients would communicate with the pharmacy via phone, fax, email website, post or webcam. We have SOPs in place to ensure this service is offered without having them to be present the pharmacy.

1.50 **Essential Service – Signposting**

1.51 **Uninterrupted Service**

1.52 Provision of signposting can be done through the opening hours of the pharmacy via phone, fax, email, post, website or webcam. Staff will be trained to assess the need for signposting and if any doubt will refer the matter to the pharmacist.

1.53 **Persons anywhere in England**

1.54 Patients anywhere in England would be able to access the signposting service from the pharmacy via phone, website, email, post or webcam. During communication the pharmacy staff will assess the need for signposting and if any doubt will refer the matter to the pharmacist.

1.55 **Safe and Effectively**

1.56 We would contact the relevant NHS organisations in Scotland. Wales and Northern Ireland to obtain resources. Furthermore, we would have access to Macmillan, NHS Choices and NHS Direct websites, as well as full internet access to further on-demand resources. Depending on the nature of patient queries and assessment of the information provided by the patient we could then either contact patients for further information refer them to their GP or signpost them to a local NHS or non NHS service as appropriate. We will provide referral notes by email, fax and post to the appropriate health and social care providers in cases where the pharmacy is unable to meet the needs of the patient. We will aim to ensure that patients are referred correctly to minimise inappropriate use of health and social care services. We will keep records of all referrals made on the PMR including any advice given to maintain audit trails.

1.57 **Without face-to-face contact**

1.58 Signposting will be delivered without face-to-face contact via the website email phone, post fax or webcam. All patients will communicate with the pharmacy via these methods and as such there will be no face-to-face patient interaction.

The SOPs in place ensure we can deliver the service without face to face contact in a distance selling model.

1.59 **Essential Service - Repeat Dispensing**

1.60 **Uninterrupted Service**

1.61 Provision of repeat dispensing throughout the opening hours of the pharmacy will be maintained by phone, fax, email, post or webcam. The Responsible Pharmacist will have undertaken the necessary training and is competent to provide the repeat dispensing service. The CPPE certificate of the Responsible Pharmacist will be provided to the local NHS team for their records. During the opening hours the Responsible Pharmacist will be supported by a suitable trained team sufficient to deliver the repeat dispensing. The pharmacy IT system will be ETP compliant to allow for repeat prescriptions to be received electronically from surgeries anywhere in England that are ETP release 2 compliant. This will be promoted to patients as a quick way to receive prescriptions from participating surgeries for nominated patients repeat and acute prescriptions for quick despatch of medicines without any delay.

1.62 **Persons anywhere in England**

1.63 Patients anywhere in England can access the Repeat Dispensing service by signing consent form which is available on the website for anyone wishing to use the service. This consent from can be emailed, faxed or posted directly to the pharmacy. Patients from surgeries that are ETP 2 compliant will have their prescriptions sent and received at the pharmacy electronically almost instantly after the Doctor signs off the electronic prescription. The prescriptions medicines will be dispensed and despatched for delivery by our in-house delivery service or the courier without any delay.

1.64 **Safe and Effectively**

1.65 Repeat Dispensing will be delivered safe and effectively via the staff completing sufficient clinical and legal assessments before dispensing the medicine. Once a patient signs up we will obtain the batch prescription (both the Repeat Authorising Prescription RA and the Repeat Dispensing Prescriptions RD) either from the surgery, electronically or via post. Either the patient will contact the pharmacy via phone, email post, website or webcam to dispense the next RD instalment prescription or the pharmacy contacts the patient when they are due their next RD instalment. Before each RD dispensing activity we will contact the patient to clarify which items are required and whether or not there has been a change in medical condition. If treatment needs to be reviewed by the prescriber, the patient will be notified by telephone and/or email. We will keep records of dates of dispensing for each individual batch for each patient, to monitor compliance. Records of interventions made by the pharmacist considered by the pharmacist to be clinically significant will be maintained on the PMR. These actions will ensure a safe and effective service is delivered for patients using the repeat dispensing service.

1.66 **Without face-to-face contact**

1.67 All repeat dispensing patients will be communicated without face-to-face contact via phone, email, post, fax or webcam. All medications will be delivered using our in-house delivery service or the City Sprint courier service and will maintain service delivery without face-to-face contact. We have SOPs in place to manage these services without face-to-face contact.

1.68 For patients who request our service and who are NOT signed up to the repeat dispensing service, we will request that they contact the pharmacy so that we can discuss their suitability for the service but also provide further information on the benefits of the service. The initial contact with the patient will be via a leaflet which will be included within their dispensed medication. Benefits will include saving time for the patient and the prescriber due to a decreased workload on both parties. A further benefit will include an improvement of medication safety as the pharmacy will check each and every request to ensure that the medication is still suitable before dispensing. During these checks, if a medication is flagged as being unsuitable or there are side effects, then the patient will be referred to the prescriber for discussion.

1.69 **Essential Service – Discharge Medicine Service**

1.70 **Uninterrupted Service**

1.71 Provision of discharge medicine service throughout the opening hours of the pharmacy will be maintained by phone, fax, email, post or webcam. The Responsible Pharmacist will have undertaken the necessary training and is competent to provide the discharge medicine service. The CPPE certificate for the Responsible Pharmacist will be provided to the local NHS team for their records. During the opening hours the Responsible Pharmacist will be supported by a suitable trained team sufficient to deliver the discharge medicine service. The pharmacy IT system will be compliant to allow for discharge medicine service to be undertaken via Pharmoutcomes website or the pharmacy dedicated NHS mailbox.

1.72 **Persons anywhere in England**

1.73 Patients anywhere in England can access the discharge medicine service via the phone, email, chat, video link. When the pharmacist identifies an intervention on the service he/she will communicate with the patient and other healthcare professionals. All interventions will be documented on their PMR record.

1.74 **Safe and Effectively**

1.75 Discharge Medicine service will be delivered safe and effectively via the staff completing sufficient clinical and legal training to provide the service. Hospitals will identify patients who will benefit from discharge medicine service and will send a referral to the patient's pharmacy via secure electronic system. When a referral is received, the pharmacist will review the information in the referral, including comparing the revised medicines prescribed to those the patient used before being admitted to hospital. If any issues are identified, these will be queried with the hospital or the general practice. Pharmacy team members will check whether there are any existing dispensed prescriptions waiting for the patient or any electronic repeat dispensing prescriptions on the NHS spine. If

there are, these need to be checked to see if they are still appropriate for the patient. The pharmacist will have a consultation with the patient and/or their carer to check their understanding of what medicines they should now be using and to provide further advice. If there are medicines the patient is no longer using, we will offer to dispose of them, to avoid potential confusion in the future. When the first prescription for the patient is received by the pharmacy following discharge, there will be a check to compare the medicines prescribed by the hospital and those prescribed by the GP. If there are discrepancies or other issues, the pharmacist will try to resolve them with the general practice. The pharmacist must use their clinical judgement when considering their actions and recommendations in respect of the service and consider the duty of confidentiality to the patient when involving a carer in discussions about the patient and their medication regimen. Relevant information will be documented on the PMR/IT System for Stage 1, 2 and 3 to ensure continuity of the service.

1.76 **Without face-to-face contact**

1.77 All discharge medicine service patients will be communicated without face-to-face contact via phone, email, post, fax or webcam. All medications will be delivered using our in-house delivery service or the City Sprint courier service and will maintain service delivery without face-to-face contact. If medicines need to be returned, this will be done in accordance to disposal of unwanted medication. We have SOPs in place to manage these services without face-to-face contact. This discharge medicine service will ensure better communication of changes to a patient's medication when they leave hospital and to reduce incidences of avoidable harm caused by medicines.

1.78 **Essential Service - Public Health (Promotion of Healthy Lifestyles)**

1.79 **Prescription linked intervention**

1.80 **Uninterrupted service**

1.81 Provision of service through the core opening hours of the pharmacy will be maintained by having a Responsible Pharmacist rostered on for all opening hours and having sufficient support staff at all times. Provision of service through the core opening hours of the pharmacy will be maintained by the pharmacy website email and telephone.

1.82 **Persons anywhere in England**

1.83 Patients anywhere in England can access these services via the pharmacy website, phone, email, chat, video link or distribution of leaflets within the prescription that is delivered to the patient. When the pharmacist identifies an intervention on a prescription he/she will communicate with the patient and other healthcare professionals. All interventions will be documented on their PMR record.

1.84 **Safe and effectively**

1.85 This service will be delivered safe and effectively by pharmacists and appropriately trained staff. At risk patients will be targeted through prescription linked intervention. Opportunistic advice will be given by the pharmacist on

specified healthy living/public health topics to patients who have their prescriptions fulfilled by the pharmacy. Staff will be trained to assess for prescription linked interventions and if any doubt will refer the matter to the pharmacist. In particular, patients with diabetes, coronary heart disease, high blood pressure, smokers and obesity. These patients will be identified through the type of medication being requested the patients PMR, or the online questionnaire completed by new patients. Once a prescription linked intervention has been made, a note will be made on the patient's PMR. This note will ensure continuity of advice and as a reference for future interactions with the patients.

1.86 **Without face-to-face contact**

1.87 The service will be delivered without face-to-face contact via telephone, email, live chat or video link. Any educational material relating to certain conditions can also be sent in the post or inserted into the packaging of any dispensed prescriptions. We have SOPs in place to manage these services without face-to-face contact.

1.88 **National Health Campaign**

1.89 **Uninterrupted Service**

1.90 Provision of service through the core opening hours of the pharmacy will be maintained by the pharmacy website, telephone, fax email, web chat or video link. Promotional material prepared by the Local Area Team and/or Public Health England will be made available for any patients. Trained staff will be available at the pharmacy to run the campaigns during the opening hours.

1.91 **Persons anywhere in England**

1.92 Patients anywhere in England can access these services via the pharmacy website, telephone, email, live chat, video link as well as sending out printed leaflets. The website will have a specific area for current health campaigns and allow outbound links to accredited organisations and clear routes to further resources.

1.93 **Safe and Effectively**

1.94 This service will be delivered safe and effectively. The pharmacy will contribute in up to 6 campaigns as directed by NHS England and Public Health England. Other campaigns may be advised by the Local Area Team/Health and Wellbeing Board. Throughout the campaigns the pharmacy will maintain a record of the number of people that receive the advice to ensure traceability. The pharmacy will use the approved content provided by the relevant bodies. This may include briefing packs, patient literature, NHS funded merchandise or services.

1.95 **Without face-to-face contact**

1.96 The service will be delivered without face-to-face contact via the pharmacy website telephone, email or live chat. We have SOPs in place to manage these services without face to face contact

1.97 **Essential Service - Support for Self Care**

1.98 **Uninterrupted Service**

1.99 Provision of service through the core opening hours of the pharmacy will be maintained by having a Responsible Pharmacist rostered on for all opening hours and having sufficient support staff at all times. Communication links to maintain the service through the core opening hours of the pharmacy will be via the pharmacy website, telephone, email, live chat or video link.

1.100 **Persons anywhere in England**

1.101 Patients anywhere in England can access these services via the pharmacy website, telephone, email, live chat or video link. The majority of interactions will come whilst giving advice to the patient using these methods.

1.102 **Safe and Effectively**

1.103 Support for self care will be delivered safe and effectively. Pharmacy staff will provide advice to patients including carers requesting help with the treatment of minor illness and long term conditions, including general information and advice on how to manage illness. Using website or telephone consultation, we can assess patients using a protocol based on the WWHAM model. Visual symptoms can be accessed via a video link if necessary. The pharmacy staff will advise on the appropriate use of the wide range of non prescription medicines which can be used in the self-care of minor illness and long term conditions. When appropriate pharmacy staff will make healthy interventions in a similar manner to that provided in promotions of healthy lifestyle service. When appropriate and where necessary, pharmacy staff will signpost patients to other health and social care providers. Records of advice given, products purchased or referrals made will be put on to the patients PMR when the pharmacist deems it to be of clinical significance. Any medication sold online will be sent to the patient via City Sprint couriers.

