

7 April 2022

REF: SHA/24675

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APPEALS AGAINST NORTH EAST AND YORKSHIRE (YORKSHIRE AND THE HUMBER) AREA TEAM, NHS COMMISSIONING BOARD "NHS ENGLAND" DECISION TO GRANT AN APPLICATION BY KARMA MEDICAL SOLUTIONS LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT 55 GRIMSBY ROAD, CLEETHORPES, NORTH EAST LINCOLNSHIRE, DN35 7AF UNDER REGULATION 25

1 Outcome

- 1.1 The Pharmacy Appeals Committee ("Committee"), appointed by NHS Resolution, quashes the decision of NHS England and redetermines the application.
- 1.2 The Committee determined that the application should be granted.

A copy of this decision is being sent to:

Rushport on behalf of Karma Medical Solutions Ltd
Sai Dutt Ltd
Temple Bright on behalf of Sandringham Road Pharmacy
Co-op
L Rowland & Co (Retail) Ltd
Humberside LPC
PCSE on behalf of NHS England

Advise / Resolve / Learn

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1 The Application

By application dated 24 April 2021, Karma Medical Solutions Limited ("the Applicant") applied to NHS Commissioning Board ("NHS England") for inclusion in the pharmaceutical list at 55 Grimsby Road, Cleethorpes, North East Lincolnshire, DN35 7AF 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 Drug Tariff part IX* (*Except items that require measuring or fitting).
- 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 not on the same site or in the same building as the premises of a provider of primary medical services with a patient list.

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

Please find below information to explain how the pharmacy procedures used within the premises will secure:

- (a) the uninterrupted provision of essential services during the opening hours of the premises, to persons anywhere in England who request those services, and
- (b) the safe and effective provision of essential services without face to face contact between any person receiving the services, whether on their own or someone else's behalf, and the applicant or the applicant's staff.

NHS England Premises Standards

- 1.4 NHS England has published premises standards that the Pharmacy will comply with, however, it should be noted that not all these standards apply directly to distance selling premises other than where a patient is accessing non-essential services.

1.5 The pharmacy will be a Healthy Living Pharmacy and comply with the change management and organisational development criteria, ensuring premises and facilities are fit for purpose and engaging with the community to deliver consistently high quality health and wellbeing services.

1.6 The pharmacy will be equipped with facilities to allow for both phone (or other live audio link) and live video communication with patients in a manner which maintains patient confidentiality.

GPhC Guidance

1.7 The Applicant will operate the pharmacy in accordance with the "Guidance for registered pharmacies providing pharmacy services at a distance, including on the internet", the content of which is considered and replicated in part below but is not intended to exhaustively replicate the entirety of the GPhC guidance which will be followed.

1.8 Specifically, but not exhaustively, the Applicant will have in place, prior to opening the following which are GPhC requirements;

Risk Assessment

1.9 A Risk Assessment document and risk matrix to help identify and manage risks. The risk assessment will look at what could cause harm to patients and people who use the pharmacy services, and what the pharmacy needs to do to keep the risk as low as possible.

1.10 The risk assessment will be reviewed quarterly and also when there are significant business or operational changes.

Audit Procedures

1.11 A regular audit programme will be in place. The audit will be an important part of the evidence which gives assurance that the pharmacy continues to provide safe pharmacy services to patients. Any issues identified will be subject to a reactive review.

1.12 The audit will, at the very least, consider;

1.12.1 staffing levels and the training and skills within the team;

1.12.2 suitability of communication methods with patients, and between staff and other healthcare providers, including between hubs and spokes and with collection and delivery points (if applicable);

1.12.3 use of specialised equipment and new technology;

1.12.4 records of decisions to make or refuse a sale;

1.12.5 systems and processes for receiving prescriptions, including EPS records of decisions to make or refuse a sale (note that the Applicant's pharmacy SOPs will require more frequent analysis of refusals to sell);

1.12.6 systems and processes for secure delivery to patients;

1.12.7 any information about pharmacy services on the website;

1.12.8 review of how the pharmacy adheres to the information security policy, Payment Card Industry Data Security Standard (PCI DSS) and data protection law;

1.12.9 feedback from patients and people who use the pharmacy services;

1.12.10 concerns or complaints received, and

1.12.11 activities of third parties, agents or contractors.

1.13 The Audit and review process will act as a Project Plan for the pharmacy to implement change and upgrades in service and training.

Reactive Review

1.14 A reactive review will take place if an audit identifies a problem, or if there is;

1.14.1 a change in the law affecting any part of the pharmacy service;

1.14.2 a significant change in any part of the pharmacy service provided, for example an increase in the number of patients the pharmacy provides services to, or an increase in the range of services the pharmacy intends to provide;

1.14.3 a data security breach;

1.14.4 a change in the technology the pharmacy uses;

1.14.5 concerns or negative feedback are received from patients or people who use the pharmacy services;

1.14.6 a review of near misses and error logs causes a concern about an activity.

Accountability

1.15 During opening hours there will always be a responsible pharmacist (RP) on site. Each area of work will have clear lines of accountability that will be set out by the superintendent pharmacist.

Record Keeping

1.16 Records in the pharmacy will be scanned in to the pharmacy IT system (including but not limited to, patient consent forms, queries, complaints, customer logs, sale refusals, and dispensing). Records will be kept for a minimum period of 7 years or longer if specific legislation requires.

Training

1.17 The Applicant will ensure that all staff are properly trained and competent to provide medicines and other professional pharmacy services safely. The GPhC has produced guidance to ensure a safe and effective team and this will form the basis of the training.

Premises

1.18 Premises will be registered with the GPhC prior to entry to the pharmaceutical list and will therefore comply with GPhC requirements for pharmacy premises.

Website

1.19 The website will be secure and follow information security management guidelines and the law on data protection. The website will use secure facilities for collecting, using and storing patient details and a secure link for processing card payments.

1.20 The website will display;

- 1.20.1 the GPhC pharmacy registration number;
- 1.20.2 the name of the owner of the registered pharmacy;
- 1.20.3 the name of the superintendent pharmacist;
- 1.20.4 the name and address of the registered pharmacy that supplies the medicines;
- 1.20.5 details of the registered pharmacy where medicines are prepared, assembled, dispensed and labelled for individual patients against prescriptions (if any of these happen at a different pharmacy from that supplying the medicines);
- 1.20.6 information about how to check the registration status of the pharmacy and the superintendent pharmacist;
- 1.20.7 details of specific services available and how to use them, i.e.
 - 1.20.7.1 Return of unwanted medicines;
 - 1.20.7.2 Patient Lifestyle Questionnaire;
 - 1.20.7.3 How to register exemptions from NHS charges;
 - 1.20.7.4 Promotion of Health Lifestyles and details of campaigns being undertaken;
 - 1.20.7.5 Procedures for Emergency Supply;
 - 1.20.7.6 Explanation of rules on non-face to face contact;
 - 1.20.7.7 Annual patient survey;
 - 1.20.7.8 Patient Information Leaflet;
- 1.20.8 the email address and phone number of the pharmacy;
- 1.20.9 details of how patients and users of pharmacy services can give feedback and raise concerns;
- 1.20.10 GPhC internet logo (linked to register entry);
- 1.20.11 Where any medicines are sold online the pharmacy will be registered with the Medicines and Healthcare products Regulatory Agency (MHRA) and to be on the MHRA's list of UK registered online retail sellers.
- 1.20.12 The pharmacy will display any required logo on every page of the website offering medicines for sale, even if they are already displaying the GPhC voluntary logo. The website will be regularly updated, clear and accurate and follow the GPhC guidance on websites.

Transparency and Choice

- 1.21 The Applicant's website and materials will specify the nature and type of services it provides and who provides those services.
- 1.22 If any part of the Applicant's pharmacy services is provided at different locations the Applicant will explain clearly to people who use pharmacy services where each part of the service is based.

Managing Medicines Safely

- 1.23 The pharmacy SOPs provide the procedures for all staff to follow to ensure that the sale and supply of medicines is done in such a manner as to minimise risk to patients. The supply or sale of any new medicine must be approved by the superintendent pharmacist as suitable for sale via distance selling.

Supplying Medicines Safely

- 1.24 The SOPs for delivery of medicines contain detailed information on the safe and effective supply of medicines via the pharmacy's own driver, Royal Mail and courier firms, including;
- 1.24.1 assess the suitability and timescale of the method of supply, dispatch, and delivery for all medicines and particularly refrigerated medicines and controlled drugs;
 - 1.24.2 ensuring that the prescriber has robust processes to check the identity of the person to make sure the medicines prescribed go to the right person - for example, by keeping to the Identity Verification and Authentication Standard for Digital Health and Care Services, which provides a consistent approach to identity checking across online digital health and care services;
 - 1.24.3 assess the suitability of packaging (for example, packaging that is tamperproof or temperature controlled);
 - 1.24.4 Ensure appropriate safeguards for all online supplies of medicines.
- 1.25 The pharmacy will monitor third-party providers, including analysis of patient feedback about deliveries and delivery times and processes.

Equipment and Facilities

- 1.26 All equipment used in the pharmacy will be sourced from manufacturers that have designed the equipment to be used in the manner in which the pharmacy intends to operate.
- 1.27 All equipment will be subject to annual performance testing and review, with specialist equipment (such as temperature monitoring) subject to monthly checks.
- 1.28 IT equipment will meet the latest security specifications and be regularly updated including the use of encrypted networks for wired and wireless communication. Access to records will be dependent on any given employee's level of authority and clearance which shall be determined by the superintendent pharmacist.

Standard Operating Procedures

- 1.29 The Applicant has already developed a draft suite of operating procedures that cover the operations of this distance selling contract. If NHS England requires any further information about any aspect of the operation of the pharmacy then the relevant SOP will be provided upon request. The Applicant has not provided all SOPs with this application as they contain commercially sensitive material.
- 1.30 It should be noted that NHS England's national policy document, "Policy for monitoring compliance with the terms of service for pharmacy and dispensing appliance contractors" (published 5 April 2013) contains a section on SOPs that states:

-2.11

"Monitoring compliance requires only the determination of whether the pharmacy has an appropriate SOP.

It does not require NHS England to carry out a detailed analysis of the content of the SOPs. Indeed, it would be unwise for an NHS England employee to carry out any detailed examination because he or she will be unable to determine what is appropriate for the individual pharmacy concerned.

Any shortcomings not identified, or suggestions made which themselves cause problems in delivery of the services could lead to NHS England itself being involved in litigation."

- 1.31 The Applicant however notes that there may be occasions where NHS England would wish to see specific SOPs if particular concerns are raised and in any such instance the Applicant would be happy to provide a copy of any requested SOPs.