1.104 **Without face-to-face contact**

1.105 This service will be delivered without face-to-face contact via telephone, email, live chat or video link. Support for Self-Care will be prevalent in all patient interactions which will be maintained using these methods. Any deliveries of OTC products will be made using City Sprint courier who will act as a third party. We have SOPs in place to manage these services without face-to-face contact

1.106 **Essential Service - Clinical Governance**

1.107 There will be a named Clinical Governance Lead who will also be the Superintendent Pharmacist, SP [D P]

1.108 **Patient and public involvement**

1.109 A practice leaflet will be easily accessible on the front page of the pharmacy website and we will also supply a paper copy to all patients when first delivering to them. Updated leaflets will sent [sic] to all registered patients should there

be any significant changes. All services provided by the pharmacy will be listed on the leaflet and whether the service is funded by the NHS or privately. In addition, the pharmacy will produce an annual patient satisfaction survey presented to patients who use our service electronically and along with delivery of medication. Patients will have the option to return the satisfaction surveys electronically or through the post via a pre-paid envelope. The results of the patient satisfaction survey will be published on the pharmacy website and practice leaflet. The results will feed into the pharmacy's continuous quality improvement scheme.

1.110 The pharmacy will also have in place procedures to deal with complaints which will be regularly reviewed to allow us to improve our performance compliant with GPhC guidance. The employed Pharmacy Manager will deal with any complaints. Procedures to deal with medication owed to patients will also be in place and patients given a written note either via email or along with their delivery of medication to inform them of exactly what is owed and when the medication is expected to be supplied. Notes of medication owed will be kept on the PMR and regularly reviewed so stock levels can be adjusted appropriately.

1.111 **Clinical audit**

1.112 The pharmacy will participate in a minimum of two clinical audits annually. At least one practice-based audit and one multidisciplinary audit determined by NHS England, the Area Team or any other relevant organisation. Suitable personnel will be made available to ensure these audits are carried out.

1.113 **Risk management**

1.114 All incident reporting will be carried out in the pharmacy and this will involve near misses using the GPhC near miss template and help identify trends or highlight weaknesses in pharmacy systems and procedures and would be rectified promptly. Any patient safety incidents will be reported to the National Patient Safety Agency (NPSA) online. We will analyse and learn from any patient safety incidents through a system of regular reviews. In addition, the pharmacist will be proactive in considering and preventing potential risks. This will include competence in risk management and the application of Root Cause Analysis. Health and Safety legislation will be complied with in order to reduce the risk of harm to pharmacy staff and the public.

1.115 All patient safety communications received at the pharmacy either by fax, email or post will be actioned by the Pharmacist and pharmacy staff promptly and records of this will be kept at the pharmacy for audit purposes. We will have adequate facilities in place to be able to dispose of any confidential waste. NHS Code of Practice on Confidentiality will also be met.

1.116 Pillport Limited have produced DRAFT- Standard Operating Procedures (SOPs) at this point in time to cover the Essential Services. These procedures will continue to be developed up until when we secure the contract and commence trading. The SOPs will be reviewed at a minimum annually or a result of changes in best practice, new regulations or as a corrective action following any adverse incidents. The Superintendent Pharmacist will be

responsible for the maintenance of the SOPs and training all staff in the SOPs relevant to their role.

1.117 All pharmacy staff will be trained in and aware of child and vulnerable adult safeguarding procedures, and have access to safeguarding arrangements and reporting to all areas of United Kingdom via access to internet at the pharmacy. Any documentation will be kept for audit purposes.

1.118 **Staffing and staff management**

1.119 There will be a set of induction packs at the pharmacy to ensure that all have access to all necessary Clinical Governance information. Appropriate training will be given to all staff relevant to their positions in the pharmacy. Staff appraisals will be conducted regularly to ensure that all members of staff meet GPhC standards. If standards are not met then support will be offered and remedial action taken. We would expect Pharmacists and any registered technicians to demonstrate continual professional development and keep records of events to meet GPhC requirements.

1.120 **Education, training and continuing professional and personal development**

1.121 All pharmacists working at the pharmacy are able to demonstrate a commitment to continuing professional development (CPD), via a CPD record and this will be in line with the national RPSGB scheme. Any necessary accreditation will be achieved prior to provision of any advanced or enhanced services.

1.122 **Use of information to support clinical governance and health care delivery**

1.123 Pharmacy staff will have full access to up to date reference sources such as the BNF and Drug Tariff and with appropriate IT links with electronic reference sources. Pillport Limited will ensure all employees will comply with data protection and confidentiality, including the Data Protection Act 2018, Human Rights Act 1998 and common law of confidentiality Pillport Limited will ensure that all employees will conform to the NHS Code of Practice on confidentiality and will have systems and policies in place to support this including ensuring all staff are appropriately trained. Employee contracts will include a duty of confidence as a specific requirement linked to disciplinary procedures.

1.124 Pharmacists will be using their own professional judgement to make records of interventions they have made and any advice they may have given. Pillport Limited will ensure that NHS direct are aware of the pharmacy's actual working hours so that they can provide appropriate information to members of the public.

1.125 **Proof of exemption/prescription charges**

1.126 If the patient is under 16 or over 60 years of age and the date of birth is printed on the front of the prescription then no check of exemption status is required. The pharmacy will make use of real time exemption checking (RTEC) via the PMR system if appropriate. For all other exemptions, the pharmacy will make

contact with the patient and ask them for proof of their exemption. The pharmacy will ask patients to send proof of exemption to the pharmacy via post, fax or as an email attachment. The exemption details can also be updated on the secure pharmacy website. The pharmacy will keep records of exemption on the PMR, including when the exemption runs out or expires. On each dispensing occasion, we would verify exemption details and seek explicit permission from the patient if they would like the pharmacy to fill in the back of the prescription on their behalf. We would make a record each time the patient gave us permission to fill in the back of the prescription on their behalf so there is an audit trail. If the patient wishes to fill in the back of the prescriptions themselves we would send the prescription to the patient via courier for them to fill in and return to us. This could be done at the same time as the medication is being delivered or prior to delivery depending on patient preference. If patient is unable to provide proof of exemption, the pharmacy would mark the back of the prescription to indicate that the exemption has not been seen. Where prescription charge(s) need to be taken, the pharmacy will have facilities in place whereby card details can be taken over the telephone or via a secure internet site. The pharmacy will cover the cost of postage by arranging for an insured courier to collect prescription charges nationally via a tracked service.

1.127 **Additional Information**

1.128 We will maintain a high level of standards regarding the premises in terms of cleanliness in order to ensure good working conditions and minimise risks of infections. This will be covered in our SOPs and also by having a cleaning rota that is monitored. All staff will be trained on basic hygiene and hand washing issues and appropriate materials will be provided to promote this."

1.129 [SOPs provided].

2 Comments to the Commissioner

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

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

2.1 Pharmaceutical Defence on behalf of the Applicant

2.1.1 "We refer to the attached letter of authorisation.

2.1.2 We have received the representations from other contractors/ interested parties regarding the proposed DSP.

2.1.3 The objections raised in the response by Stow Pharmacy appear to be financially motivated responses which the committee will be fully aware is not one of tests that needs to be satisfied under Regulation 25 or 64. Furthermore, the response does not address any of the tests that need to be satisfied under Regulation 25 or 64. Also, the committee must only

regard the application as it appears in front of them and not concern itself with any matters which relate to the possibility of future behaviour as there is no cogent evidence of this, nor can there ever be. We say the representations made by Stow Pharmacy are borne not out of altruist intentions but are out of fear of losing NHS Market Share to another provider. We ask the committee to fully disregard the apparent self-protectionist response from Stow Pharmacy.

2.1.4 The objections raised in the response by Netteswell Pharmacy again appear to be financially motivated responses. With fear of repetition, the committee will be fully aware is not one of tests that needs to be satisfied under Regulation 25 or 64. Furthermore, the response does not address any of the tests that need to be satisfied under Regulation 25 or 64. Also, the committee must only regard the application as it appears in front of them and not concern itself with any matters which relate to the possibility of future behaviour as there is no cogent evidence of this, nor can there ever be. We say the representations made by Netteswell Pharmacy are borne not out of altruist intentions but are out of fear of losing NHS Market Share to another provider. We ask the committee to fully disregard the apparent self-protectionist response from Netteswell Pharmacy.

2.1.5 The objections raised by Promising Healthcare Ltd add little. If nothing, to the committee's decision-making processes for this application. The committee will be fully aware that an application, in order to be considered by the committee, must have already met the fitness checks and also a meticulous check of the application by PCSE to ensure that the application is correct. Any suggestion that the application for is invalid at this stage is plainly incorrect, is a complete disregard for the checks and balances that the application has already been subjected to and we say a very loose attempt to muddy the waters in order to detract the committee from considering the pertinent regulatory tests in Regulations 25 and 64.

2.1.6 Turning to the points raised by Promising Healthcare Ltd in relation to the SOPs we begin with a general comment that the committee are reminded that it is not the function of the committee to approve or disapprove of the SOPs as there are various ways that the applicant could organise itself in order to comply with the various requirements of the Regulations. This comment also applies to the opening hours that the applicant has stated upon the relevant application form. Most of the points raised by Promising Healthcare Ltd refer to the day to day running of the pharmacy using the SOPs or to the practicalities of running a pharmacy i.e the use of delivery drivers and couriers to deliver all medication from the pharmacy. At this point, it is pertinent to state that the terms "delivery driver" and "courier" refer to the same delivery service that will be offered and the committee should disregard any suggestion made by Promising Healthcare Ltd that the applicant would not be able to organise itself to be able deliver to ALL NHS services without face-to-face contact. Of course, if the committee saw fit, they may direct that the SOPs be resubmitted to the ICB for further consideration before the applicant begins to operate under the NHS

contract, if the application is successful. Furthermore, there is no evidence before the committee that any patient group would suffer undue detriment or be discriminated against due to the assertion that there would be a perceived lack of access. A similar comment can be made regarding the suggestion by Promising Healthcare Ltd that there would be a lack of communication with patients. Promising Healthcare Ltd have not, in our opinion, have not provided any cogent evidence or arguments within their objections.

2.1.7 Finally, we turn to the points raised by Community Pharmacy Essex. Without fear of repetition, the committee will be fully aware that an application, in order to be considered by the committee, must have already met the fitness checks and also a meticulous check of the application by PCSE to ensure that the application is correct. Any suggestion that the application for is invalid at this stage plainly incorrect, is a complete disregard for the checks and balances that the application has already been subjected to and we say a very loose attempt to muddy the waters in order to detract the committee from considering the pertinent regulatory tests in Regulations 25 and 64. We make the same comment regarding the point raised about the proposed core hours. Finally, we say that the committee have been supplied with a robust set of SOPs in order to be able to satisfy itself that the relevant tests un der Regulation 25 and 64 will be met.

2.1.8 The committee must also ask itself the real reason why the objections have been placed. Is it out of genuine need to prevent an unnecessary provision of services or is it out of the other parties' fear of financial detriment and reduced market share of the NHS prescription business. We say that the objection has been raised not out of a genuine need to prevent unnecessary provision but as a further attempt to undermine and block the DSP application through fear of financial detriment to other contractors in the locality. We say they have attempted to muddy the waters and is an ill-conceived attempt, by those who have responded to this application, so that they are able to retain their respective market share of NHS business.

2.1.9 We ask the committee to assess the application on the evidence presented already by ourselves. We urge the committee to find that ALL NHS services would be delivered without face-to-face contact and that this service would be uninterrupted during the core hours stipulated. Finally, we urge the committee to find that the services would be delivered in a safe, secure and effective manner."