Pharmacy Systems And Procedures

- 1.32 All Essential Services will be delivered in accordance with:
- 1.32.1 Company Standard Operating Procedures;
 - 1.32.2 NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013;
 - 1.32.3 NHS Act 2006;
 - 1.32.4 Human Medicines Regulations 2012;
 - 1.32.5 GPhC - Professional Standards and Guidance on Distance Selling Pharmacies;
 - 1.32.6 Relevant Data Protection laws.
- 1.33 This will ensure that the Applicant provides safe, effective and uninterrupted provision of all essential services to persons anywhere in England who request those services during the opening hours of the premises. Essential Services will be provided without face to face contact between anyone receiving the services, whether on their own or someone else's behalf, and the pharmacy staff.
- 1.34 The Applicant's wholly Internet/Delivery Pharmacy will operate from secure premises, with a controlled entry system, to which members of the public will not have access. Any patient that requests essential services to be provided at the premises will be informed that the pharmacy is not permitted to provide those services at the premises.
- 1.35 Access to information about the provision of NHS Essential Services will be achieved by using:
- 1.35.1 Telephone;
 - 1.35.2 The website will enable patients or their carers to communicate remotely but directly allowing quick and easy access and provide clear unambiguous details of how safe, efficient, uninterrupted NHS Essential Services will be provided by the Pharmacist and qualified, knowledgeable, experienced support staff on duty throughout the opening hours of the pharmacy premises without having 'face to face' contact with the patient or their representative.
 - 1.35.3 Email;
 - 1.35.4 Postal services.

- 1.36 All NHS services will be delivered free of charge in accordance with the NHS Act 2006.
- 1.37 Essential Services may be delivered using:
 - 1.37.1 Telephone, including text messaging where appropriate;
 - 1.37.2 Electronic Prescription Service (EPS);
 - 1.37.3 Website;
 - 1.37.4 Email;
 - 1.37.5 Royal Mail postal service;
 - 1.37.6 Courier service;
 - 1.37.7 Specialist Waste Management Services;
 - 1.37.8 Live video services;
 - 1.37.9 Specialist cold chain courier services will ensure the integrity of the cold chain and the maximum stability of thermo-labile drugs by packing, transporting and delivering in such a way that their integrity, quality and effectiveness is always preserved. This will be a dedicated, fully monitored and temperature controlled delivery service.

Provision of NHS Essential Services

Dispensing Services

- 1.38 Prescriptions will be received by the EPS, post, and fax or where practicable, with the patient's informed consent, collected from a surgery. Prescriptions will be clinically and legally assessed to determine if they can be dispensed.
- 1.39 In the event of any clinical or legal issues with the prescription the pharmacist will follow Standing Operating Procedures to resolve these issues before dispensing items. This may involve contacting the prescriber as soon as possible to make sure the patient receives their medication without delay.
- 1.40 When appropriate prescription interventions take place, for example drug/drug interactions, suspected over/under prescribing, etc. the pharmacist on duty will telephone and discuss with the prescriber and patient prior to dispensing or delivering the medication.

Repeat Dispensing Services

- 1.41 The Terms of Service require pharmacy contractors to ensure that 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, including, where appropriate, advice that encourages the patient to discuss repeat dispensing of that medicine with a prescriber at the provider of primary medical services whose patient list the patient is on.
- 1.42 Such advice will be provided by the Pharmacy using its permissible methods of non-face-to-face contact with patients.

- 1.43 Dispensing of repeat NHS prescriptions including those dispensed in dosette boxes as may be required under the Equality Act 2010 will be carried out in partnership with patients, carers, pharmacists and prescribers. It will cover requirements additional to those for dispensing, assessing the patients' need for repeat supply. Any clinical issues identified will be addressed to the prescriber.
- 1.44 Where considered necessary by a pharmacist, the patient may be contacted by telephone and given verbal advice in addition to information delivered with the repeat prescription.
- 1.45 Medicines will only be supplied where the pharmacist is satisfied that the patient is taking and is likely to continue to take the drug appropriately and is not suffering from any side effects which indicate the need or desirability to review the patient's treatment.

Urgent Supply and Emergency Supply

- 1.46 Whilst the Distance Selling nature of the pharmacy is such that Urgent Supply or Emergency Supply is unlikely to occur as often as in a retail pharmacy, all staff will be aware of the procedures to be followed in the event of such a request.
- 1.47 The request may be received from a Prescriber (Urgent Supply) or from a Patient (Emergency Supply).
- 1.48 The following conditions must apply to the request made by a prescriber:
 - 1.48.1 The Pharmacist must be satisfied that the request is from the appropriate authorised prescriber, see list above.
 - 1.48.2 The Pharmacist is satisfied that a prescription cannot be supplied immediately due to an emergency.
 - 1.48.3 The Prescriber agrees to provide a written prescription within 72 hours.
 - 1.48.4 The medication is supplied in accordance with the prescriber's directions.
 - 1.48.5 The medication is permitted to be supplied on an Emergency Supply basis.
 - 1.48.6 An emergency supply cannot be provided for a Schedule 1, 2 or 3 CD except Phenobarbital for epilepsy by a UK registered prescriber.
 - 1.48.7 EEA prescribers cannot request an emergency supply of any Schedule 1 - 5 CD.

1.49 Full records of the supply will be kept as per the relevant SOP.

1.50 The following conditions must apply to the request made by a patient:

Interview

1.51 The Pharmacist must interview the patient. The interview may not be by way of face to face contact and must be by other means, e.g., telephone, Skype.

Records

1.52 An entry must be made in the POM register on the day of supply and record all the relevant details.

1.53 The label for the dispensed medicine must contain the words "Emergency Supply".

Faxed Prescriptions

- 1.54 A 'faxed prescription' or other forms of scanned prescriptions do not fall within the definition of a legally valid prescription because it is not written in indelible ink, and has not been signed by an appropriate practitioner. A faxed / scanned prescription can confirm that at the time of receipt a valid prescription is in existence, but no medicines should be supplied until the original prescription is received.
- 1.55 The pharmacist should not dispense against faxed prescriptions and instead uses the Emergency Supply procedures.

Delivery of Urgent Supplies

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

Disposal of Unwanted Medicines

- 1.57 Patients will have a number of options for disposal of unwanted medicines.
 - 1.57.1 A specialist waste management company will provide safe and secure disposal of unwanted medicines by collection of unwanted medicines from patients and residential homes.
 - 1.57.2 Patients wishing to return unwanted medicines to the pharmacy may do so by courier, which will be provided and paid for by the pharmacy.
 - 1.57.3 Patients in locality may contact pharmacy by phone or email to arrange collection of unwanted medicines from their home or work by pharmacy staff.
- 1.58 Appropriate packaging will be sent to patients in advance and details of the service and how to book a collection will be available on the Pharmacy website.
- 1.59 Upon return to the pharmacy unwanted medicines will be sorted and placed in disposal units ready for waste management services to collect. The disposal service will be advertised on the website/app and marketing leaflets.

Promotion of Healthy lifestyles

- 1.60 Identification of patients for promotion of healthy lifestyles can take two forms, namely, passive or active.
- 1.61 Active patients will be those who have chosen to access the Lifestyle Questionnaires via the website or returned them by post and who are then identified from the results as patients to whom further information should be sent, or who should be called to follow up on the results and offer additional support and information.
- 1.62 Passive patients are those where the identification happens as part of another interaction with the patient, but where the patient does not appear to be actively seeking additional assistance. For example, the dispensing of a prescription which identifies the patient as having high blood pressure.
- 1.63 All patients who have prescriptions dispensed or purchase medicines from the pharmacy will be asked to fill in the Lifestyle Questionnaire which will ask for details

such as existing medical conditions, height, weight and also lifestyle questions such as whether a patient is a smoker and how much exercise they normally have on a weekly basis.

- 1.64 Leaflets will be delivered to patients with their medication. Those identified (Active or Passive) as having medical conditions such as diabetes, coronary heart disease, COPD, Asthma, high blood pressure, smokers, overweight individuals, etc. or being at risk from them or other conditions will also receive targeted campaigns to increase the patient's knowledge and understanding of health issues relevant to them. The website will also be used to promote healthy lifestyles.

Health Campaigns

- 1.65 The Pharmacy will take part in national health campaigns to promote public health messages to their patients across England. This will be achieved by sending out leaflets with prescriptions during specific targeted campaign periods and providing additional advice and learning resources via the website.
- 1.66 Patients will be directed to the learning resources via email, text and other on face-to-face communication so that they are aware of the campaign.
- 1.67 Patients should also be assessed for participation in at least one clinical audit and whichever of the following that the NHSCB specifies-

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

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

Signposting and Support for Self-Care

- 1.68 Patient will be signposted to health and social care providers and/or any other assistance available whenever necessary. To assess whether patients require advice to minimise inappropriate use of health or social care services the pharmacist will use the same "Active and Passive" assessment tool already set out above.
- 1.69 Where it appears to the pharmacist, after reviewing the assessment and having regard to the need to minimise inappropriate use of health and social care services and of support services, that a person using the pharmacy would benefit from advice to help manage their medical condition then advice will be provided via non face to face methods of communication and this will include advice on both treatment options, non-prescription medicines and lifestyle advice.
- 1.70 If a patient;
- 1.70.1 requires advice, treatment or support that the pharmacy cannot provide; but
- 1.70.2 another provider, of which the pharmacy is aware, of health or social care services or of support services is likely to be able to provide that advice, treatment or support,
- 1.71 The pharmacy will provide contact details of that provider to that person and will, in appropriate cases, refer that person to that provider.

Referral for Certain Appliances

- 1.72 Where, on presentation of a prescription form or repeatable prescription, the pharmacy is unable to provide an appliance or stoma appliance customisation because the provision of the appliance or customisation is not within the pharmacy's normal course of business, the pharmacist will-
- 1.72.1 if the patient consents, refer the prescription form or repeatable prescription to another NHS pharmacist or to an NHS appliance contractor; and
- 1.72.2 if the patient does not consent to a referral, provide the patient with contact details of at least 2 people who are NHS pharmacists or NHS appliance contractors who are able to provide the appliance or stoma appliance customisation (as the case may be), if these details are known to the pharmacist.
- 1.73 In appropriate cases, the pharmacist will keep and maintain a record of any information given or referral made to facilitate auditing and follow up care.

Support for People with Disabilities

- 1.74 This service will be provided in accordance with the Equality Act 2010. The Applicant will make reasonable pharmaceutical adjustment to ensure that those who qualify for help under the Act are provided with the right compliance aids.
- 1.75 The Applicant will conduct an initial assessment with the patient, carer or representative to assess the support required to improve medication compliance. Such assessments will be carried out without patients having to access the pharmacy premises, so that no face-to-face contact at the premises will take place.
- 1.76 Compliance aid systems such as blister packs/dosette boxes will be provided in compliance with both service levels 1 & 2 respectively.

Clinical Governance

Note: Clinical Governance is not an 'essential service' and is therefore dealt with briefly in this submission.

- 1.77 The Applicant will be involved in and comply with all the components of clinical governance including, but not limited to, compliance with standard operating procedures, patient safety incident and near miss reporting, demonstrating evidence of Pharmacists and Pharmacy Technician CPO, conducting clinical audits and patient satisfaction surveys, and drug recalls.
- 1.78 'How to Make a Complaint or compliment' will be displayed and downloadable from the pharmacy website or upon request by telephone or post a copy will be posted.
- 1.79 All staff will be qualified or undergoing nationally accredited training. They will be competent to deliver the highest standards of Clinical Governance. All staff will receive individual and collective training, development and education provided in-house or from accredited external providers.
- 1.80 All staff will have an annual appraisal, receive and provide feedback.
- 1.81 The Pharmacy will conduct an annual Patient Satisfaction Survey / Community Pharmacy Patient Questionnaire ("CPPQ") based on the template recommended by the PSNC.
- 1.82 Details of the survey (as per PSNC website) can be found at <http://psnc.org.uk/contract-it/essential-service-clinical-governance/cppq/>

- 1.83 The survey will be adapted to reflect the operation of a distance selling pharmacy, i.e.
- 1.83.1 Distributed via email, post and with delivery drivers/couriers.
 - 1.83.2 References to "visiting" the pharmacy changes to reflect non face to face contact methods used.
 - 1.83.3 Ratings for the pharmacy based on physical characteristics changed to reflect actual method of use, i.e. ease of use of website as opposed to "comfort and convenience of the waiting areas".

Information Governance

- 1.84 The pharmacy will be registered and comply with Data Protection Act and the General Data Protection Regulation (GDPR). It will also comply with the Access to Health Records Act 1990. It will publish its Freedom of Information Act Publication Scheme on its website and copies will be made available on request. All patient data will be kept private and confidential in accordance with NHS and legal obligations on data security, protection and confidentiality.
- 1.85 The pharmacy will receive support from the PMR provide [sic] to ensure that continuous access to the Electronic Prescription System is maintained.
- 1.86 Two members of staff will have the ability to login to the PMS system on all days (where there are 2 or more staff members working) and the NHS mail system will be checked every day for both general emails and also for any referrals under the Discharge Medicines Service.

Discharge Medicines Service ("DMS")

- 1.87 When NHS patients are discharged from hospital or there is, for other reasons, a transfer of care of them between different providers of NHS services, community pharmacies may be asked to perform a three stage service in respect of the patient, principally linked to changes in medication. The second and third stages of this service are linked to the first prescription presented post-discharge or post-transfer. Issues of concern may be raised by the pharmacy contractor not only with the patient or their carer but also with their general practitioner.
- 1.88 Under the DMS the pharmacy must provide assistance and support to, and in respect of, an NHS patient
- 1.88.1 recently discharged from hospital who is referred to the pharmacy for advice, assistance and support in respect of the patient's medication regimen by the staff of the hospital in which the patient stayed; or
 - 1.88.2 who is otherwise referred to the pharmacy for advice, assistance and support in respect of the patient's medication regimen by the staff of an NHS trust or NHS foundation trust as part of arrangements linked to the transfer of care between different providers of NHS services.
- 1.89 The service allows and requires the pharmacy to help not only the patient directly, but also (within the bounds of confidentiality) their carers and also provide them with assistance and support.
- 1.90 The service is designed in 3 Stages, where each Stage builds on the last to provide additional support if required to the patient or, where appropriate their carer.
- 1.91 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.

- 1.92 If the DMS referral requesting that the pharmacy provides the DMS includes circumstances in which the pharmacy is not to provide, or is to cease to provide the DMS service, then the Pharmacy is not to, or is to cease to, provide the DMS in those circumstances (for example, X's or Y's admission or readmission to hospital).

Pandemic Treatment Protocol ("PTP")

- 1.93 The pharmacy will provide medicines properly requested under any PTP arrangements.

- 1.94 The RP should (and if requested to do so by the person being supplied must)

1.94.1 Provide an estimate of the time the drug will be ready and delivered.

1.94.2 If the drug is not ready by the time then provide a revised estimate of when the drug will be ready and continue to update the patient on this time should the estimate change.

1.94.3 Contact the patient to confirm dispatch of the medication.

- 1.95 In addition to the normal requirements, the dispensing label on the packaging of the product supplied must also contain the additional wording shown below;

1.95.1 THIS PRODUCT IS BEING SUPPLIED IN ACCORDANCE WITH THE [INSERT NAME] PANDEMIC TREATMENT PROTOCOL

- 1.96 And insert the name of the relevant protocol.

Refusal to Supply under PTP

- 1.97 The pharmacy may refuse to provide an order for a drug that is or is purportedly in accordance with a PTP where—

1.97.1 the RP reasonably believes it is not a genuine order for the person who requests, or on whose behalf is requested, the provision of the drug;

1.97.2 providing it would be contrary to the RP's clinical judgement;

1.97.3 the RP or other persons are subjected to or threatened with violence by the person who requests the provision of the drug, or by any person accompanying (see footnote re "accompanying") that person; or

1.97.4 the person who requests the provision of the drug, or any person accompanying (see footnote re "accompanying") that person, commits or threatens to commit a criminal offence.

- 1.98 The pharmacy must refuse to provide, pursuant to a PTP, an order for a drug that is or is purportedly in accordance with the PTP where P is not satisfied that it is in accordance with the PTP. Any refusal to supply must be noted on the patient and / or pharmacy record system.

Delivering Medicines

- 1.99 The Responsible Pharmacist (RP) has overall responsibility for ensuring the delivery of medicines to intended patients. Medicines must be delivered safely and with appropriate instructions.

- 1.100 The RP must take adequate measures to ensure that the delivery mechanism used is secure and that medicines are delivered to the intended user promptly, safely, and in a condition appropriate for use. If the delivery to patients is local, this will be undertaken by the delivery driver except fridge lines which must be sent by courier. All other nationwide deliveries (other than fridge lines) will be delivered by Royal Mail special delivery or courier and signed for by the patient, their notified carer or other patient authorised representative. Fridge Lines will be delivered by courier (see further below).
- 1.101 Medicines will be packed, transported and delivered in such a way that their integrity, quality and effectiveness are preserved. The delivery mechanism used will provide a verifiable audit trail for medicine from the initial request through to its final delivery, or its return to the pharmacy in the event of a delivery failure. Packaging must maintain patient privacy and confidentiality.
- 1.102 Choice of packaging will depend on the nature of the items being delivered and the appropriate level of protection must be used to ensure that the item can withstand the normal rigours of the delivery process.
- 1.103 All packaging must have the tamper proof seals provided in the pharmacy attached to the packaging so that any tampering with the packaging will be evident.
- 1.104 Medicine for local delivery which is not fragile and to be delivered by the delivery driver can be packaged using the pharmacy bags supplied for standard prescription items.
- 1.105 Medicines classified as non-flammable or non-toxic must be securely closed and placed in a leak-proof container such as a sealed polythene bag (for liquids) or a sift proof container (for solids). Must be tightly packed in strong outer packaging and must be secured or cushioned to prevent any damage.
- 1.106 This means that for postal / courier items, either:
- 1.106.1 At the very least - padded envelopes even for non-fragile items as this will help to ensure the integrity of the manufacturers packaging.
- 1.106.2 For most items - bubble wrap and where necessary, polystyrene filler, placed within a cardboard box. Cardboard boxes must be the re-enforced type.
- 1.106.3 Large or any fragile medicines should be packed into cardboard boxes with bubble packaging and filling material to protect from damage.
- 1.107 The patient, carer or notified, authorised patient representative must always sign and date a receipt to prove safe receipt of the medicines. A patient who is not at home when delivery is attempted will be informed using a non-delivery notice and an alternative delivery date will be arranged.
- 1.108 A list of the approved cold chain couriers is available within the Pharmacy. Coldchain items should be stored in styrofoam filled cardboard boxes prior to being passed to the courier and marked with the "FRAGILE" and "FRIDGE LINE" stickers. Additional packing will not be required as the courier company will transport the boxes in vans with cold chain sections that protect the integrity of the box and are fully monitored. Pharmacy staff should be aware that some thermolabile products can be damaged by excessive cold as well as heat. Items such as ice packs can cause freezing in medicines which is damaging to them. The courier service is a dedicated, fully monitored and temperature controlled delivery service. Any breach of the cold chain is automatically notified to the driver who will then follow the failed delivery procedure and notify the pharmacy accordingly so that re-delivery can be arranged. Where the cold chain breach notice is issued items may not be re-used.

Controlled Drugs

Delivery of Controlled Drugs

1.109 There is provision within controlled drugs legislation to cover occasions when a controlled drug (CD) may temporarily be in the possession of a third party, e.g. a delivery person or postal carrier, while it is being transferred from one authorised person to another authorised person who is entitled to be in possession of the drug. Delivery of CD will be carried out by couriers with pharma grade specialist facilities to meet specific quality and validation requirements for healthcare products. This includes Home Office licensed controlled drug stores. The couriers will have the following UK Licenses and Standards:

1.109.1 MHRA Wholesale Dealer License;

1.109.2 MHRA Manufacturers Importers License;

1.109.3 MHRA IMP License;

1.109.4 ISO 9001: 2000 Certified;

1.109.5 Meet all Home Office safe custody and record keeping requirements.

Return and Destruction of CONTROLLED DRUGS

1.110 Appropriate packaging will be sent to patients in advance with instructions for packaging any returned medicines and this will be provided and paid for by the pharmacy. The Superintendent Pharmacist will specify the appropriate method of collection depending on the items being returned and the distance from the pharmacy. Patients may also be signposted to alternate pharmacies if they prefer to return medicines to a different pharmacy. Any 'returned' Controlled Drugs must not be re-used or entered into the CD register. The Applicant will denature and render them irretrievable as soon as possible in order to avoid storage problems and an increased security risk.

1.111 Destruction must be witnessed by another member of staff. If not immediately destroyed, they should be segregated from main stock, clearly marked 'Patient Returns' to minimise the risk of errors and inadvertent supply and stored securely in a CD Cabinet waiting to be denatured. A record of destruction will be recorded in a separate CD Destruction Register designated for this purpose and will be available in the pharmacy for inspection.

Cover for Breaks / Working Time Directive

1.112 Any breaks in working time taken by the RP will be covered by a second pharmacist who will then assume the responsibility of the RP.

Contingency Planning

1.113 The Applicant will have accounts direct to pharmacy manufacturers and many full-line and short-line pharmaceutical wholesalers to try and increase the availability of stock and reduce Owings. A Contingency Plan will be in place to ameliorate the effects of any disruption to provision of pharmaceutical services such as medicines shortage, postal strike, EPS systems failure, etc.

Verification of Declarations of Prescription Exemptions

1.114 The reverse of the prescription should be fully completed (other than age exempt patients) in black ink.

- 1.115 Where evidence of exemption is required or provided by the patient it can be sent to the pharmacy for verification via the delivery driver and then returned to the patient. The PMR system should be updated to reflect that necessary check has been carried out and a note of when the next check is required should be entered onto the system. The Regulations require a patient to produce 'satisfactory evidence' to confirm exemption. Where appropriate (i.e. for deliveries made other than by the pharmacy's delivery driver), the patient may scan or fax copies of the evidence to the pharmacy (or use the postal / courier service, but see NOTE below) and the pharmacy can record that the evidence provided was not in the original format. It is for the pharmacist in charge to determine if the evidence is satisfactory or not and, if not, then cross the 'Evidence not Seen' box.
- 1.116 The type of exemption and date of expiry will be recorded in their Patient Medication Record. If they are not exempted prescription charge payments will be made using a secure on-line payment method.
- 1.117 Exemptions may be sent to the pharmacy by post and the pharmacy will pay for postage and return the exemption to the patient free of charge. Faxed and scanned email copies of exemptions are also acceptable. The nature of any exemption will be recorded on the PMR system with a copy attached to the patient's file.
- 1.118 Payment for prescription charges will be received via the secure payment portal on the website and when payment is received the prescription will be marked as paid.