3 The Decision

The Commissioner considered and decided to refuse the application. The decision letter dated 21 November 2025 states:

3.1 "Hertfordshire and West Essex ICB has considered the above application and I am writing to confirm that it has been refused. Please see the enclosed report for the full reasoning.

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

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

PSRC report

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

3.4 "**Decision Wording - CAS-370737-P6B1D3**

3.5 **Application in respect of distance selling premises: Pillport Limited.**

3.6 The Pharmaceutical Services Regulations Committee (hereafter referred to as "the Committee") considers all pharmaceutical services applications for the 6 Integrated Care Boards (ICB) within the East of England footprint. NHS Hertfordshire & West Essex ICB

3.7 (HWE ICB) hosts the meeting on behalf of the 6 ICBs, in accordance with the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 as amended (hereafter referred to as "the Regulations").

3.8 Address of proposed premises: Unit 6, Willow House, Stadium Way, Harlow, Essex, CM18 6DX.

3.9 The Committee considered this excepted application in respect of distance selling premises, which was determined under the following Regulations:

3.10 **Regulation 31: Refusal: same or adjacent premises**

3.11 The Committee noted there is no person on the pharmaceutical list providing or undertaking to provide pharmaceutical services from or adjacent to the premises.

3.12 The Committee agreed it was not required to refuse the application under the provisions of Regulation 31.

3.13 **Regulation 25: Distance selling premises applications**

3.14 The Committee noted that the application was made before 23rd June 2025.

3.15 Regulation 25(2)(a)

3.16 The Committee noted that where the application asks at section 6.1, “In my/our view this application should not be refused pursuant to Regulation 25(2)(a) for the following reasons,” the applicant had stated:

3.16.1 *“Application 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.”*

3.17 The Committee noted that the premises in respect of which the application is made, 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.

3.18 The Committee agreed it is not required to refuse the application under the provisions of Regulation 25(2)(a).

3.19 **Regulation 25(2)(b)**

3.20 The Committee considered the information which had been provided by the applicant in relation to its procedures for the provision of essential services, including any Standard Operating Procedures (SOPs) that it intends to use at the proposed pharmacy premises.

3.21 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 without face-to-face contact.

3.22 As of June 2025, the Regulations were amended and therefore will also require the Committee to be satisfied the pharmacy premises are likely to secure the safe and effective provision of all pharmaceutical services (not just essential services) without face-to-face contact at the pharmacy premises.

3.23 The Committee considered the documents provided by the applicant, namely:

3.23.1 Pillport Chapter 18 - Annex 1 Application Form

3.23.2 Pillport DSP SOPs

3.23.3 Pillport Draft SOPs

3.24 The Committee noted the full representations/comments made which were found in the representations section on page 18 of the Committee report.

3.25 The Committee was informed of an omission within the Committee Report with regards to the Discharge Medicines Service (DMS). It was confirmed that a review of the DMS SOP was conducted and reported that the Committee may be satisfied that it has been provided with sufficient information to meet the requirements of paragraphs 22B and 22C, Schedule 4 of the Regulations.

3.26 The Committee considered each essential service in paragraphs 3 to 22 of Schedule 4 of the Regulations as this is the approach of NHS Resolution (NHSR).

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

3.27.1 Dispensing of drugs and appliances

3.27.2 Urgent supply without a prescription

3.27.3 Preliminary matters before providing ordered drugs or appliances

3.27.4 Providing ordered drugs or appliances

3.27.5 Refusal to provide drugs or appliances ordered

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

3.27.7 Disposal service in respect of unwanted drugs

3.27.8 Promotion of healthy lifestyles

3.27.9 Prescription linked intervention

3.27.10 Public health campaigns

3.27.11 Signposting

3.27.12 Support for self-care

3.28 **Dispensing of drugs and appliances**

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

3.30 The Committee noted the following summary:

3.31 Document: Pillport Ltd - SOPs Pharmacy Procedures

3.31.1 **Page: 1**

3.31.2 Section: How non-electronic prescriptions will be presented by the patient

3.31.3 Details:

3.31.4 Patient posts prescription to pharmacy and/or prescription received via EPS.

3.31.5 The medication is delivered nationwide via a tracked delivery service. There will be no charge to the patient for delivery of medication dispensed against NHS prescriptions.

3.31.6 **Page: 2**

3.31.7 Section: Essential Service – Dispensing

3.31.8 Details:

3.31.9 All prescriptions dispensed will be delivered using a dedicated courier service provided by City Sprint... This will include the delivery of prescriptions received via post, fax and EPS.

3.31.10 **Page: 3**

3.31.11 Section: Patient counselling and delivery

3.31.12 Details:

3.31.13 Prior to medication being delivered, staff will contact patient to confirm delivery address, date and time. Deliveries will be monitored with the online courier tracking service.

3.31.14 **Page: 4**

3.31.15 Section: Cold chain delivery

3.31.16 Details:

3.31.17 Cold chain products will be packed in such a way as to ensure that the required temperatures are maintained throughout the journey.

3.32 The Committee noted that the Safe and Effective Supply of Medicinal Products SOP provided further information.

3.33 The Committee noted that the Delivering Medicines Safely and Effectively SOP provided further information.

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

3.35 **Urgent supply without a prescription**

3.36 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.

3.37 Document: Pillport Ltd - SOPs Pharmacy Procedures

3.37.1 **Page: 4**

3.37.2 Section: Acute or Urgent Dispensing Requests

3.37.3 Details:

3.37.4 Any acute, urgent medication received by ETP or directly via courier from a surgery for patients anywhere in England can be dispensed and dispatched the same day using City Sprint who offer a 24 hour, 365 day service for any type of delivery.

3.38 The Committee noted that on pages 7 and 8 of the Safe and Effective supply of Medicinal Products SOP, the applicant provided information on how they propose to safely and effectively receive requests from prescribers for urgent supplies of drugs and appliances.

3.39 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 6 of Schedule 4.

3.40 **Preliminary matters before providing ordered drugs or appliances**

3.41 The Committee considered whether the applicant had explained how evidence will be sought and provided with regards to the patients' entitlement to exemption or remissions from NHS Charges.

3.42 Document: Pillport Ltd - SOPs Pharmacy Procedures

3.42.1 **Page: 12**

3.42.2 Section: Proof of exemption/prescription charges

3.42.3 Details:

3.42.4 The pharmacy will make use of real time exemption checking (RTEC) via the PMR system if appropriate. For all other exemptions, the pharmacy will make contact with the patient and ask them for proof of their exemption. The pharmacy will ask patients to send proof of exemption to the pharmacy via post, fax or as an email attachment. The exemption details can also be updated on the secure pharmacy website.

3.42.5 The pharmacy will keep records of exemption on the PMR, including when the exemption runs out or expires. On each dispensing occasion, we would verify exemption details and seek explicit permission from the patient if they would like the pharmacy to fill in the back of the prescription on their behalf.

3.42.6 If the patient wishes to fill in the back of the prescriptions themselves, we would send the prescription to the patient via courier for them to fill in and return to us.

3.43 The Committee noted that the Safe and Effective Supply of Medicinal Products SOP provided information.

3.44 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 7(3) of Schedule 4.

3.45 **Providing ordered drugs or appliances**

3.46 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).

3.47 Document: Pillport Ltd - SOPs Pharmacy Procedures

3.48 Cold Chain Maintenance

3.48.1 **Page: 3–4**

3.48.2 Section: Delivery of Refrigerated Medicinal Products

3.48.3 Details:

3.48.4 Cold chain products will be packed in such a way as to ensure that the required temperatures are maintained throughout the journey…Temperatures will be strictly controlled and monitored with calibrated temperature probes to provide temperature data for the entire journey. If the temperature is outside of the required range, then the product will be deemed unsafe to deliver, marked as waste and returned to the pharmacy for destruction.

3.48.5 Validated medical cool boxes will be used… gels/ice packs will be added… thermometer(s) will be calibrated annually

3.49 Controlled Drugs – Misuse of Drugs Regulations 2001

3.49.1 **Page: 3**

3.49.2 Section: Controlled Drug (CD) Deliveries

3.49.3 Details:

3.49.4 Controlled Drug (CD) deliveries will be undertaken by City Sprint who are accredited to handle and transport CDs… Their drivers will only deliver the CD to the named recipient and they will ask for photographic proof of ID.

3.49.5 In the instance of a failed delivery attempt, City Sprint will return any CDs to their overnight safe storage facility and the pharmacy will be contacted to arrange alternative delivery date to patient

3.49.6 **Page: 2**

3.49.7 Section: Premises Security

3.49.8 Details:

3.49.9 Schedule 1, 2 and relevant 3 drugs will always be stored in a locked CD cabinet. Security of premises will be reviewed regularly.

3.50 The Committee noted that further information was available in the following SOPs:

3.50.1 Fridge Temperature Monitoring SOP

3.50.2 Dispensing of Controlled Drugs SOP

3.50.3 Delivery of Schedule 2 Controlled Drugs SOP

3.51 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 to this regard.

3.52 **Refusal to provide drugs or appliances ordered**

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

3.54 Document: Pillport Ltd - SOPs Pharmacy Procedures

3.54.1 **Pages: 6**

3.54.2 Section: Essential Service – Repeat Dispensing

3.54.3 Detail:

3.54.4 Before each RD dispensing activity, we will contact the patient to clarify which items are required and whether or not there has been a change in medical condition.

3.54.5 If treatment needs to be reviewed by the prescriber, the patient will be notified by telephone and/or email.

3.54.6 Records of dates of dispensing for each individual batch for each patient, to monitor compliance. Records of interventions made by the pharmacist considered by the pharmacist to be clinically significant will be maintained on the PMR.

3.55 The Committee noted that the Repeat Dispensing SOP provided further information. However, the SOP stated the following under the scope section on page 1, "*Procedure covers repeat dispensing services operated between this pharmacy and participating local GP Practices for those patients who wish to take advantage of them*". This signalled that the applicant would only offer this to patients registered with a local GP and not to everyone in England.

3.56 Based on the information before it, the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 9(4) of Schedule 4.

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

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

3.59 Document: Pillport Ltd - SOPs Pharmacy Procedures

3.59.1 **Pages: 7**

3.59.2 Section: Repeat Dispensing – Patient Engagement and Advice

3.59.3 Detail:

3.59.4 For patients who request our service and who are NOT signed up to the repeat dispensing service, we will request that they contact the pharmacy so that we can discuss their suitability for the service but also provide further information on the benefits of the service.

3.59.5 The initial contact with the patient will be via a leaflet which will be included within their dispensed medication.

3.59.6 Benefits will include saving time for the patient and the prescriber due to a decreased workload on both parties. A further benefit will include an improvement of medication safety as the pharmacy will check each and every request to ensure that the medication is still suitable before dispensing.

3.60 The Committee noted that the Repeat Dispensing SOP provided further information. However, the SOP stated the following under the scope section on page 1, “Procedure covers re-peat dispensing services operated between this pharmacy and participating local GP Practices for those patients who wish to take advantage of them”. This signalled that the applicant would only offer this to patients registered with a local GP and not to everyone in England.

3.61 Based on the information before it, the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with 10(1) of Schedule 4.

3.62 **Disposal service in respect of unwanted drugs**

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

3.64 Document: Pillport Ltd - SOPs Pharmacy Procedures

3.64.1 **Pages: 4-5**

3.64.2 Section: Essential Service – Disposal of Unwanted Medication

3.64.3 Detail:

3.64.4 Provision for disposal of unwanted medications can be requested by any patients during the core opening hours of the pharmacy. This can be requested via telephone, fax, email or webcam.

3.64.5 We would provide patients with adequate packaging so medication can be returned securely via City Sprint couriers at no charge to the patient.

3.64.6 Returned medication will be stored in UN type containers provided by PHS. Returned solid medicines/ampoules, liquids and aerosols will be separated.

3.64.7 Schedule 2 and 3 Controlled Drugs that are subject to safe custody regulations which are returned by patients will be segregated from other returned medicines and stored in compliance with the Safe Custody Regulations until they have been rendered irretrievable.

3.64.8 The pharmacy will hold a waste management license… the courier collecting returned medication is registered as a waste carrier… full records of any waste collected and disposed of [will be kept] for at least three years.

3.65 The Committee noted that the Safe and Effective Disposal of Medicines SOP and the Destruction of Controlled Drugs SOP described this.

3.66 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 paragraphs 13 - 15 of Schedule 4.

3.67 **Promotion of healthy lifestyles**

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

3.69 Document: Pillport Ltd - SOPs Pharmacy Procedures

3.69.1 Pages: 8-9

3.69.2 Section: Essential Service – Public Health (Promotion of Healthy Lifestyles)

3.69.3 Detail:

3.69.4 Prescription Linked Intervention

3.69.5 Patients with long-term conditions (e.g. diabetes, coronary heart disease, high blood pressure, obesity, smoking) will be identified through:

3.69.6 Type of medication requested

3.69.7 Patient's PMR

3.69.8 Online questionnaire completed by new patients

3.69.9 Opportunistic advice will be given by the pharmacist on specified healthy living/public health topics… Once a prescription linked intervention has been made, a note will be made on the patient's PMR.

3.69.10 National Health Campaigns

3.69.11 Promotional materials from Public Health England and the Local Area Team will be made available.

3.69.12 Campaigns will be delivered via:

3.69.13 Website

3.69.14 Telephone

3.69.15 Email

3.69.16 Live chat

3.69.17 Video link

3.69.18 Printed leaflets

3.69.19 The pharmacy will contribute in up to 6 campaigns as directed by NHS England and Public Health England. The pharmacy will maintain a record of the number of people that receive the advice to ensure traceability.

3.70 The Committee noted that the Self-care and healthy lifestyle promotion SOP described this.

3.71 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 16 – 18 of Schedule 4.

3.72 Prescription linked intervention

3.73 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.

3.74 Document: Document: Pillport Ltd - SOPs Pharmacy Procedures

3.74.1 Pages: 8

3.74.2 Section: Essential Service – Public Health (Promotion of Healthy Lifestyles), Subsection: 1. Prescription Linked Intervention

3.74.3 Detail:

3.74.4 At risk patients will be targeted through prescription linked intervention. Opportunistic advice will be given by the pharmacist on specified healthy living/public health topics to patients who have their prescriptions fulfilled by the pharmacy.

3.74.5 Staff will be trained to assess for prescription linked interventions and if any doubt will refer the matter to the pharmacist.

3.74.6 In particular, patients with diabetes, coronary heart disease, high blood pressure, smokers and obesity. These patients will be identified through the type of medication being requested, the patient's PMR, or the online questionnaire completed by new patients.

3.75 The Committee noted that the Self-care and healthy lifestyle promotion SOP described this.

3.76 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 17 of Schedule 4.

3.77 **Public health campaigns**

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

3.79 Document: Pillport Ltd - SOPs Pharmacy Procedures

3.79.1 **Pages: 9**

3.79.2 Section: Essential Service – Public Health (Promotion of Healthy Lifestyles), Subsection: 2. National Health Campaigns

3.79.3 Detail:

3.79.4 The pharmacy will contribute in up to 6 campaigns as directed by NHS England and Public Health England. Other campaigns may be advised by the Local Area Team/Health and Wellbeing Board.

3.79.5 Promotional material prepared by the Local Area Team and/or Public Health England will be made available for any patients.

3.79.6 Throughout the campaigns the pharmacy will maintain a record of the number of people that receive the advice to ensure traceability.

3.79.7 The pharmacy will use the approved content provided by the relevant bodies. This may include briefing packs, patient literature, NHS funded merchandise or services.

3.80 The Committee noted that the Self Care and Healthy Lifestyle Promotion SOP contained some information; however, reference was made to PCT rather than the current commissioner.

3.81 Based on the information before it, the Committee was satisfied that it has been provided with information sufficient to show that there would be compliance with paragraph 18 of Schedule 4.

3.82 **Signposting**

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

3.84 Document: Pillport Ltd - SOPs Pharmacy Procedures

3.84.1 **Pages: 5-6**

3.84.2 Section: Essential Service – Signposting

3.84.3 Detail:

3.84.4 Provision of signposting can be done through the opening hours of the pharmacy via phone, fax, email, post, website or webcam.

3.84.5 Staff will be trained to assess the need for signposting and if any doubt will refer the matter to the pharmacist.

3.84.6 We would contact the relevant NHS organisations in Scotland, Wales and Northern Ireland to obtain resources. Furthermore, we would have access to Macmillan, NHS Choices and NHS Direct websites, as well as full internet access to further on-demand resources.

3.84.7 We will provide referral notes by email, fax and post to the appropriate health and social care providers in cases where the pharmacy is unable to meet the needs of the patient.

3.84.8 We will keep records of all referrals made on the PMR including any advice given to maintain audit trails.

3.85 The Committee noted that the Self-care and healthy lifestyle promotion SOP contained further information.

3.86 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 paragraphs 19 – 20 of Schedule 4.

3.87 **Support for self-care**

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

3.89 Document: Pillport Ltd - SOPs Pharmacy Procedures

3.89.1 **Page: 10**

3.89.2 Section: Essential Service – Support for Self Care

3.89.3 Detail:

3.89.4 Pharmacy staff will provide advice to patients including carers requesting help with the treatment of minor illness and long term conditions, including general information and advice on how to manage illness.

3.89.5 Using website or telephone consultation, we can assess patients using a protocol based on the WWHAM model.

3.89.6 Records of advice given, products purchased, or referrals made will be put on to the patients PMR when the pharmacist deems it to be of clinical significance.

3.90 The Committee noted that the Self Care and Healthy Lifestyle Promotion SOP had information included.

3.91 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 paragraphs 21 – 22 of Schedule 4.

3.92 **Advanced/Enhanced Services**

3.93 The Committee noted the applicant had not listed any advanced or enhanced services to be undertaken.

3.94 **Regulation 25 – Distance Selling Premises Requirements**

3.95 Regulation 25 requires that NHS England must refuse an application for a distance selling pharmacy unless it is satisfied that:

3.95.1 The pharmacy will provide uninterrupted essential services during opening hours to persons anywhere in England.

3.95.2 The pharmacy will provide safe and effective pharmaceutical services without face-to-face contact at the pharmacy premises between the patient (or their representative) and the pharmacy staff.

3.96 **Consider impact of decision on those with protected characteristics under the Equalities Act 2010 and is this in accordance with NHS England/the ICB's Public Sector Equality Duty**

3.97 **Consider impact of decision on NHS England/the ICB's duty on health inequality**

3.98 The Committee agreed this would not be affected if granting this application.

3.99 The Committee noted that Regulation 66 was not included in the report, however, if granted this would not apply as the applicant has not undertaken to provide any advanced or enhanced services (directed services).

3.100 The Committee agreed to refuse the application on the grounds that Regulation 25(2)(b)(1) was not met as the repeat dispensing SOP indicates this service will be restricted to a particular patient group e.g. those that live locally.

3.101 The Chair asked whether all decision makers agreed. All decision makers confirmed agreement.

3.102 **Decision**

3.103 The Committee agreed to refuse the application as not all the requirements set out in Regulation 25 (2)(b)(i) have been met.

3.103.1 The Committee could not be satisfied that all pharmaceutical services are likely to be secured for persons anywhere in England.

3.104 The Committee agreed that Pillport Ltd has the right to appeal the decision."

4 The Appeal

Using NHS Resolution's online appeal form dated 1 December 2025, Pharmaceutical Defence on behalf of the Applicant appealed against the Commissioner's decision. The grounds of appeal are:

4.1 "The decision letter and attached decision report did not contain enough information so that the applicant could be satisfied that the application had been fully considered. Both the decision letter and reasons are attached.

4.2 It is submitted that the decision letter and decision report provided by Hertfordshire and West Essex ICB:

4.2.1 The committee in the decision report appears to have:

4.2.1.1 Failed to take into account the draft nature of the full suite of SOPs provided by the applicant AND / OR

4.2.1.2 Explain how the committee applied the law to the application that they were tasked with deciding on AND / OR

4.2.1.3 Contained a predetermined decision which was to refuse the application AND / OR

4.2.1.4 Failed to take into account that it is not the committees function to approve or disapprove of the applicants SOPs

4.2.2 No person, be that the applicant or a member of the public, could be satisfied that the committee reached the correct decision based on the inadequate information provided in the refusal decision and letter.

4.2.3 The decision is therefore:

4.2.3.1 Unsafe as no person, be that the applicant or a member of the public, could be satisfied that the committee reached the correct decision based on the inadequate information provided in the refusal decision and letter.

4.2.4 The applicant requests that the committee hear the appeal and consider the application afresh.

4.2.5 To assist the appeals committee, we have not added the original application in this bundle and we have not added the decision letter. Both of these documents can be found under the original reference number CAS-370737-P6B1D3.

4.2.6 We have submitted SOPs with this bundle and ask the committee to take these SOPs into account."

4.2.7 [SOPs provided]

5 Summary of Representations

Having reviewed the Commissioner's paperwork, it was noted that a copy of North & South Essex Local Medical Committees' response to the application was not circulated. A copy was therefore circulated to interested parties. This is a summary of representations received on the appeal.

5.1 The Commissioner

5.1.1 "Please note that from the 1 April 2023, community pharmacy contracting and commissioning has been delegated to Integrated Care Boards (ICBs). Hertfordshire and West Essex (HWE) ICB are hosting the function on behalf of the six East of England ICBs. The six ICBs have formed one Pharmaceutical Services Regulation Committee (PSRC) which is also hosted by HWE ICB.

5.1.2 Thank you for your letter dated 9 December 2025 advising that Pharmaceutical Defence Ltd has submitted an appeal on behalf of Pillport Ltd (the Appellant) against the decision to refuse their application for inclusion in the pharmaceutical list to provide pharmaceutical services as a distance selling pharmacy under Regulation 25 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended (the Regulations).

5.1.3 The ICB note the comments made by NHS Resolution in their letter of 9 December 2005 in regard to representations not being circulated and can confirm that the 45-day LMC representations were not circulated by Primary Care Support England (PCSE), who are commissioned on behalf of NHS England. There is no reason for this other than it appears to have been an error. We apologise for this oversight on their behalf. PCSE have confirmed that the Applicant's 14-day comments in response to the 45-day comments were not circulated to interested parties nor is there any requirement to do so.

5.1.4 Having reviewed the grounds of appeal made by Pharmaceutical Defence Ltd on behalf of Pillport Ltd (the Appellant) for inclusion in the pharmaceutical list for a Distance Selling Pharmacy at Unit 6, Willow House, Stadium Way, Harlow, Essex, CM18 6DX, the ICB remains of the opinion that this application should be refused.

5.1.5 The Appellant is appealing on the following grounds: [see paragraphs 4.1 to 4.6 above].

5.1.6 The ICB confirms that the application and all associated documents submitted by the Appellant were fully considered. The Committee is aware that their function is not to approve or disapprove SOPs however it needs to be assured that based on the information submitted, the regulatory tests are met. They were not. Likewise, the Committee cannot pre-empt what a final version of a SOP may include and must make a determination based on the information presented at the time. The documentation did not contain the necessary information required to demonstrate that they meet the tests as set out in the Regulations.

5.1.7 On appeal, the Appellant has provided no new information and therefore the ICB remain of the opinion that the application should be refused."