Pharmacy Profile

- 1.119 The pharmacy profile will be properly maintained in the NHS Digital Directory of Services.

Central Alerting System

- 1.120 The pharmacy will maintain access to the MHRA Central Alerting System using the premises specific NHS mail email address which will be checked on a daily basis.

Registration of the Premises with the GPhC

- 1.121 It is not lawful to operate a Pharmacy without registering the premises and Superintendent Pharmacist with the GPhC. The Applicant will apply to register the premises with the GPhC following the grant of an NHS Contract application. The GPhC will send an inspector to inspect the premises for approval before commencement of any Pharmacy services. The GPhC has a team of inspectors who undertake the routine monitoring and inspection of premises.

Practice leaflet

- 1.122 Nothing in the Applicant's practice leaflet, or publicity material in respect of the listed chemist premises, in material published on behalf of the Applicant publicising services provided at or from the listed chemist premises or in any communication (written or oral) from the Applicant or the Applicant's staff to any person seeking the provision of essential services will represent, either expressly or impliedly, that -
- (i) the essential services provided at or from the premises are only available to persons in particular areas of England, or
 - (ii) the Applicant is likely to refuse, for reasons other than those provided for in the Applicant's terms of service, to provide drugs or appliances ordered on prescription forms or repeatable prescription forms which are presented by particular categories of patients (for example, because the availability of essential services from the Applicant is limited to other categories of patients).

Advanced or Enhanced Services

- 1.123 The pharmacy will only offer services that can be delivered remotely and do not require patients to attend the premises.'

2 The Decision

NHS England considered and decided to grant the application. The decision letter which appears to have been originally sent on 2 December 2021 although the actual letter is dated 29 November 2021, states:

- 2.1 NHS England has considered the above application and is writing to inform you that it has been granted for the following reasons:
- 2.2 Regulation 31 does not apply as there is no pharmacy at the same or adjacent premises to the proposed site. There is no suggestion that any of the nearby pharmacies are in any way connected with this application.
- 2.3 Regulation 25 (2) (a) were met as no primary care provider with a patient list is present within the same premises as the proposed site.
- 2.4 Regulation 25 (2) (b) were met as the Applicant has demonstrated how services will be provided remotely, and without interruption throughout the given opening hours.
- 2.5 Regulation 64 - sets out the specific conditions to be met by the Applicant for Distance Selling Premises:
- 2.5.1 The Applicant must not offer to provide pharmaceutical services, other than directed services, to persons who are present or in the vicinity of the pharmacy premises.
- 2.5.2 The means by which persons receive services from the pharmacy must be otherwise than at the pharmacy premises.
- 2.5.3 The pharmacy premises must not be on the same site or in the same building as the premises of a provider of primary medical services with a patient list.
- 2.5.4 The pharmacy procedures must ensure the uninterrupted provision of essential services, during the pharmacy opening hours, to persons anywhere in England who request the services and must ensure the safe and effective provision of essential services without face-to-face contact between the person receiving the services and the pharmacy staff.
- 2.5.5 The pharmacy must not produce any practice leaflet, publicity material or any other communication, which expressly or impliedly states that access to the essential services provided by the pharmacy are only available to persons in particular areas of England or that the pharmacy is likely to refuse to provide essential services or prescribed drugs or appliances to particular categories of patients.
- 2.6 Discussed and supported that granting the application would not disadvantage pharmacies and cause inequality in the area.
- 2.7 Appeal rights are granted for Rowlands Pharmacy, Cottingham Pharmacy and Sai Dutt Ltd.

3 The first Appeal

In an appeal form sent to NHS Resolution dated 26 December 2021, Sai Dutt Ltd appealed against NHS England's decision. The grounds of appeal are:

In response to "What type of application was originally made eg unforeseen benefits, distance selling etc?" on the appeal form, Sai Dutt Ltd stated:

- 3.1 Unforeseen benefits
- 3.2 Section 13G of the 2006 Act (duty as to reducing inequalities)
- 3.3 The National Health Service (Procurement, Patient Choice and Competition) (No. 2) Regulations 2013 6(1)
- 3.4 Regulation 18(2) a. By granting this application it may significantly detrimental to the local community pharmacies
- 3.5 Section 13K of the Act 2006 (duty to promote innovation)
- 3.6 The Conflict of interest in the NHS
- 3.7 May lead to promotion of unethical practices such as inducement, prescription directions
- 3.8 By granting the application would disadvantage local pharmacies within close proximity Rowlands Pharmacy 600 yards away, Co-operative pharmacy which is located 100 yards and the Cottingham Pharmacy which is located 1 mile away.

In response to "Please provide below a concise and reasoned statement of your grounds of appeal" Sai Dutt Ltd stated:

- 3.9 This application must be refused on the following basis:
Regulation 31 2(a) ("the existing services")
- 3.10 There are Drugs4delivery providing distance pharmaceutical services which can be considered ("the existing services") which is providing service the distance selling pharmacy services.
- 3.11 Sai Dutt Ltd kindly draws attention to the following which is the Prescription source for the Drugs4Delivery for September 2021.
- 3.12 Following proves that Drugs4Delivery service is only obtaining prescription from the local surgeries which is detrimental to the local pharmacies.
- 3.13 Table Number 1: You can clearly see all the Prescribing Organisations are local surgeries in the Grimsby and its surrounding area which is a clear breach of regulation 2013.

(Courtesy the NHSBSA September 2021)

Practice Code	Prescribing organisation	Items	Market Share
B81015	Clee Medical Centre	1,768	4.96%
B81039	The Roxton Practice	1,886	2.9%
B81030	Scartho Medical Centre	1,353	5.27%
B81016	Pelham Medical Group	1,056	6.33%
B81023	The Chantry Health Group	828	5.93%
B81031	Fieldhouse Medical Group	595	2.44%
Y01948	Open Door	484	10.8%
281077	Woodford Medical Practice	535	3.16%

B81656	Raj Medical Centre	505	4.34%
B81055	The Lynton Practice	522	4.88%
Y02684	Quayside Medical Centre	439	10.23%
B81012	Dr Ap Kumar	452	5.58%
B81606	Stirling Medical Centre (Matthews)	431	5.53%
B81620	Biswas B	250	4.78%
B81087	Birkwood Medical Centre	273	1.45%
B81003	Beacon Medical	335	0.99%
B81642	Dr Oz Qureshi	207	2.23%
B81664	Humberview Surgery	225	6.89%
B81108	Dr A Sinha	261	2.91%
B81697	Dr P Suresh Babu	230	4.65%

- 3.1 Above table is a living example, what the Department of Health Evidence submitted for the statutory review into the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 “demonstrated sudden drops in the dispensing volume at bricks and mortar pharmacies following the opening of a distance-selling pharmacy located nearby”, the DH said.
- 3.2 Also by granting this application may lead to subversion of the 2013 Regulations for the purpose of local supply as another DSP which is Drug4Delivery is doing in the area. [sic] (Please refer to the table Number 1). Overall, by approving this DSP, there will be more inequalities in the areas and section 13G of the 2006 Act will not be honoured if this application is approved.
- 3.3 Overall, by approving this DSP, there will be disadvantage pharmacies and inequalities in the areas and section 13G of the 2006 Act will not be honoured if this application is approved. [sic]

Breach of Section 13K of the Act 2006 (duty to promote innovation)

- 3.4 There being innovative approaches taken with regard to the delivery of pharmaceutical services (taking into account also the NHSCB's duties under section 13K of the 2006 Act (duty to promote innovation), DSP is not new innovation. There are already one DSP which is only providing services to the local community [sic]. Drugs4delivery which clearly detrimental to the other pharmacies, Sai Dutt Ltd's question to the committee is what benefits this Karma Medical solution DSP would bring to the community and across England. Although there is no statutory requirement to provide floor plan, however, any organised pharmacy professional would at least provide innovative design. Once again, act 2006 duty to innovation, possibly has not been followed. [sic]

Prescription Direction and the Conflict of interest in the NHS

- 3.5 The same review by the DH also stated that The Department of Health and Social Care (DH) has recommended tightening the rules around distance-selling pharmacies after seeing “strong evidence” of prescription direction. Approving this DSP, may or possibly lead to a prescription direction due to following reasons:
- 3.6 Directors work at Cleve Medical Centre as GPs.
- 3.7 Four of the five directors of Karma Medical Solution Ltd (owners) are doctors at Cleve Medical Centre. (Please see evidence attached: a copy from the company house for the Karma Medical Solutions Ltd and a copy from the Cleve Medical Centre doctors list. [no attachment was provided by Sai Dutt Ltd]. The Department of Health found strong evidence of prescription direction with DSPs, in this case, it may become reality as Cleve Medical Centre is located at 323 Grimsby Road and coincidentally the Karma Medical Centre applied to open DSP at 55 Grimsby Road which is 600 yards away. Sai Dutt Ltd's question to NHS England is why we create a situation by approving this

application, where current owners & directors of the Karma Medical Centre who are the GPs at the Clee Medical Centre who would see patients behind the closed door and who would be prescribing medications and sending them electronically. This could create a conflict of interest.

3.8 Breach of The National Health Service (Procurement, Patient Choice and Competition) (No. 2) Regulations 2013.

3.9 Sai Dutt Ltd would like to draw [your] attention to The National Health Service (Procurement, Patient Choice and Competition) (No. 2) Regulations 2013 which clearly states following: Conflicts between interests in purchasing health care services and supplying such services

(1) A relevant body must not award a contract for the provision of health care services for the purposes of the NHS where conflicts, or potential conflicts, between the interests involved in commissioning such services and the interests involved in providing them affect, or appear to affect, the integrity of the award of that contract.

(2) In relation to each contract that it has entered into for the provision of health care services for the purposes of the NHS, a relevant body must maintain a record of how it managed any conflict that arose between the interests in commissioning the services and the interests involved in providing them.

(3) An interest referred to in paragraph (1) includes an interest of—

(a) a member of the relevant body,

(b) a member of its governing body,

(c) a member of its committees or sub-committees or committees or sub-committees of its governing body, or

(d) an employee.

3.10 According to The National Health Service (Procurement, Patient Choice and Competition) (No. 2) Regulations 2013 6(1) the NHS England must not grant this application as it may create a conflict of interest in the NHS as the GPs who are currently prescribers at the Clee Medical Centre; coincidentally directors of the Karma Medical Solutions and as Department of Health suggested there are strong evidence of the prescription direction where DSP involved which is a clear indication of the conflict of interest in the NHS.

3.11 It would be a clear breach of The National Health Service (Procurement, Patient Choice and Competition) (No. 2) Regulations 2013 6(1) if this DSP application granted by the NHS England. This application needs to be refused on the basis of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 as this is an application for “unforeseen benefits”.

Breach of General Medical council guidelines

3.12 Sai Dutt Ltd would like to draw [your] attention to the General Medical Council guidelines set out that doctors must not allow any financial or commercial interests in a pharmacy to influence the advice given to patients. Failure to adhere to these professional standards could result in an investigation for professional misconduct. By granting this application, it may lead to a situation where the owners of the Karma Medical solutions conveniently applied to set up pharmacy on the same road which is 55 Grimsby Road, just 600 yards away where all four owners work as GPs. Once again, Sai Dutt Ltd’s question to the NHS England, why can’t we prevent this kind of situation from occurring in the first place by refusing this application.