5.2 Pharmacy Sales & Consultancy on behalf of Promising Healthcare Ltd t/a Greenway Pharmacy

5.2.1 "We are in receipt of your letter dated 9th December 2025 informing us of the above appeal.

5.2.2 On behalf of Promising Healthcare Ltd, who provide pharmaceutical services from premises at 73 Sherwood House, Bush Fair, Harlow, Essex, CM18 6NW, I would like to comment on the appeal and the 14 day comments that were not shared as part of the process. Please find attached our letter of authority to act on client's behalf in this matter.

5.2.3 NHS Resolution 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:

5.2.3.1 all essential services will be provided without interruption during the proposed opening hours of the pharmacy;

5.2.3.2 all essential services will be made available to anybody in England who wishes to access them;

5.2.3.3 all essential services are likely to be secured in a safe and effective manner;

5.2.3.4 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.

5.2.4 Whilst we appreciate the SOPs themselves are not subject to any approval, the content of them either supports their application or it doesn't.

5.2.5 We would make the following representations on each part of the regulatory test:

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

5.2.7 There is minimal reference in the information provided to show how services will be provided during any unplanned absences of the pharmacist during the core opening hours. It is inevitable that occasions will arise when the pharmacist is absent and unless suitable contingency procedures are in place the above obligation will not be complied with.

5.2.8 Additionally, the core opening hours provided do not allow for a break during the day. The DSP regulations require services to be provided "without interruption". This means the pharmacist will be working for at least 9 hours per day without any break. This may not be safe and casts doubt over wherever it would be possible to provide essential pharmacy services with any interruption.

5.2.9 We would suggest that NHS Resolution should request additional evidence from the applicant that such cover will be provided.

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

5.2.11 From the information provided, it is still 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.

5.2.12 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.

5.2.13 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.

5.2.14 It is not up to the third party to provide evidence, it is up to the appellant to provide evidence that their application fully satisfies the regulatory test, rather than partially satisfies it.

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

5.2.16 *(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.*

5.2.17 The application makes reference to either a staff driver or a courier but fails to describe in more detail the decision-making process between the two routes available and how the appellant will ensure that deliveries by courier will be met with reasonable promptness.

5.2.18 There are contradictions in the information provided by the applicant. In the document titled "Pillport Limited- SOPs Pharmacy Procedures" the section which discusses Dispensing states:

5.2.18.1 *"All prescriptions dispensed will be delivered using a dedicated courier service provided by City Sprint (www.citysprinthealth.co.uk)"*.

5.2.19 However, in the section on the Discharge Medicines Service the document states:

5.2.19.1 "*All medications will be delivered using our in-house delivery service or the City Sprint courier service*".

5.2.20 It is clear that the appellant has not fully considered its operating model in respect of deliveries, a fundamental consideration for any DSP. In that case, NHS Resolution cannot be satisfied that the pharmacy will comply with the relevant regulations, despite the assertions made.

5.2.21 It would be very difficult for the panel to make a decision in the absence of clarity on the operating model and, as the burden of proof is on the appellant to demonstrate that the application fully satisfies the regulatory test, without this information, NHS Resolution may not be in a position to approve this application.

5.2.22 <u>Additional considerations</u>

5.2.23 The appellant has amended the SOPs from the first draft provided to remove the reference to" local GPs". It could be construed that their intentions were clearly set out in the initial application that they will only to [sic] providing pharmacy services to the local population and to not provide a national service thereby failing the regulatory test.

5.2.24 The appeal is accompanied by a set of "Draft SOPs". At the beginning of the document, the following statement is made:

5.2.24.1 THESE ARE SOPs THAT ARE ***DRAFT IN NATURE*** *NO FACE-TO-FACE CONTACT WITH PATIENTS OR THEIR REPRESENTATIVES IS PERMITTED WHEN DELIVERING ANY NHS SERVICES UNLESS DIRECTED BY THE ICB / LOCAL AREA TEAM*

5.2.24.2 While care has been taken to remove any suggestion of face-to face contact while delivering NHS Pharmacy Services, there may still be references to this. In the Final SOP bundle, all references to face-to-face contact for NHS services will be removed.

5.2.25 The onus is on the applicant to provide accurate and comprehensive information with their application. It cannot caveat this information by simply stating that 'this is draft and the final version may be different'. The panel cannot be satisfied that the pharmacy will comply with the regulatory requirements unless it is in possession of a finalised document against which compliance can be measured as they are relying on them as evidence to support the application.

5.2.26 In our opinion, the appellant has failed to provide sufficient information to enable NHS Resolution to be confident that the application meets the requirements of Regulation 25. That being the case the application must be refused.

5.2.27 Should NHS Resolution wish to convene an oral hearing to determine this application, our client would wish to attend."

5.3 Netteswell Pharmacy

5.3.1 "We would like to object the new proposed approval of Distance Selling Pharmacy (DSP) in Harlow. We would like to add following points to the original objection:

5.3.2 **Regulations under the health and social care act 2012: As per Chapter 11, paragraph 16 as below:**

5.3.3 **16. If the applicant fails to provide a precise location with the excepted application, this would be classed as missing relevant information for the purposes of paragraph 11 of Schedule 2.**

5.3.4 **Address provided on the application : Unit 6, Willow house, Stadium way, Harlow, Essex, CM18 6DX. This address does not provide a precise location and there may be different business running at this address or this address does not exist. It may require a new planning permission from the Harlow council. Hence, we are not satisfied that the pharmaceutical services will be delivered in a safe, secure and effective manner.**

5.3.5 **SOPs for - 'Roles and Responsibility of Pharmacy Staff', is missing. It was not mentioned if staff including the delivery driver would have a valid DBS check. It was also mentioned under SOPs for ' Delivering medicines safely and effectively' in P5 that - 'Ask patient that the medicines received are required by the patient to help minimise waste. It was not made clear if patient does not need some medicines at the time of delivery to avoid wastage then how these medicines would be handled and safely brought back and if patient's doctor would be notified. There is a risk that these medicines can be abused if the delivery driver does not report**

back. Hence, I would strongly believe that SOPs are not adequate and it would risk patient safety and misuse of medicines.

5.3.6 Approving such an application without such safeguards threatens both patient care and the long-term resilience of the community pharmacy network in Harlow. Adequate monitoring arrangements should be put into place to make sure essential services are not provided to people from or in the vicinity of the registered pharmacy premises, for example by having a "shop-front" or delivering medicines to customers waiting in the premises' car park.

5.3.7 We would like to thank you for your time for understanding our concerns. We are hopeful that you agree with us and help the local community by not having another DSP locally in Harlow.

5.3.8 Thank you for all your support."

6 Summary of Observations

This is summary of observations received.

6.1 Pharmaceutical Defence on behalf of the Applicant

6.1.1 "I am writing on behalf of the Appellant, Pillport Ltd, in response to the representations received regarding the above appeal. We have reviewed the comments submitted by the Integrated Care Board (ICB), Pharmacy Sales & Consultancy (PSC) on behalf of Promising Healthcare Ltd, Netteswell Pharmacy, the Local Pharmaceutical Committee (LPC), the Local Medical Committee (LMC), and Boots UK Ltd.

6.1.2 Our responses to the specific points raised are detailed below.

6.1.3 **Response to Representations by PSC (on behalf of Promising Healthcare Ltd)**

6.1.4 Draft Nature of SOPs

6.1.5 PSC argues that the panel "cannot be satisfied that the pharmacy will comply with the regulatory requirements unless it is in possession of a finalised document" because the submitted SOPs are marked as "draft".

6.1.6 We submit that Standard Operating Procedures (SOPs) are, by definition, living documents that are subject to constant review and update. The Regulations require the Applicant to demonstrate that procedures will be in place to safely deliver services. The content of the SOPs provided clearly demonstrates a safe and effective system of work. The marking of "Draft" is a formality indicating they are pre-operational; it does not invalidate the robust clinical governance framework they describe.

6.1.7 Pharmacist Absence and Breaks

6.1.8 PSC suggests that the core opening hours do not allow for a break and that coverage for unplanned absence is insufficient.

6.1.9 The operation of the pharmacy will be conducted in strict accordance with the Responsible Pharmacist (RP) Regulations. The SOPs cover "Roles and Responsibility of Pharmacy Staff" (referenced in), ensuring that appropriate staff are authorised to carry out specific tasks. Unplanned absences are managed through standard contingency planning, including the use of locum pharmacists, as is standard practice across the sector. The suggestion that a 9-hour day "may not be safe" is a subjective assertion unsupported by evidence; pharmacists routinely work such shifts with appropriate rest breaks managed within the workflow, during which time the RP remains in charge.

6.1.10 Accessibility and Discrimination

6.1.11 PSC alleges that the reliance on websites or apps discriminates against patients with disabilities (e.g., sight or hearing loss).

6.1.12 This assertion is incorrect. Distance Selling Pharmacies (DSPs) are required to make reasonable adjustments under the Equality Act. The Applicant's model utilises multiple communication methods, including telephone, email, and webcam/video links. These methods actually enhance accessibility for housebound patients or those with mobility issues compared to traditional brick-and-mortar pharmacies.

6.1.13 Delivery Model Contradictions

6.1.14 PSC claims there are contradictions regarding the use of "in-house" drivers versus "City Sprint" couriers.

6.1.15 There is no contradiction. A robust DSP model requires flexibility. As stated in the SOPs, the pharmacy utilises both an in-house delivery service and a courier service (City Sprint) depending on the location of the patient and the urgency of the delivery. The decision-making process is operational: in-house drivers are generally used for local deliveries, while national deliveries utilise the courier network. This ensures "reasonable promptness" is met across the whole of England.

6.1.16 PSC, on behalf of their client Promising Healthcare Ltd have not, in our opinion, have not provided any cogent evidence or effective arguments within their objections.

6.1.17 **Response to Representations by Netteswell Pharmacy**

6.1.18 Location and Planning Permission

6.1.19 Netteswell Pharmacy questions the existence of the address "Unit 6, Willow House" and raises concerns regarding planning permission.

6.1.20 The application address is specific and clearly defined. Issues regarding planning permission are a matter for the local authority and

are distinct from the "fitness to practice" [sic] or regulatory test required by NHS Resolution. The granting of a pharmacy contract is often a prerequisite for finalising lease and planning arrangements.

6.1.21 DBS Checks and Staff Responsibilities

6.1.22 Netteswell Pharmacy notes that the SOP for 'Roles and Responsibility of Pharmacy Staff' was not explicitly attached or detailed regarding DBS checks.

6.1.23 The SOPs provided reference the 'Roles and Responsibility' document as an integral part of the governance framework. It is a standard requirement for all pharmacy staff involved in patient-facing roles (including delivery drivers accessing patients' homes) to undergo appropriate checks, including DBS where applicable. The Applicant confirms all staff will be appropriately vetted.

6.1.24 Minimising Waste and Driver Discretion

6.1.25 Netteswell Pharmacy argues that asking patients if they require medicines to minimize waste risks abuse if the driver does not report back.

6.1.26 The procedure described in the "Delivering Medicines Safely and Effectively" SOP is a safety mechanism, not a risk. It prevents the stockpiling of unwanted medicines. The SOP explicitly states that if a delivery fails or items are not handed over, the driver must "inform the authorised pharmacy staff upon return". This ensures the pharmacist is alerted and can contact the patient's prescriber if necessary.

6.1.27 Another DSP in the locality

6.1.28 Netteswell Pharmacy states that the resilience of the community pharmacy network in Harlow is threatened if this application is approved.

6.1.29 This plays no part in the decision-making process under Regulations 25 and 64. As such, this comment must be disregarded. We also comment that this plainly shows that the response by Netteswell Pharmacy is financially motivated as they are more concerned with their own viability than giving patients a choice of dispensing pharmacy contractors.

6.1.30 We say the representations made by Netteswell Pharmacy are borne not out of altruist intentions but are out of fear of losing NHS Market Share to another provider. We ask the committee to fully disregard the apparent self-protectionist response from Netteswell Pharmacy.

6.1.31 **Response to Hertfordshire and West Essex ICB**

6.1.32 The ICB maintains that the application should be refused based on the information previously submitted. The ICB maintains that they did consider all of the documents.

6.1.33 It is not the ICB's role to give a decision post their decision document which is the subject of this appeal. The ICB have still not set out, in part or at all, how they arrived at the decision. It appears that the ICB are trying to shut the stable door after the horse has bolted. The Appellant requests that NHS Resolution considers the application afresh. We maintain that the SOPs provided are comprehensive and demonstrate that the Appellant will meet the requirements of Regulation 25, providing essential services to the whole of England without face-to-face contact.

6.1.34 **Other Representations**

6.1.35 We note the correspondence from Community Pharmacy Essex (LPC), North & South Essex Local Medical Committees (LMC), and Boots UK Ltd. These parties have offered no substantive objections to the appeal at this stage.

6.1.36 **Conclusion**

6.1.37 The committee must also ask itself the real reason why the objections have been placed. Is it out of genuine need to prevent an unnecessary provision of services or is it out of the other parties' fear of financial detriment and reduced market share of the NHS prescription business. We say that the objection has been raised not out of a genuine need to prevent unnecessary provision but as a further attempt to undermine and block the DSP application through fear of financial detriment to other contractors in the locality. We say they have attempted to muddy the waters and is an ill-conceived attempt, by those who have responded to this application, so that they are able to retain their respective market share of NHS business.

6.1.38 The Appellant has provided a robust suite of Standard Operating Procedures that cover all essential services, including Dispensing, Delivery, Cold Chain integrity, and Discharge Medicines Service. We submit that the "Draft" status of these documents is a prudent approach to pre-opening governance and does not constitute a failure to meet the regulatory test.

6.1.39 The Appellant is committed to providing a safe, effective service that is available to all persons in England. We confirm that we are content for the appeal to be determined on the papers, or we are willing to attend an oral hearing should the Committee deem it necessary.

6.1.40 We ask the committee to assess the application on the evidence presented already by ourselves. We urge the committee to find that ALL NHS services would be delivered without face-to-face contact and that this service would be uninterrupted during the core hours stipulated. Finally, we urge the committee to find that the services would be delivered in a safe, secure and effective manner."

7 Consideration

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

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

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

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

7.5 As a preliminary matter, the Committee noted that Netteswell Pharmacy state that "*Regulations under the health and social care act 2012: As per Chapter 11, paragraph 16 as below:*

> *16. If the applicant fails to provide a precise location with the excepted application, this would be classed as missing relevant information for the purposes of paragraph 11 of Schedule 2.*

Address provided on the application: Unit 6, Willow house, Stadium way, Harlow, Essex, CM18 6DX. This address does not provide a precise location and there may be different business running at this address or this address does not exist. It may require a new planning permission from the Harlow council. Hence, we are not satisfied that the pharmaceutical services will be delivered in a safe, secure and effective manner."

7.6 In response, the Applicant states that "*Netteswell Pharmacy questions the existence of the address "Unit 6, Willow House" and raises concerns regarding planning permission. The application address is specific and clearly defined. Issues regarding planning permission are a matter for the local authority and are distinct from the "fitness to practice" or regulatory test required by NHS Resolution. The granting of a pharmacy contract is often a prerequisite for finalising lease and planning arrangements".*

7.7 The Committee noted that paragraph 11 of Schedule 2 of the Regulations is in relation to "*Relevant information or documentation"* that is missing *"as regards any routine or excepted application".*

7.8 The Committee noted that the application form states that "*A full address must be provided – 'best estimates' are not acceptable. The regulations do not allow the premises to be on the same site or in the same building as the premises of a provider of primary medical services with a patient list.".*

7.9 The Committee noted this requirement is as a result of Regulation 25(2)(a) which states that:

> *(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;*

7.10 The Committee therefore noted it is correct that a precise address must be given for distance selling applications, however the Committee noted that the

Commissioner had accepted the address provided by the Applicant when the application form was submitted and it was therefore not a matter for the Committee to consider further nor was the matter of planning permission.

Regulation 31

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

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

(2) This paragraph applies where -

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

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

(ii) adjacent premises; and

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

7.12 In response to the question in the application form on this point, the Applicant stated that "*Not applicable as no other pharmacy in same or adjacent premises".*

7.13 Whilst Netteswell Pharmacy do not dispute this, they do state that "*Address provided on the application: Unit 6, Willow house, Stadium way, Harlow, Essex, CM18 6DX. This address does not provide a precise location and there may be different business running at this address or this address does not exist".* The Committee noted it had no information before it to suggest that these businesses were on the pharmaceutical list or had undertaken to provide pharmaceutical services. Further, the Commissioner in its decision report stated that "*The Committee agreed it was not required to refuse the application under the provisions of Regulation 31".*

7.14 Therefore, based on the information provided, the Committee was not required to refuse the application under the provisions of Regulation 31.

Regulation 25

7.15 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."

7.16 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)

7.17 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)

7.18 As far as Regulation 25(2)(a) is concerned, the Committee had regard to the application form in which the Applicant states "*Application 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*".

7.19 Whilst Netteswell Pharmacy do not dispute this, they do state that "*Address provided on the application: Unit 6, Willow house, Stadium way, Harlow, Essex, CM18 6DX. This address does not provide a precise location and there may be different business running at this address or this address does not exist".* The Committee noted it had no information before it to suggest that these businesses were a "*provider of primary medical services with a patient list*" and further noted that the Commissioner in its decision report stated that "*the premises in respect of which the application is made, 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*". Based on the information before it, the Committee was 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)

7.20 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.

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

7.22 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.

7.23 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, representations, observations and the updated SOPs provided on appeal which the Applicant has prepared or commissioned.

7.24 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 updated SOPs and additional information in order to satisfy itself that it is appropriate to grant the application, the absence of which would require it to reject it.

7.25 The Committee considered whether the Applicant had explained the arrangements which ensure that, for appliances which require fitting / measuring, a registered pharmacist measures / fits them. The Committee noted that on the application form the Applicant had not indicated that it wished to supply any appliances.

7.26 The Committee noted that the Applicant's pharmacy procedures state:

7.26.1 *"If a prescription is received for an appliance which requires measuring and fitting, the patient will be telephoned and emailed to state that the pharmacy cannot provide this service because the pharmacy must operate without face to face contact. The patient will then be advised that they would need to have the prescription dispensed by a pharmacy where a pharmacist would be able to measure and fit the appliance. We would facilitate this by gaining the permission of the patient to contact their nominated pharmacy and explaining the situation. We would then return the prescription to the patient or to the NHS spine so that the prescription can be dispensed."*

7.27 The Committee noted that on receipt of such requests, the Applicant would contact the patient and signpost them to another provider of the service in their area. In the event that the application is granted, the Applicant would not therefore, be able to provide such appliances that require measuring and/or fitting to patients.

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

7.29 Pharmacy Sales & Consultancy state that "*There is minimal reference in the information provided to show how services will be provided during any unplanned absences of the pharmacist during the core opening hours. It is inevitable that occasions will arise when the pharmacist is absent and unless suitable contingency procedures are in place the above obligation will not be complied with. Additionally, the core opening hours provided do not allow for a*

break during the day. The DSP regulations require services to be provided "without interruption". This means the pharmacist will be working for at least 9 hours per day without any break. This may not be safe and casts doubt over wherever it would be possible to provide essential pharmacy services with any interruption".

7.30 In response, the Applicant states that "*PSC suggests that the core opening hours do not allow for a break and that coverage for unplanned absence is insufficient. The operation of the pharmacy will be conducted in strict accordance with the Responsible Pharmacist (RP) Regulations. The SOPs cover "Roles and Responsibility of Pharmacy Staff" (referenced in), ensuring that appropriate staff are authorised to carry out specific tasks. Unplanned absences are managed through standard contingency planning, including the use of locum pharmacists, as is standard practice across the sector. The suggestion that a 9-hour day "may not be safe" is a subjective assertion unsupported by evidence; pharmacists routinely work such shifts with appropriate rest breaks managed within the workflow, during which time the RP remains in charge*".

7.31 The Committee noted that the Applicant's pharmacy procedures state that:

7.31.1 "*Provision of service through the opening hours of the pharmacy will be maintained by having a Responsible Pharmacist present at all times during the pharmacy opening hours and having sufficient support staff at all times. The pharmacy website will run throughout these hours together with a phone, fax, email and webcam service. If the responsible pharmacist is required to leave the premises, a further pharmacist will be on hand to ensure that there is no break in pharmacist cover during the opening hours".*

"Provision of service through the core opening hours of the pharmacy will be maintained by having a Responsible Pharmacist rostered on for all opening hours and having sufficient support staff at all times. Provision of service through the core opening hours of the pharmacy will be maintained by the pharmacy website email and telephone."

7.32 Based on the information before it, the Committee was therefore satisfied that the provision of essential services would be without interruption.

7.33 With regard to services being available to persons anywhere in England, the Commissioner stated that "*The Committee could not be satisfied that all pharmaceutical services are likely to be secured for persons anywhere in England".*

7.34 Further, the Commissioner stated that "*The Committee noted that the Repeat Dispensing SOP provided further information. However, the SOP stated the following under the scope section on page 1, "Procedure covers re-peat dispensing services operated between this pharmacy and participating local GP Practices for those patients who wish to take advantage of them". This signalled that the applicant would only offer this to patients registered with a local GP and not to everyone in England".*

7.35 The Committee noted that in its appeal, the Applicant states that "*We have submitted SOPs with this bundle and ask the committee to take these SOPs into account"* and in the updated SOPs provided on appeal, the wording had been updated to remove reference to "local" GP practice. The Repeat Dispensing SOP on page 68 of the appeal states that:

> *"Procedure covers repeat dispensing services operated between this pharmacy and participating GP Practices for those patients who wish to take advantage of them".*

7.36 On this point, Pharmacy Sales & Consultancy state that "*The appellant has amended the SOPs from the first draft provided to remove the reference to" local GPs". It could be construed that their intentions were clearly set out in the initial application that they will only to* [sic] *providing pharmacy services to the local population and to not provide a national service thereby failing the regulatory test."* However, the Committee must consider the information before it and not on assumptions.

7.37 Further, Pharmacy Sales & Consultancy state that "*From the information provided, it is still 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. 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. 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".*

7.38 In response, the Applicant states that "*PSC alleges that the reliance on websites or apps discriminates against patients with disabilities (e.g., sight or hearing loss). This assertion is incorrect. Distance Selling Pharmacies (DSPs) are required to make reasonable adjustments under the Equality Act. The Applicant's model utilises multiple communication methods, including telephone, email, and webcam/video links. These methods actually enhance accessibility for housebound patients or those with mobility issues compared to traditional brick-and-mortar pharmacies".*

7.39 The Committee noted that the Applicant's pharmacy procedures state that:

7.39.1 "*Patients anywhere in England can access these services via our pharmacy website a direct phone line to the pharmacy, fax, email as well as webcam. Internet connections at the pharmacy will be provided by the NHS HSCN network via BT.*

All prescriptions dispensed will be delivered using a dedicated courier service provided by City Sprint (www.citysprinthealth.co.uk). This will include the delivery of prescriptions received via post, fax and EPS. City

Sprint will also be delivering cold chain items and CDs. This is addressed in the SOPs which have been included".

7.40 Based on the information before it, the Committee was satisfied that the provision of essential services would be available to persons anywhere in England.

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

7.42 The Committee noted the references in the pharmacy procedures, updated SOPs and supporting information which sets out how the Applicant intends to provide pharmaceutical services without face to face contact by using permissible methods of communication which includes email, telephone and video calls.