Cold chain transport

- 3.13 Sai Dutt Ltd note that in SHA/24544, [Primary Care Appeals] refused a DSP application because they were not satisfied that items which require cold chain transport could be satisfactorily received by the patient. They state the following “...*there was nothing provided by the Applicant to demonstrate that an audit process or appropriate system is in place which would highlight any items, which might have ceased to be refrigerated in transit and therefore be compromised, and how these would be prevented from being given to the patient. In addition, Committee noted SOP 3 specifically defines a failed delivery as one where there has been no one there to accept delivery. It therefore does not include a situation where the cold chain has been compromised in transit, and the SOP does not set out how such a situation would be recognised and dealt with. The Committee was not therefore confident, as it is required to be, that all dispensed cold chain products would be delivered in a safe and effective manner*”. Sai Dutt Ltd trust that NHS England will consider this view when reaching their decision on this application.

Nominations

- 3.14 NHS England will be aware that the Applicant, in this case, consists of a number of GPs of a local GP practice. Regulation 30 of Schedule 4 to the NHS Pharmaceutical and Local Pharmaceutical Regulations 2013 concerns inducements. Sai Dutt Ltd wish to be assured that NHS England has suitable processes in place to monitor changes to prescriptions nominations such that they are able to intervene should this regulation not be being complied with. In addition, Sai Dutt Ltd note the 2015 guidance issued jointly by pharmacy bodies and the BMA regarding patient choice and note that patient choice is a fundamental part of NHS services. Again, Sai Dutt Ltd seek reassurance that NHS England has procedures in place to intervene should patient choice be affected in any way.

Regulation 24(2)(b) & 13K of the Act 2006 (duty to promote innovation)

- 3.15 Regulation 24(2)(b) requires an Applicant to provide details of the pharmacy's procedures. That is, the procedures that will be adopted by the Applicant in its operation of the proposed pharmacy.
- 3.16 In relation to section 7 of the application form, the Applicant refers to the information attached to the application form, being a document which is described as “further information in relation to provision of essential services in accordance with the regulatory requirements for distance selling pharmacies. The document is watermarked “Rushport” on every page, and has the words “Rushport Advisory LLP-Client approved service description” at the foot of the each page.
- 3.17 It is evident from a reading of the information provided by the Rushport that this is not information proposed pharmacy, rather, it is generic “off-the-shelf” information which has been prepared not by the Applicant but the Rushport Advisory and which has been used by Rushport advisory in support of similar applications in the past.
- 3.18 The point Sai Dutt Ltd is making that there are no innovative ideas have been used when proposing application for the distance selling pharmacy as the NHS England has duty to promote innovation Section 13K of the Act 2006 (duty to promote innovation).

Problem with the Proposed Premises:

- 3.19 This is evident from the fact that there is no details about the actual pharmacy in the information provided. There is no acknowledgement of the location of the proposed premises (within a parade of shops), and the inherent risk of patients being offered essential pharmaceutical services whilst present in the vicinity of the premises. There is reference to providing dispensing services differently if the patient lives “Locally”, but no description of what “local” means in the context of this application. There is reference

to hub and spoke dispensing and collection and delivery points “if applicable” – which is generic nature of the information provided by Rushport.

- 3.20 In fact, there is nothing on the face of the information prepared and submitted by Rushport that would even suggest that it related to a pharmacy that would be operated by the Karma Medical Solution Limited for premises at 55 Grimsby Road, Cleethorpes.

National Service

- 3.21 As NHS England will be aware, a distance selling pharmacy must be in a position to provide pharmaceutical services to patients anywhere in England. It is of note that the directors of Karma Medical Service Limited are all GPs who are partners at the nearby Clee Medical Centre. There is, therefore clear concern that the GP directors of the Applicant intend only to provide a local dispensing service (in particular to patients of the Clee Medical Centre) rather than a national service. This is not addressed by the Applicant.

Conclusion

- 3.22 If the application granted, Sai Dutt Ltd is afraid that they have to give this in the news that how conflict of interests are not taken seriously in the NHS. Allowing DSP to open so within close proximity is a serious threat to the local community pharmacies as it is only creating inequalities and disadvantage to the existing pharmacies. Also, granting application may give rise to unethical practices such as prescription directions.

- 3.23 All in all, the Department of Health and Social Care review (2018) The Department of health recommends that DSPs to declare any vested or significant interests – including if any of the business owners or partners, are themselves, or have family members who are prescribers of NHS prescriptions dispensed by the DSP. So in this case, the prescribers are the owners of the DSPs. This application needs to be refused on the basis that all 4 directors are the GPs at the Clee Medical centre, as the DH suggested, all 4 GPs will be prescribing NHS prescriptions which may possibly be dispensed at the new DSP if this application approved. Sai Dutt Ltd would recommend to the NHS England that all 4 GPs needs declare that they are directors of the new DSP.

4 NHS England processing

- 4.1 The appeal from Sai Dutt Ltd was circulated to interested parties by NHS Resolution on 4 January 2022.
- 4.2 Following the circulation of the appeal, it was brought to NHS England’s attention that the decision report contained an error in the naming of the parties that had been granted the right of appeal by NHS England. PCSE has confirmed that the report stated that Cottingham Pharmacy and Sai Dutt Ltd had the right of appeal, however both of these entities are the same. PCSE, on behalf of NHS England, confirmed to Primary Care Appeals that the decision report should have granted appeal rights to Sandringham Road Pharmacy. Consequently Sandringham Road Pharmacy were incorrectly notified that they did not have a right of appeal and further Sandringham Road Pharmacy advised PCSE that they had not received notification of the decision.
- 4.3 NHS England, on receipt of a request from Temple Bright, the representative of Sandringham Road Pharmacy, agreed to re-issue the decision letter to Sandringham Road Pharmacy. PCSE advised Primary Care Appeals that a revised decision letter notifying Sandringham Road Pharmacy of the decision and providing a right of appeal (within 30 days of the date of the letter) was sent to Temple Bright on 6 January 2022.

5 The second Appeal

In a letter dated 1 February 2022, Temple Bright on behalf of Sandringham Road Pharmacy Limited appealed against NHS England’s decision. The grounds of appeal are:

- 5.1 Temple Bright act for Sandringham Road Pharmacy Limited which is included in the HWB's pharmaceutical list for premises at 36 Sandringham Road, Cleethorpes, DN35 9HB.
- 5.2 On behalf of Sandringham Road Pharmacy Limited, Temple Bright write to appeal a decision of NHS England to grant an application by Karma Medical Solutions Limited for inclusion in the pharmaceutical list for premises at 55 Grimsby Road, Cleethorpes, DN35 7AF. The decision was notified to Sandringham Road Pharmacy Limited by letter dated 6th January 2022.
- 5.3 Sandringham Road Pharmacy Limited's ground of appeal is that NHS England failed to provide any reasons for the decision reached. In its letter to PCSE dated 29th November 2021, NHS England stated the regulatory test which applied to the determination of this application but failed to explain why it concluded that the application met the relevant regulatory test.
- 5.4 For the reasons given in Sandringham Road Pharmacy Limited's representations to NHS England, this application does not meet the requirements of regulation 25 and should have been refused.

Regulation 25

- 5.5 As NHS Resolution will be aware, the application has been submitted pursuant to regulation 25 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 ("the Regulations"), being an excepted application for distance selling premises.
- 5.6 It is therefore incumbent upon the Applicant to provide suitable and sufficient information to satisfy NHS England (or NHS Resolution on appeal) that the Applicant has in place procedures which are likely to secure the uninterrupted, safe and effective provision of all essential pharmaceutical services without face-to-face contact and irrespective of where in England the patient may live.
- 5.7 Whilst an Applicant need not repeat every element of the Terms of Service in its application documents, where compliance with a paragraph of the Terms of Service would ordinarily require face to face contact (and would be straightforward in that context), the Applicant must explain how it is going to achieve compliance (and therefore safe and effective provision) in the distance selling context.
- 5.8 It is evident from the information provided by the Applicant in its application form that NHS Resolution cannot be satisfied that the application meets the requirements of regulation 25.
- 5.9 Regulation 25(2) (b) requires an Applicant to provide details of the pharmacy's procedures; that is, the procedures that will be adopted by the Applicant in its operation of the proposed pharmacy.
- 5.10 In relation to section 7 of the application form, the Applicant refers to the information attached to the application form, being a document which is described as "Further information in relation to provision of essential services in accordance with the regulatory requirements for distances selling pharmacies". The document is watermarked "Rushport" on every page and has the words "Rushport Advisory LLP – Client Approved Service Description" at the foot of each page.
- 5.11 It is evident from a reading of the information provided by Rushport that this is not information for the proposed pharmacy; rather, it is generic and "off-the-shelf" information which has been prepared not by the Applicant but by Rushport Advisory and which has been used by Rushport Advisory in support of similar applications in the past.

- 5.12 This is evident from the fact that there is no detail about the actual pharmacy in the information provided. There is no acknowledgement of the location of the proposed premises (within a parade of shops), and the inherent risk of patients being offered essential pharmaceutical services whilst present in the vicinity of the premises. There is reference to providing dispensing services differently if the patient lives “locally”, but no description of what “local” means in the context of this application. There is reference to hub and spoke dispensing and collection and delivery points “if applicable” – which is further evidence of the generic nature of the information provided by Rushport.
- 5.13 In fact, there is nothing on the face of the information prepared and submitted by Rushport that would even suggest that it relates to a pharmacy that would be operated by Karma Medical Solutions Limited for premises at 55 Grimsby Road, Cleethorpes.
- 5.14 The information provides that SOPs have been prepared and are available. Temple Bright understand that Rushport Advisory provides applicants with generic SOPs to support an application, but the SOPs are not routinely sold to applicants at the NHS England stage and are only purchased if the application proceeds to appeal.
- 5.15 NHS Resolution is therefore invited to consider – as NHS England should have done, but appears not to have done - whether, in fact, there are suitable and sufficient procedures in place at the time that this application is to be determined, and to request the relevant SOPs from the Applicant or, if they have not been provided, to refuse the application.
- 5.16 To the extent that SOPs are provided by the Applicant, NHS Resolution is invited to consider whether these are SOPs that will be used by the pharmacy (that is, that they are SOPs that demonstrate how the proposed pharmacy will be operated safely and effectively in the distance selling context) or if they are generic SOPs that have been provided simply to secure the grant of this application. If NHS Resolution concludes that they fall within the latter category then the Applicant has failed to satisfy the requirements of regulation 25 and the application should be refused.