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

7.44 The Committee noted that the Applicant had stated "*NONE*" in response to the question in the application form on this point. As a result of this amendment, the Committee noted that the Applicant would not be able to provide any pharmaceutical services to patients who are present at its premises.

7.45 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.

7.46 The Committee was satisfied that the provision of pharmaceutical services would be without face to face contact.

7.47 The Committee went on to consider whether the safe and effective provision of pharmaceutical services was likely to be secured.

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

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

7.49.1 Dispensing of drugs and appliances

7.49.2 Urgent supply without a prescription

7.49.3 Preliminary matters before providing ordered drugs or appliances

7.49.4 Providing ordered drugs or appliances

7.49.5 Refusal to provide drugs or appliances ordered

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

7.49.7 Disposal service in respect of unwanted drugs

7.49.8 Promotion of healthy lifestyles

7.49.9 Prescription linked intervention

7.49.10 Health campaigns

7.49.11 Signposting

7.49.12 Support for self-care

7.49.13 Discharge medicines service

7.49.14 Websites and health promotion zones

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

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 the Applicant's pharmacy procedures state:

7.52.1 *"Essential Service – Dispensing…*

All prescriptions dispensed will be delivered using a dedicated courier service provided by City Sprint (www.citysprinthealth.co.uk). This will include the delivery of prescriptions received via post, fax and EPS. City Sprint will also be delivering cold chain items and CDs. This is addressed in the SOPs which have been included…

City Sprint is approved by the MHRA and has fully trained couriers to deal with all pharmacy deliveries including controlled drugs and fridge items. As well as collecting prescriptions from surgeries and collection of unwanted waste medication from patients. This will ensure there is no face to face contact.

Delivery of Refrigerated Medicinal Products - For cold chain products, delivery times will always be pre-arranged with the patient to minimise the risk of failed delivery. The patient's contact number will be given to the City Sprint delivery driver so they can again call the patient

approximately 15-30 minutes prior to so they can check that somebody will be at the address to receive the medication. Cold chain products will be packed in such a way as to ensure that the required temperatures are maintained throughout the journey and the medicines are transported in accordance with their labelling requirements to maintain product integrity.

For delivery of medication with short journey times of less than 3 hours, validated medical cool boxes will be used as recommended by the MHRA. For extended journeys, gels/ ice packs will be added to the packaging to maintain appropriate temperatures throughout. Extra caution will be taken with regards to the positioning of these packs within the consignments as this would be deemed extremely important as they must not be allowed to come into direct contact with the medicines being delivered. Temperatures will be strictly controlled and monitored with calibrated temperature probes to provide temperature data for the entire journey. This will be done by the courier driver. Temperatures will be recorded at the beginning of the journey and again at the point of delivery to ensure it stays between 2-8°C. If the temperature is outside of the required range, then the product will be deemed unsafe to deliver, marked as waste and returned to the pharmacy for destruction. Thermometer(s) will be calibrated annually against a certified standard to ensure safe and effective use. When used to deliver medication, the City Sprint delivery driver must only remove the item from cold storage once the patient has answered the door and verified their identity. In the event of failed delivery, the cold storage item must be returned to the pharmacy as soon as possible, with the maximum and minimum temperatures again being recorded at the point of return. Once again, if temperature monitoring suggests that the medication may have been transported outside of the required range, then the product will be destroyed by the pharmacy and then item will be re-dispensed by the pharmacy. Once again, a new delivery will be agreed with the patient prior to redelivery."

7.53 The Committee considered the above information related to the delivery of cold chain items by courier (City Sprint) only.

7.54 The Committee noted that in the updated SOPs, the "Delivering Medicines Safely and Effectively" SOP on page 36 of the appeal states that:

7.54.1 *"Note that the terms delivery driver and courier are used throughout this SOP and are interchangeable…*

… PREPARATION FOR DELIVERY

Delivery Driver

…

Ask the dispensary staff for any fridge packages that need to be delivered…

…Sign the reverse of the prescription to indicate that the prescription has been collected by the driver / courier…

…DELIVERY

Delivery Driver

While in transit, medicines must always be secured and remain in the drivers possession or left in the vehicle. The vehicle must be locked, the windows must be closed, and the medicines should be kept out of sight

Medicines usually requiring storage in a fridge must be kept in a cool box during transit

Travel to the correct address

Politely introduce yourself and explain why you are present

Confirm your identity and hand over the medicines to the patient/carer or authorised designated person. Do Not hand over medicines to someone who is not the patient/carer or authorised designated person

Ask the patient to check the name, address, and number of packages. Confirm exemption evidence if necessary

Ask the patient to check that the medicines received are required by the patient to help minimise wastage

Ask the patients if they will require their repeats again next month

Ask the patient to write their name and sign to indicate receipt of the medication in the Driver's delivery record book – where this isn't possible, the reason should be recorded by the delivery driver

Courier

Follow the procedure set out by the company who they are employed by

FAILURE TO DELIVER

Driver

If the patient is not home during the agreed delivery slot:

Complete a 'Not at Home' Card detailing information about arranging a re-delivery

Post the pharmacy card through the letter box

Do NOT push through medicines through the letterbox

Do NOT leave the medicines outside the door

Inform the authorised pharmacy staff upon return to the pharmacy

Where schedule 2 or 3 CDs or fridge lines are not delivered, inform the pharmacist upon return to the pharmacy

Courier

Follow the procedure set out by the company who they are employed by…

… FOLLOWING DELIVERY OR ATTEMPTED DELIVERY

Authorised pharmacy staff

Check the Drivers Delivery record book

For packages which have not been delivered

Contact the patient to confirm the next details for a re-delivery

Return the package to the delivery storage area or the fridge if applicable

DELIVERY VIA COURIER

Authorised pharmacy staff

Medicines should only be couriered when it is impractical to deliver via the delivery driver. CDs must NOT be couriered outside of the UK. City Sprint will be used for this purpose

Check with the pharmacist before agreeing to courier medicines

Pharmacy bags should be packaged in a box with bubble wrap or similar packaging to prevent any damage during transit

Ensure that a return address for the pharmacy is marked on the package

Mark the package with the words 'Urgent Medical Supplies' but do not describe the exact contents of the package

Packages should be sent via a traceable/auditable service."

7.55 The Committee noted that Pharmacy Sales & Consultancy state that "*There are contradictions in the information provided by the applicant. In the document*

titled "Pillport Limited- SOPs Pharmacy Procedures" the section which discusses Dispensing states:

> *"All prescriptions dispensed will be delivered using a dedicated courier service provided by City Sprint (www.citysprinthealth.co.uk)". However, in the section on the Discharge Medicines Service the document states:*
>
> > *"All medications will be delivered using our in-house delivery service or the City Sprint courier service".*
>
> *It is clear that the appellant has not fully considered its operating model in respect of deliveries, a fundamental consideration for any DSP. In that case, NHS Resolution cannot be satisfied that the pharmacy will comply with the relevant regulations, despite the assertions made.*

It would be very difficult for the panel to make a decision in the absence of clarity on the operating model and, as the burden of proof is on the appellant to demonstrate that the application fully satisfies the regulatory test, without this information, NHS Resolution may not be in a position to approve this application."

7.56 In response, the Applicant states that "*There is no contradiction. A robust DSP model requires flexibility. As stated in the SOPs, the pharmacy utilises both an in-house delivery service and a courier service (City Sprint) depending on the location of the patient and the urgency of the delivery".*

7.57 Further, Netteswell Pharmacy state that "*It was also mentioned under SOPs for ' Delivering medicines safely and effectively' in P5 that - 'Ask patient that the medicines received are required by the patient to help minimise waste. It was not made clear if patient does not need some medicines at the time of delivery to avoid wastage then how these medicines would be handled and safely brought back and if patient's doctor would be notified. There is a risk that these medicines can be abused if the delivery driver does not report back. Hence, I would strongly believe that SOPs are not adequate and it would risk patient safety and misuse of medicines".*

7.58 In response, the Applicant states that "*The procedure described in the "Delivering Medicines Safely and Effectively" SOP is a safety mechanism, not a risk. It prevents the stockpiling of unwanted medicines. The SOP explicitly states that if a delivery fails or items are not handed over, the driver must "inform the authorised pharmacy staff upon return". This ensures the pharmacist is alerted and can contact the patient's prescriber if necessary".*

7.59 Whilst the Committee noted that the Applicant's pharmacy procedures state that cold chain items will be delivered by courier only, the Applicant's SOPs provided on appeal state that such items will also be delivered by the pharmacy's own delivery driver

7.60 With regard to cold chain deliveries by the pharmacy's own delivery driver, whilst the Committee noted reference to using a "cool box", there was nothing provided by the Applicant to demonstrate how this would appropriately maintain medicines at the correct temperature, the monitoring of the temperature and that an audit process or appropriate system is in place which would highlight

any items, which might have ceased to be correctly refrigerated in transit and therefore be compromised, and how these would be prevented from being given to the patient. The Committee noted that the Applicant's SOP states *"Where…fridge lines are not delivered, inform the pharmacist upon return to the pharmacy"* but there was a lack of information regarding safe segregation and storage of such items if delivery had been unsuccessful.

7.61 Therefore, the Committee could not be satisfied, as it was required to be, that during transit with the pharmacy's own delivery driver, the cold chain would be maintained and monitored throughout. Further there was no information to explain what would happen in the event of a failed/ missed delivery by the pharmacy delivery driver.

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

Other considerations

7.63 The Committee noted that in its decision report, the Commissioner had made findings in relation to certain aspects of the Terms of Service. Further, the Committee also noted other comments on appeal which it considered important to address.

Dispensing of drugs and appliances

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

7.65 The Committee noted the Applicant's pharmacy procedures state that:

7.65.1 *"All prescriptions dispensed will be delivered using a dedicated courier service provided by City Sprint (www.citysprinthealth.co.uk). This will include the delivery of prescriptions received via post, fax and EPS. City Sprint will also be delivering cold chain items and CDs".*

7.66 The Committee also noted that in the updated SOPs, the "The Safe and Effective Supply of Medicinal Products" SOP on page 9 of the appeal covers the procedure for "*RECEIVING A PRESCRIPTION (NHS OR PRIVATE) ELECTRONIC (ETP) OR POST*".

7.67 Further, the "Discharge Medicines Service" SOP on page 80 of the appeal states that "*All medications will be delivered using our in-house delivery service or the City Sprint courier service and will maintain service delivery without face-to-face contact*".

7.68 The Committee noted that Pharmacy Sales & Consultancy state that "*There are contradictions in the information provided by the applicant. In the document titled* "*Pillport Limited- SOPs Pharmacy Procedures" the section which discusses Dispensing states:*

"All prescriptions dispensed will be delivered using a dedicated courier service provided by City Sprint (www.citysprinthealth.co.uk)". However, in the section on the Discharge Medicines Service the document states:

> *"All medications will be delivered using our in-house delivery service or the City Sprint courier service".*

It is clear that the appellant has not fully considered its operating model in respect of deliveries, a fundamental consideration for any DSP. In that case, NHS Resolution cannot be satisfied that the pharmacy will comply with the relevant regulations, despite the assertions made.

It would be very difficult for the panel to make a decision in the absence of clarity on the operating model and, as the burden of proof is on the appellant to demonstrate that the application fully satisfies the regulatory test, without this information, NHS Resolution may not be in a position to approve this application."

7.69 In response, the Applicant states that "*There is no contradiction. A robust DSP model requires flexibility. As stated in the SOPs, the pharmacy utilises both an in-house delivery service and a courier service (City Sprint) depending on the location of the patient and the urgency of the delivery".*

7.70 Whilst the Committee noted the contradiction, it considered it had enough evidence to be satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 5(2) and 5(3) of Schedule 4.