Face-to-face contact

- 5.17 Regulation 25(2)(b)(ii) of the Regulations requires the Applicant to demonstrate that it has in place procedures which will secure the safe and effective provision of essential pharmaceutical services “without face-to-face contact...”.
- 5.18 This is reflected in regulation 64(3)(a) which provides that, should the application be granted, it would be a condition of the Applicant’s inclusion in the pharmaceutical list that it must “not offer to provide pharmaceutical services, other than directed services, to persons who are present at (which includes in the vicinity of), the listed chemist premises.”
- 5.19 Furthermore, regulation 64(3)(b) provides that the Applicant must not provide, or offer to provide, essential services to patients who are present at the listed premises.
- 5.20 The Applicant’s proposed premises are within a row of shops which, themselves, are open to the public and, consequently, there will be “passing trade”. Where patients are present at, or in the vicinity of, the premises there is therefore an inherent risk that patients will request and/or be offered, or will receive, NHS essential services and it is incumbent upon the Applicant to demonstrate – with details of the specific procedures – how the Applicant will comply with the regulations.
- 5.21 The Applicant does not deal with this potential issue (because the information it provides is generic) and provided very little information to reassure NHS England that patients will not receive, or be offered, an essential pharmaceutical service whilst passing the proposed premises.

Provision of essential services

- 5.22 Regulation 25(2)(b) requires the Applicant to satisfy NHS England (or NHS Resolution on appeal) that the Applicant will provide all NHS essential pharmaceutical services safely and effectively to patients anywhere in England who request those services.
- 5.23 NHS Resolution must therefore consider Part 2 of schedule 4 to the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013. NHS Resolution must have regard to each essential service individually and consider whether the Applicant has provided sufficient information to satisfy it that the requirements of regulation 25(2)(b) would be met for each essential service.
- 5.24 Having regard to regulation 25(2)(b) and Part 2 of schedule 4, it is evident that the Applicant has failed to provide sufficient information in relation to each individual essential service.
- 5.25 In its application form, the Applicant provides little detail as to how each service will be provided in the distance selling context. Much of the information provided by the Applicant in relation to essential services is not specific to the proposed pharmacy. The Applicant merely lists the requirements contained within the terms of services and then gives various methods by which any distance selling pharmacy may achieve compliance. The Applicant therefore provides some (albeit insufficient) information about how compliance may be achieved by a distance selling pharmacy but fails to detail how the proposed pharmacy itself will comply with these requirements.

National service

- 5.26 As NHS Resolution will be aware, a distance selling pharmacy must be in a position to provide pharmaceutical services to patients anywhere in England. It is of note that the directors of Karma Medical Services Limited are all GPs who are partners at the nearby Clee Medical Centre. There is, therefore, a clear concern that the GP directors of the Applicant intend only to provide a local dispensing service (in particular to patients of the Clee Medical Centre) rather than a national service. This is not addressed by the Applicant.

Conclusion

- 5.27 In conclusion, in the absence of suitable or sufficient information from the Applicant regarding the procedures that it will have in place for the provision of all essential services, NHS England could not properly have been satisfied that the requirements of regulation 25 were met. On behalf of Sandringham Road Pharmacy Limited Temple Bright therefore invite NHS Resolution to uphold the appeal and to refuse this application.

6 Summary of Representations

This is a summary of representations received on the appeals.

6.1 NHS ENGLAND (RESPONSE TO SAI DUTT APPEAL)

6.1.1 Thank you for your letter dated 4th January 2022 in relation to the above appeal.

6.1.2 NHS England has considered the regulations and the responses are below:

6.1.3 In relation to Regulation 31. [quoted in full]

NHS England Response

6.1.4 Regulation 31, Paragraph 2(a) does not apply as there is no pharmacy at the same or adjacent premises to the proposed site, nor is there any suggestion that any of the nearby pharmacies are in any way connected with this

application. The Applicant is not providing pharmaceutical services from the proposed premises currently or adjacent premises and so Regulation 31, Paragraph 2(b) is also not applicable.

6.1.5 [At appendix A] are the maps, street views and measurements from the proposed premises to nearby pharmacy and medical provision to illustrate where the proposed premises are in relation to existing pharmaceutical provision.

6.1.6 Measurements (taken from google maps) to illustrate distance between proposed premises and nearby medical and pharmacy provision.

From	To	Distance
55 Grimsby Road, Cleethorpes, DN35 7AF	Cottingham Pharmacy, 342 Wellington Street, Grimsby, DN32 7FR	0.6 miles
55 Grimsby Road, Cleethorpes, DN35 7AF	Rowlands Pharmacy, 323a Grimsby Road, Cleethorpes, DN35 7ES	0.6 miles
55 Grimsby Road, Cleethorpes, DN35 7AF	Lincolnshire Co-op/Cleethorpes Pharmacy, 121 Grimsby Road, Cleethorpes, DN35 7DG	0.1 mile

6.1.7 In relation to Regulation 25, and bearing in mind this is a reconsideration of the application, the matters to which consideration will be given are:

(1) Section 129(2A) 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) The NHSCB 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 the NHSCB is satisfied that the pharmacy procedures for the pharmacy premises are likely to secure –

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

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

NHS England Response

6.1.8 This was not a reconsideration, but further clarification was required in relation to two representations made who asked for the application to be refused stating that “there will be more inequalities in the areas and section 13G of the

2006 Act will not be honoured if this application is approved". The Committee asked for further clarification of this at the meeting on 27 October 2021 which was provided at the meeting on 24 November 2021. This clarification was provided and is outlined below:

- 6.1.9 This refers to the National Health Service Act 2006 - <https://www.legislation.gov.uk/ukpga/2006/41/section/13G> duty as to reducing inequalities which states that:

The Board must, in the exercise of its functions, have regard to the need to—

(a) reduce inequalities between patients with respect to their ability to access health services, and

(b) reduce inequalities between patients with respect to the outcomes achieved for them by the provision of health services.

- 6.1.10 The Committee took this to mean that the representations who raised this [sic] were saying that by allowing another Distance Selling Pharmacy (DSP) in Cleethorpes that the number of prescriptions dispensed by bricks and mortar pharmacies will be disadvantaged, hence causing an inequality. The Committee considered this but granted the application at the November meeting.

- 6.1.11 In relation to Regulation 25, the Committee were assured that all of these were met.

- 6.1.12 The Applicant responded to the concerns raised by Cottingham Pharmacy when they were raised within the original application and the Committee were assured by this response.

- 6.1.13 NHS England hope this provides [you] with the information you require

6.2 NHS ENGLAND (RESPONSE TO SANDRINGHAM ROAD PHARMACY APPEAL)

- 6.2.1 Thank you for your letter dated 1 February 2022 in relation to the above appeal.

- 6.2.2 NHS England has considered the regulations and the responses are below:

- 6.2.3 In relation to Regulation 25, and bearing in mind this is a reconsideration of the application, the matters to which consideration will be given are: [Regulation 25 as quoted above at 6.1.7]

NHS England Response

- 6.2.4 This was not a reconsideration, but a further clarification was required in relation to two representations made who asked for the application to be refused stating that "there will be more inequalities in the areas and section 13G of the 2006 Act will not be honoured if this application is approved". The Committee asked for further clarification of this at the meeting on 27 October 2021 which was provided at the meeting on 24 November 2021/ the clarification was provided and is outlined below:

- 6.2.5 This refers to the National Health Service Act 2006 - <https://www.legislation.gov.uk/ukpga/2006/41/section/13G> duty as to reducing inequalities which states that:

The Board must, in the exercise of its functions, have regard to the need to—

(a) reduce inequalities between patients with respect to their ability to access health services, and

(b) reduce inequalities between patients with respect to the outcomes achieved for them by the provision of health services.

- 6.2.6 The Committee took this to mean that the representations who raised this [sic] were saying that by allowing another Distance Selling Pharmacy (DSP) in Cleethorpes that the number of prescriptions dispensed by bricks and mortar pharmacies will be disadvantaged, hence causing an inequality. The Committee considered this but granted the application at the November meeting.

Standard Operating Procedures (SOPs)

- 6.2.7 In relation to the issue raised by Sandringham pharmacy in relation to the Standard Operating Procedures (SOPs) not being submitted as part of the process. It is not necessary for them to be submitted as part of the application and the Committee were happy to support the application without seeing these. However, a full set of SOPs were submitted as part of the initial response to Sandringham, and other interested parties, to provide assurance in relation to the issues raised.

Face to Face Contact

- 6.2.8 The initial response from the Applicant to Sandringham Pharmacy clarifies that, in relation to face-to-face contact, that they are aware that such services should not be provided to patients as part of being a distance selling pharmacy (DSP).
- 6.2.9 In relation to Regulation 25, the Committee were assured that all of these were met.
- 6.2.10 The Applicant responded to the concerns raised by Sandringham Pharmacy when they were raised within the original application and the Committee were assured by this response.

6.3 RUSHPORT ADVISORY LLP ON BEHALF OF THE APPLICANT (RESPONSE TO SAI DUTT LTD APPEAL)

- 6.3.1 Thank you for your letter of 4 January 2022 and follow up email of 7 January 2022 confirming that the appeal was deemed valid. Rushport Advisory LLP act for Karma Medical Solutions Limited in the above application and have been instructed by the Applicant to submit the following reply to the appeal submitted by Sai Dutt Limited.
- 6.3.2 Rushport Advisory LLP have addressed each point raised by the Appellant in the same order as their appeal form.

Regulation 31

- 6.3.3 This appeal point is misconceived. There is no connection between Drugs4Delivery and the Applicant nor do they operate from the same or adjacent premises as proposed by the Applicant.

Breach of Section 13K of the Act 2006 (duty to promote innovation)

- 6.3.4 This appeal point is misconceived. There is no requirement for the Applicant to offer "new innovation".

Prescription Direction and the Conflict of interest in the NHS

6.3.5 This appeal point is misconceived and attempts to predict the future. The Applicant and its directors are fully aware of their legal and ethical responsibilities.

6.3.6 Sub point 3.2 is likewise misconceived as the Regulations quoted do not apply in this case as this is not a procurement exercise.

Breach of General Medical council guidelines

6.3.7 This appeal point is misconceived and attempts to predict the future. My client and its directors are fully aware of their legal and ethical responsibilities.

Cold Chain Transport

6.3.8 This appeal point is misconceived as different evidence from an entirely different case is not relevant as this application must be considered on its own merits.

Nominations

6.3.9 This appeal point is misconceived and attempts to predict the future. The Applicant and its directors are fully aware of their legal and ethical responsibilities.

Regulation 24(2)(b) & 13K of the Act 2006 (duty to promote innovation)

6.3.10 This appeal point is misconceived. There is no requirement for the Applicant to offer “new innovation” and no restriction on using procedures sourced from third parties. Almost all pharmacies source their operating procedures from third parties.

Problem with the Proposed Premises:

6.3.11 This appeal point is misconceived. NHS England’s contract monitoring team would be responsible for ensuring that the Applicant complies with their Terms of Service after they open. The Applicant and its directors are fully aware of their legal and ethical responsibilities.

National Service

6.3.12 This appeal point is misconceived. The Applicant has been very clear that they will provide essential services to any patient in England who requests them.

6.3.13 Rushport Advisory LLP are of course aware that the Committee will not only address the appeal points raised by the Appellant but will also consider the correct test to be applied under regulation 25. Rushport Advisory LLP therefore refer the Committee to the updated copy of Applicant’s SOPs attached with this letter and confirm that they should be used when considering this appeal.

6.4 RUSHPORT ADVISORY LLP ON BEHALF OF THE APPLICANT (RESPONSE TO SANDRINGHAM ROAD PHARMACY APPEAL)

6.4.1 Thank you for your letter of 3 February 2022. Rushport Advisory LLP act for Karma Medical Solutions Limited in the above application and have been instructed by the Applicant to submit the following reply to the appeal submitted by the representative of Sandringham Road Pharmacy

- 6.4.2 Rushport Advisory LLP have addressed each point raised by the Appellant in the same order as their letter of appeal.
- 6.4.3 Page 1 of the letter discusses the legal test. On page 2 the Appellant repeats arguments about procedures being provided by third parties (in this case Rushport Advisory LLP) that the Committee has rejected on many occasions. As the Committee will be aware, almost all pharmacies use SOPs sourced from third parties and this includes “normal” 40 hour retail pharmacies and distance selling pharmacies.
- 6.4.4 In any event the Committee has a copy of the Applicant’s SOPs and can consider the content of these as part of this appeal.

Face to Face Contact

- 6.4.5 The Appellant repeats the legal test and speculates about an “inherent risk” that the Applicant will breach their Terms of Service. the Applicant is fully aware of their obligations under regulation 64(3)(a) and (b) and has explained how they will comply with those obligations.

Provision of essential services

- 6.4.6 The Committee has a copy of the Applicant’s SOPs and can consider the content of these as part of this appeal.

National Service

- 6.4.7 The Applicant is fully aware of their obligations to provide essential services to any person in England who requests them and will provide services to all such persons.
- 6.4.8 Whilst the Committee already has a copy of the Applicant’s SOPs Rushport Advisory LLP have attached them with this reply for the sake of completeness.

6.5 SAI DUTT LTD (APPELLANT)

- 6.5.1 Sai Dutt Ltd would like to make representation about the SOPs. These generic SOPs do not meet regulation 25(2) as:

- 6.5.1.1 The SOPs do not reflect that the pharmacy procedures for the pharmacy premises are likely to be secure;

- 6.5.1.2 The SOPs do not reflect that the uninterrupted provision of essential services, during the opening hour of the premises, to persons anywhere in England who request those services;

- 6.5.1.3 The SOPs do not reflect that the safe and effective provision of essential services;

GPhC Guidance

- 6.5.1.4 The SOPs do not comply with the guidance published by the General Pharmaceutical Council for registered pharmacies providing pharmacy services at a distance;

- 6.5.1.5 The SOPs do not comply with all aspects of the supply and delivery of pharmacy services;

Provision of NHS Essential services

6.5.1.6 The SOPs do not meet essential services to Regulation 64(3)(E)(ii);

Reg 25(2)(b) – the pharmacy procedures

6.5.2 The Applicant provided SOPs; the Applicant provided information which do not demonstrates that their procedures will comply with the regulations.

6.5.3 On the 4th January 2022, the Applicant provided generic copies for SOPs which were prepared by the Rushport LLP; It is evident from a reading of the information provided by the Rushport that this is not information relating to the proposed pharmacy, rather, it is generic “off-the-shelf” information which has been prepared not by the Applicant but the Rushport Advisory and which has been used by Rushport Advisory in support of similar applications in the past. Sai Dutt Ltd’s question to you that it is not the Rushport Advisory LLP who is going to run the pharmacy. So, all the risk assessments are irrelevant to this DSP. As a pharmacist myself, Sai Dutt Ltd would be doing their own risk assessment for their pharmacy, using a pre-prepared risk assessment may not be relevant. The Committee may agree with the point that by using pre-prepared SOPs from the non-pharmaceutical entity such the Rushport Advisory LLP, the Applicant may miss out important risk-assessment points of particular relevance to that DSP, and so could, put patients’ safety at risk.

6.5.4 2.15, specifically: 2.15.1 The Applicant has not stated that an RP will always be onsite (during opening hours) and/or 2.15.2 that cover (relief or locum pharmacist) will be procured if for any reason the RP is offsite. 2.16 Based on the limited information provided, the Committee could not be satisfied that services would be provided without interruption.

Services available without interruption

6.5.5 Sai Dutt Ltd learned that the Applicant had proposed total opening hours of 9am to 12pm and 1pm to 6pm, Monday to Friday (40 hours, all core), but that no further information was provided originally or subsequently by the Applicant to explain how essential services will be provided, without interruption, to patients living anywhere in England.

6.5.6 Point 32 Preparing for the absence of the RP

“The pharmacy team must be instructed that in the absence of a RP the second pharmacist is responsible for the operation of the pharmacy and is responsible for: Sales of GSL and advice about GSL, P and POM medicines”

6.5.7 As this DSP is in the shop parade at 55 Grimsby Road. There are risk that members of public can walk in the 55 Grimsby Road retail shop and the members of public may buy GSL and P medicines. The SOP mentions that sale of GSL and advice about the GSL. As the SOP does not provide further information on how the Sales of GSL and advice about the GSL and P medicines will be executed. This suggests that the DSP is pharmacy is planning sale GSL and P medicine face to face to the public in the absence of RP. As a DSP, the Applicant cannot provide face to face sales of GSL and advice about GSL, P medications. In fact, face to face advice or sales is not permitted with a DSP.

6.5.8 Point 32.5 Known Risks

Unforeseen circumstances leading to sudden and immediate loss of the Responsible Pharmacist on duty.

6.5.9 SOP 32 does not state what will happens if they cannot find the Second Pharmacist cover if RP is absent. As there are locum Pharmacist shortages

many times the pharmacy is not able to find cover. The Applicant has not identified that point and business continuity has not been maintained. The SOP fails to even identify that how the prescription will be delivered or refer to other pharmacies [sic]. How the patient will get their medication(s). How the essential service will be maintained uninterrupted.

- 6.5.10 Based on the limited information provided, Sai Dutt Ltd are convinced that services could not be provided without interruption.
- 6.5.11 Pharmacy systems and procedures, SOP 3 "*Patients will access these services primarily through our website but will also be able to contact the pharmacy by phone during the pharmacy's opening hours to make arrangements to access services*". However, due to the DSP location which is shop parade where any member of public can walk-in easily.[sic]
- 6.5.12 The proposed location for the DSP is 55 Grimsby Road which is a shop parade. The 55 Grimsby Road is open to the public and access to the proposed premises is not strictly controlled"
- 6.5.13 SOP 32 "*mentions about the sale of GSL and P counter line*" due their location the patients may ended up walk-in to the 55 Grimsby Road [sic], may end up getting service face-to-face. It is unlikely that at 55 Grimsby Road essential services will be provided remotely. Especially, there are Lincolnshire Co-op Cleethorpes Pharmacy at 121 Grimsby Road in the same shop parade.
- 6.5.14 SOPs Contacting a Prescriber which may create the conflict of interest in the NHS
 - 6.5.14.1 SOP 7, Pharmaceutical & Legal Assessment, "dosages with the Prescriber contacted for out of licence use, discuss with the prescriber, contact with the prescriber.
 - 6.5.14.2 SOP 8, 8.5 "Process for prescription issues, when contacting prescriber"
 - 6.5.14.3 SOP 8.7, "you need to contact a prescriber"
 - 6.5.14.4 SOP 8.8 "the pharmacist needing to go back to the prescriber".
 - 6.5.14.5 SOP 10.7 What if there is no access to the EPS?
 - 6.5.14.6 SOP 11.7 Perform professional clinical check, "Any prescriptions with handwritten amendments made by the prescriber will need to be referred back to the prescriber for either a new electronic prescription correctly written, or a non-EPS prescription."
 - 6.5.14.7 SOP 11.8 Produce labels for items on prescription and record exemption status "Will need to be referred back to the prescriber for either a new electronic prescription"
 - 6.5.14.8 SOP 14. Emergency Supply and Urgent Supply, "Prescriber (Urgent supply at the request of the prescriber)"
 - 6.5.14.9 SOP 20.8, "contact the prescriber to confirm the validity of the prescription".
- 6.5.15 Communication with the multidisciplinary team is essential for any pharmacy. Especially contacting a prescriber is necessary. The nearest medical centre is at 323 Grimsby Road DN35 7XE where all four prescribers are the owner of the 55 Grimsby Road DN35 7AF. The point Sai Dutt Ltd is making is, contacting

a prescriber may create a situation where conflict in the NHS arise. Sai Dutt Ltd would request a committee to reconsider their decision to approve this application.

- 6.5.16 Sai Dutt Ltd is of the view that the following requirements were not met adequately: The SOPs provided by the Applicant do not meet.

Safe and effective provision of services

- 6.5.17 SOP Point 6.11 Exempt NHS Prescriptions: of the further information (at the end of the application, originally provided by the Applicant), stated that evidence of exemption from the NHS prescription charge could be supplied either by giving to the pharmacy's driver (in appropriate cases), by post and by scanning/faxing copies to the pharmacy.

- 6.5.18 SOP 6.11 Exempt NHS Prescriptions, it is noted from the application that:

- 6.5.19 It may need to be recorded that the original was not presented, it states that pharmacy staff should not refuse to dispense but it does not give full information about how it will be delivered to the patient. As dispensing medication is one matter and delivering to the patient is the other matter. So, the SOP states only about the dispensing medication but it is failed to explain whether the patient will get the medication or not. In case, if the patient does not have NHS exemption, if the patient requires life-saving therapy, it may cause delay in obtaining life-saving therapy.

- 6.5.20 That any originals sent to the pharmacy will be returned securely to the patient by a delivery driver or recorded delivery, also it states whether this would be at cost to the pharmacy but failed to provide risk-assessment that what would happen if it got lost while delivering. The SOP failed to mention procedure what to do if breach of the patient confidentiality occurs when the exemption may get lost in transit.

- 6.5.21 Sai Dutt Ltd kindly draw committee attention that there was no mention of whom in the pharmacy will decide if the evidence is satisfactory or not and/or whether evidence is acceptable when not in original format.

- 6.5.22 SOP point 6.11 "the patient may scan or fax copies of the evidence to the pharmacy". Additionally, professional point of view that faxes remain a high-risk area for inappropriate disclosure of sensitive personal information. The Applicant has indicated exemption information could be provided by fax although no assurances have been provided around ensuring the security of said faxed information. In fact, the fax is no longer in line with NHS regulations due to poor data security.

- 6.5.23 SOP 6.11 Additional Notes

"You will not be held responsible if patients do not provide evidence, or if they provide evidence which is false. If you are in any doubt as to whether the evidence is genuine or appropriate, you should mark the 'Evidence not seen' box on the back of the prescription form with an 'X'.

"You are in no way responsible for the accuracy of the patient's declaration; this remains the responsibility of the patient."

- 6.5.24 Sai Dutt Ltd kindly remind committee that the Responsible Pharmacist is responsible for whole operation including exemption checking.