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 regime has not changed in any way and there has been no changes to the patient's health, which may indicate the desirability of review the patients treatment.

7.72 The Commissioner stated that "*The Committee noted that the Repeat Dispensing SOP provided further information. However, the SOP stated the following under the scope section on page 1, "Procedure covers re-peat dispensing services operated between this pharmacy and participating local GP Practices for those patients who wish to take advantage of them". This signalled that the applicant would only offer this to patients registered with a local GP and not to everyone in England. Based on the information before it, the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 9(4) of Schedule 4".*

7.73 The Committee noted that in its appeal, the Applicant states that "*We have submitted SOPs with this bundle and ask the committee to take these SOPs into account"* and in the updated SOPs provided on appeal, the wording had been updated to remove reference to "local" GP practice. The Repeat Dispensing SOP on page 68 of the appeal states that:

"Procedure covers repeat dispensing services operated between this pharmacy and participating GP Practices for those patients who wish to take advantage of them".

7.74 On this point, Pharmacy Sales & Consultancy state that "*The appellant has amended the SOPs from the first draft provided to remove the reference to" local GPs". It could be construed that their intentions were clearly set out in the initial application that they will only to* [sic] *providing pharmacy services to the local population and to not provide a national service thereby failing the regulatory test."* However, the Committee must consider the information provided and not on assumptions.

7.75 The Committee also noted the Applicant's pharmacy procedures state:

7.75.1 *"Essential Service - Repeat Dispensing…*

Repeat Dispensing will be delivered safe and effectively via the staff completing sufficient clinical and legal assessments before dispensing the medicine. Once a patient signs up we will obtain the batch prescription (both the Repeat Authorising Prescription RA and the Repeat Dispensing Prescriptions RD) either from the surgery, electronically or via post. Either the patient will contact the pharmacy via phone, email post, website or webcam to dispense the next RD instalment prescription or the pharmacy contacts the patient when they are due their next RD instalment. Before each RD dispensing activity we will contact the patient to clarify which items are required and whether or not there has been a change in medical condition. If treatment needs to be reviewed by the prescriber, the patient will be notified by telephone and/or email. We will keep records of dates of dispensing for each individual batch for each patient, to monitor compliance. Records of interventions made by the pharmacist considered by the pharmacist to be clinically significant will be maintained on the PMR. These actions will ensure a safe and effective service is delivered for patients using the repeat dispensing service."

7.76 The Committee further noted that in the updated SOPs, the "Repeat Dispensing" SOP on page 70 of the appeal states that:

7.76.1 *"BEFORE SUPPLYING SUBSEQUENT BATCH ISSUES*

Check:

The pharmacy holds the master repeatable prescription

The master repeatable prescription is in date

Pharmacy holds the batch issue or the patient sends it in

Batch issues are presented in numerical order (batch issues are indicated as number 1 of 12, 2 of 12 etc.) in the space normally used for signing

There is no legal requirement to dispense in numerical order, but it is good practice and helps avoid confusion

Any problems on the original master repeatable prescription are corrected and reflect in batch issue

If the patient requires all items, is using medicines, appliances or reagents properly, and is not suffering any side-effects

There have been no changes in patient's circumstances since the last supply, e.g.:

Hospital admission

Hospital outpatient clinic visit

New symptoms

Taking OTC medicines

If there is any concern about the safety or appropriateness of a repeat prescription:

Contact the patient and advise them to make an appointment with the GP

Contact the GP (or other health care provider) directly."

7.77 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

7.78 The Committee considered whether the Applicant had explained how appropriate advice about the benefits of repeat dispensing is given to any patient who (i) has 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.

7.79 The Commissioner stated that "*The Committee noted that the Repeat Dispensing SOP provided further information. However, the SOP stated the following under the scope section on page 1, "Procedure covers re-peat dispensing services operated between this pharmacy and participating local GP Practices for those patients who wish to take advantage of them". This signalled that the applicant would only offer this to patients registered with a local GP and not to everyone in England. Based on the information before it, the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with 10(1) of Schedule 4".*

7.80 The Committee noted that in its appeal, the Applicant states that "*We have submitted SOPs with this bundle and ask the committee to take these SOPs*

into account" and in the updated SOPs provided on appeal, the wording had been updated to remove reference to "local" GP practice. The Repeat Dispensing SOP on page 68 of the appeal states that:

> *"Procedure covers repeat dispensing services operated between this pharmacy and participating GP Practices for those patients who wish to take advantage of them".*

7.81 On this point, Pharmacy Sales & Consultancy state that "*The appellant has amended the SOPs from the first draft provided to remove the reference to" local GPs". It could be construed that their intentions were clearly set out in the initial application that they will only to* [sic] *providing pharmacy services to the local population and to not provide a national service thereby failing the regulatory test."* However, the Committee must consider the information provided and not on assumptions.

7.82 The Committee also noted that the Applicant's pharmacy procedures state:

7.82.1 *"Essential Service - Repeat Dispensing…*

> *For patients who request our service and who are NOT signed up to the repeat dispensing service, we will request that they contact the pharmacy so that we can discuss their suitability for the service but also provide further information on the benefits of the service. The initial contact with the patient will be via a leaflet which will be included within their dispensed medication. Benefits will include saving time for the patient and the prescriber due to a decreased workload on both parties. A further benefit will include an improvement of medication safety as the pharmacy will check each and every request to ensure that the medication is still suitable before dispensing. During these checks, if a medication is flagged as being unsuitable or there are side effects, then the patient will be referred to the prescriber for discussion."*

7.83 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

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

7.85 Netteswell Pharmacy state that "*It was also mentioned under SOPs for ' Delivering medicines safely and effectively' in P5 that - 'Ask patient that the medicines received are required by the patient to help minimise waste. It was not made clear if patient does not need some medicines at the time of delivery to avoid wastage then how these medicines would be handled and safely brought back and if patient's doctor would be notified. There is a risk that these medicines can be abused if the delivery driver does not report back. Hence, I would strongly believe that SOPs are not adequate and it would risk patient safety and misuse of medicines".*

7.86 In response, the Applicant states that "*The procedure described in the "Delivering Medicines Safely and Effectively" SOP is a safety mechanism, not a risk. It prevents the stockpiling of unwanted medicines. The SOP explicitly states that if a delivery fails or items are not handed over, the driver must "inform the authorised pharmacy staff upon return". This ensures the pharmacist is alerted and can contact the patient's prescriber if necessary".*

7.87 The Committee noted the Applicant's pharmacy procedures state:

7.87.1 *"Essential Service - Disposal of Unwanted Medication*

Uninterrupted Service

Provision for disposal of unwanted medications can be requested by any patients during the core opening hours of the pharmacy. This can be requested via telephone, fax, email or webcam. All staff will be trained to deal with such enquiries.

Persons anywhere in England

Patients anywhere in England can request for safe disposal of their unwanted medication from our pharmacy via phone, fax, email, post or webcam.

Safe and Effectively

Patients, anywhere in England, can contact the pharmacy for collection of their unwanted medicines. We will take details of medication being returned by patients and assess if we are allowed to take them. We would provide patients with adequate packaging so medication can be returned securely via City Sprint couriers at no charge to the patient. All legal records will be kept and we would have procedures in place to comply with Hazardous Waste Regulations and we would keep any additional legal records such as those required for Controlled Drugs. Returned medication can be collected from patients' homes and residential homes but we will not be accepting from nursing homes. Returned medication will be stored in UN type containers provided by PHS.

Returned medication will be stored in UN type containers provided by PHS. Returned solid medicines/ ampoules, liquids and aerosols will be separated. Schedule 2 and 3 Controlled Drugs that are subject to safe custody regulations which are returned by patients will be segregated from other returned medicines and stored in compliance with the Safe Custody Regulations until they have been rendered irretrievable. As the Environment Agency has suggested that the denaturing of CDs is likely to constitute a waste treatment, the pharmacy will hold a waste management license. We will ensure that the courier collecting returned medication is registered as a waste carrier with each local environmental agency office that it operates in. We will keep full records of any waste collected and disposed of for at least three years.

Without face-to-face contact

Disposal of unwanted medication will be delivered without face-to-face contact via City Sprint couriers or, for local requests, out in-house delivery service. This courier service will provide a third party delivery. Patients would communicate with the pharmacy via phone, fax, email website, post or webcam. We have SOPs in place to ensure this service is offered without having them to be present the pharmacy."

7.88 The Committee also noted that in the updated SOPs, the "The Safe and Effective Disposal of Medicines" SOP on page 70 of the appeal states that:

7.88.1 *"WHOM WASTE CAN BE ACCEPTED FROM*

Authorised pharmacy staff

Within this pharmacy, unwanted medicines may be accepted from the following:

Patients resident in their own homes

Patients in residential homes

Patients anywhere in England

RECEIVING WASTE MEDICINES

Authorised pharmacy staff

Patients anywhere in England can contact the pharmacy for collection of their unwanted medicines.

We will take details of medication being returned by patients and assess if we are allowed to take them.

Check for sharps or chemicals. (Chemicals should not be accepted for disposal, and patients signposted appropriately.

Only accept returned sharps where there is a waste disposal service for sharps. The patient must be asked to carefully remove these items before unwanted medicines can be accepted

Signpost the patient to the most appropriate route for disposal (May be their usual GP practice or by local authority collection)

We would provide patients with adequate packaging so medication can be returned securely via delivery driver/ City Sprint couriers at no charge to the patient.

Ask the patient to estimate the amount of waste and nature of the waste, e.g. any CDs

Provide the patient with the required number of plastic bags, with tamper proof seals for CDs

Explain that a driver/ courier will be coming round to collect the medication when convenient for the patient

Once collected, the driver should place the medication in a box that has the facility to be closed with a lid. This is to ensure the returned medicines do not get mixed up with the deliveries

If the medicines cannot be dealt with immediately, then:

Handle the returned medicines only using the handles of the bag or the top of the bag or container, ensuring there is no risk of the contents spilling from the bag

If the returned medicines cannot be sorted immediately, then make sure the bag or container is clearly marked and stored separately from other pharmacy stock. Temporarily store the bag or container for processing at a later time according to the procedure outlines below

If the medicines can be dealt with immediately, then process according to the procedure outlined below

All legal records will be kept and we would have procedures in place to comply with Hazardous Waste Regulations and we would keep any additional legal records such as those required for Controlled Drugs.

Returned medication can be collected from patients' homes and residential homes but we will not be accepting from nursing homes.

Returned medication will be stored in UN type containers provided by PHS.

Returned solid medicines/ ampoules, liquids and aerosols will be separated.

Schedule 2 and 3 Controlled Drugs that are subject to safe custody regulations which are returned by patients will be segregated from other returned medicines and stored in compliance with the Safe Custody Regulations until they have been rendered irretrievable.

As the Environment Agency has suggested that the denaturing of CDs is likely to constitute a waste treatment, the pharmacy will hold a waste management license.

We will ensure that the courier collecting returned medication is registered as a waste carrier with each local environmental agency office that it operates in.

We will keep full records of any waste collected and disposed of for at least three years."

7.89 Based on all of the information before it, 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.

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

Summary

7.91 On the information before it, the Committee could not be satisfied that there are procedures likely to secure the safe and effective provision of pharmaceutical services as required by Regulation 25(2)(b).

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

7.92.1 confirm the Commissioner's decision;

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

7.92.3 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.

7.93 Even though the Committee had reached the same decision as the Commissioner, it had done so for different reasons. In those circumstances, the Committee determined that the decision of the Commissioner must be quashed.

7.94 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.

7.95 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.

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

8 Decision

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

8.2 The Committee:

8.2.1 quashes the decision of the Commissioner; and

8.2.2 redetermines the application as follows -

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

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

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

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

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

8.2.3 The application is refused.

Case Manager
Primary Care Appeals