- 6.5.25 SOP 6.14 Paid NHS Prescription

“Check to see if any fees have been paid and if so, was the correct amount paid? Contact the patient to arrange payment using the secure payments system using the “customer not present” option. If no fees have been paid or there is a discrepancy between fees paid and those due, the patient should be contacted and directed to pay the appropriate fees via the online payment system”

- 6.5.26 Sai Dutt Ltd request the committee noted that there was no mention within the application or SOPs of what would happen to the patient medication if no payment came through online. What would happen if there were technical fault in the online payment system? No mentioned in the SOP where the patient will be signposted? There could be a possibility that the patient may not receive their treatment. As you can see it is a generic SOP, as a pharmacy professional Sai Dutt Ltd cannot approve this generic approach. It is clearly reflected here that proper risk-assessment has not been carried out. The SOPs have many flaws. It is putting the patient safety at risk. [sic]

SOP 17.16 Cold chain delivery via courier

- 6.5.27 SOP does not satisfy that item which require cold chain transport could be satisfactorily received by the patient:
- 6.5.28 SOP does not state that which courier company will be used. It is just state that “Specialist Courier company”. [sic]
- 6.5.29 It states “Fully monitored” but fails to mention what is the temperature range will be monitored? What happens if temperature breach occurs?
- 6.5.30 It states “temperature controlled” but does not specify the temperature range that is 2 to 8 Degree Celsius.
- 6.5.31 The SOP does not mention that what would happen to the patient(s) fridge line medication? In case of temperature breach the patient may end up not receiving their medication. For example, in case of breach, the patient may not receive lifesaving fridge line such as Insulin. Once again, the generic format of SOP is simply putting patient life at risk as it fails to explain what to do when temperature breach occurs?

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

- 6.5.32 It does not state that what about the driver delivering the fridge line notifying the responsible Pharmacist in case of temperature breach.
- 6.5.33 “How the driver will be notified if medicine is compromised during transit so that delivery can be aborted” We need reassurance or professional responsibility of driver to carry this out?
- 6.5.34 “There was nothing in the SOP provided by the Applicant to demonstrate that an audit process or appropriate system is in place which would highlight any items, which might have ceased to be refrigerated in transit and therefore be compromised, and how these would be prevented from being given to the patient.”
- 6.5.35 Failed delivery point 17.18 the items that have failed to be delivered to the pharmacy by the courier.
- 6.5.36 It states the pharmacy must arrange for immediate re-delivery, but it fails to mention that what happens if the patient needs the medication urgently, it fails

to mention that where the pharmacy can signpost them in the event of the fail delivery and if the stock return back to the pharmacy.

- 6.5.37 Failed delivery of cold chain 17.18 items subject to a cold chain breach may not be re-used and must be segregated from the pharmacy stock.
- 6.5.38 This SOP fails describe what would happen to that segregated fridge line. If it is segregated inappropriately there may be a risk that it may ended up being used up again which could be put patients' health at risk. It fails to mention the fridge line stock which had experienced temperature breach needs to be disposed of appropriately.

Cytotoxic fridge lines

- 6.5.39 Generic SOP 17.18 Cold chain via Courier does not even mention about that Cytotoxic medication that required refrigeration and how it will handle in the pharmacy and how it will be delivered.
- 6.5.40 Within the SOP information provided by the Applicant there was minimal information included about how cold-chain medicines will be delivered. It is very generic and to run pharmacy more robust standard operating procedures required.
- 6.5.41 Generic SOP 17.18 fails to provide the process for monitoring/auditing temperatures during transit.

Limited information was included within the original application/information provided by the Applicant.

- 6.5.42 First SOP 21.5 Does not provide information about delivery of Schedule 4 and 5 controlled drugs.
- 6.5.43 SOP 21.5 does not provide information about what to do if CD delivered to the wrong address. It only states "*The patient must have given authorisation for a representative to take receipt of CDs on their behalf*" but does not provide information about how the delivery driver or courier company will ensure that the controlled drugs have been delivered to the right person.
- 6.5.44 Generic SOP 21.5 "*A robust audit trail is essential when controlled drugs are involved*" but it does not provide standard operating procedure for how the audit trail will be conducted. It does not provide me enough information about the audit trail procedure.
- 6.5.45 Generic SOP 21.5 "*CDs should be in a separate bag to any other medication being delivered and the bags should be attached together.*"
- 6.5.46 However, it does not describe what happens if CD bag left behind in the van.
- 6.5.47 Generic SOP 21.5, "*CDs and any other medicines on that patient's delivery must be stored in the lockable compartment of the delivery van and out of sight.*"
- 6.5.48 It does not give any risk-assessment information about the scenario delivery van gets broken into and it does not provide information who to report in the event of any robbery of the CDS from the van.
- 6.5.49 Although SOP 21.5 does mention that the driver must check the identity of the person ensure that it is the patient or authorised representative. However, no information was provided relating verifying the ID of the person taking delivery (for example, if the recipient is not the patient themselves, then ensuring that

they have been authorised by the patient to take delivery). Moreover, it does not mention what kind of the ID is acceptable such as Photographic ID such as Passport or Driving License to ensure the authorise person is the correct person. It is worth to mentioned that how this data will be stored by the driver and how communicated back to the DSP? [sic]

- 6.5.50 For example, as anyone can show up the bank card which has not got the photograph which may be hard verify the correct person. [sic]
- 6.5.51 Sai Dutt Ltd would urge the committee note down that the information provided in the SOPs still did not provide any further information regarding verifying the ID of person taking delivery so could not assured on this process.
- 6.5.52 SOP 21.5 For all successful deliveries the Controlled Drug delivery sheet signed by the patient or online courier delivery record should be cross-referenced with the prescription and CD register prior to the prescription being processed as part of the end of day procedure.
- 6.5.53 No procedure has been explained if online courier delivery record fails due to technical issues. It may lead to CD discrepancies.
- 6.5.54 Only very limited information included in the event of unsuccessful delivery of the Controlled Drug.
- 6.5.55 SOP 21.7 Once again no or very little information provided about unsuccessful deliveries. In the event of unsuccessful delivery due to the pharmacy not having controlled medication in stock. The SOP does not explain the patient will be signposted to the nearest pharmacies. [[vc [sic]
- 6.5.56 The SOP states that where the time of attempted delivery means that the return cannot be made on the same day, the courier will store the drugs at their approved warehouse overnight.
- 6.5.57 Sai Dutt Ltd would like to ask couple of questions to the committee:
 - 6.5.57.1 Where are the Approved warehouse located where controlled drug can be stored overnight?
 - 6.5.57.2 The CD approved warehouse, would the approved warehouse keep CDs in the locked cupboard?
 - 6.5.57.3 Would the approved warehouse have Responsible Pharmacist onsite to handle CDs the next day?
 - 6.5.57.4 What would happen if CD discrepancies occurred?
 - 6.5.57.5 This approved warehouses even approved by the Medicines and Healthcare products Regulatory Agency to handle controlled drugs. That is a big question.
 - 6.5.57.6 Sai Dutt Ltd doubts that the Applicant has even done risk assessment around unsuccessful controlled drug delivery. Sai Dutt Ltd doesn't think so there are any approved warehouse exists which are allowed to handle controlled drug delivery. [sic]
 - 6.5.57.7 Allowing so called "approved warehouse" to handle the controlled drug delivery the next day may put patients' lives at risk as Approved warehouse may ended up delivering to patients instead of sending back to the pharmacy.

6.5.57.8 Although there are courier companies who handles CDs but not overnight as it creates a bigger risk for the patient receiving incorrect delivery of the CDs as there may not be a responsible pharmacist on the site at the approved warehouse.

6.5.58 The SOP is failing to meet this standard as controlled drugs not being stored securely overnight and not sufficiently safeguarded from unauthorised access

6.5.59 The Applicant not only putting patient safety at the risk but the generic SOP provided by the Rushport Advisory LLP is clearly breaching The Controlled Drugs (Supervision of Management and Use) Regulations 2006.

Palliative care controlled drugs prescriptions

6.5.60 The SOP does not explain how Palliative care controlled drug (end of life treatment) which could be required by the patient urgently on the same day will be delivered. Also, the SOP fails to explain what protocol will be followed in case of Palliative care CDs prescription received by the pharmacy.

6.5.61 First, none of the section of the SOP even mentions anything about how the end-of-life treatment will be dealt with.

6.5.62 Second, none of the section of the SOP mentions what to do if certain controlled drug prescription received for the Palliative care treatment and if the pharmacy has not got end-of-life injections in the stock.

6.5.63 Third, the SOP does not state where will the patient be signposted.

6.5.64 Only very limited information was included within the SOP 21 for Controlled Drug and stated that medications supplied to patient and about the unsuccessful CD delivery:

6.5.65 The SOP 21 fails to demonstrate what happens in the event when the patients have any query about their controlled drugs delivery. It does not even mention as simple procedure as of placing a compliment slip stating the name and contact details of the pharmacist in the event of queries. [sic]

6.5.66 The SOP 21 fails to identify which is highly likely, which occurs more often that the patients may have queries about their CD delivery. It does not provide any robust procedure about how to deal with patient query. For example, if patient receives wrong quantity, wrong strength, wrong dosage, wrong drug of their controlled drug. It does not state in these event what the patient suppose to do. The problem with this SOP is it is absolutely unsafe.

6.5.67 SOP 21 is outdated. It states that at hand-over to driver / courier ensure any falsified medicines regulations or guidance is followed.

6.5.68 SOP 21 is outdated as the 'safety features' elements of the EU Falsified Medicines Directive (FMD, 2011/62/EU) and Delegated Regulation (2016/161) cease to have effect in Great Britain from 31 December 2020.

6.5.69 Although imagine as a good practice the DSP wants to follow it, unfortunately the SOP does not state how the delivery driver will follow that regulation. No information provided about how it will be followed.

6.5.70 Although the application provided additional information was received via the SOPs regarding packaging for cold chain and security of CDs, no further information had been provided by the Applicant (via the SOPs or otherwise) regarding suitable packaging (e.g. tamper evident) for all items for delivery i.e. not just cold chain and/or CDs.

- 6.5.71 SOP 12.6 Owings for CDs *“All Owings for CDs should have ‘CD’ marked on the owing slip and the customer should be contacted and informed that their prescription must be successfully delivered within 28 days.”*
- 6.5.72 Once again limited information provided, Controlled drug SOP does not about what to do if any schedule 1,2,3 & 4 controlled drug undelivered prescription exceeds 28 days.
- 6.5.73 The SOP does not have robust procedure to prevent controlled drug prescriptions being delivered out after their validity of 28 days.
- 6.5.74 The CD SOP does not provide any information on how schedule 1 controlled drugs will be delivered.
- 6.5.75 The CD SOP fails to provide any details on how to deal with CD incidents and what time frame to report any CD related incidents. For example, the GPhC recommends 48 hours
- 6.5.76 The generic format of the SOPs provided by the Applicant :
- 6.5.76.1 It is not professional and specific this pharmacy.
- 6.5.77 It breaches principles set by the General Pharmaceutical Council.
- 6.5.77.1 It breaches principle 1: The governance arrangements safeguard the health, safety and wellbeing of patients and the public.
- 6.5.77.2 It breaches Principle 3: The environment and condition of the premises from which pharmacy services are provided, and any associated premises, safeguard the health, safety and wellbeing of patients and the public.
- 6.5.77.3 It breaches Principle 4: The way in which pharmacy services, including the management of medicines and medical devices, are delivered safeguards the health, safety and wellbeing of patients and the public.
- 6.5.77.4 Principle 5: The equipment and facilities used in the provision of pharmacy services safeguard the health, safety and wellbeing of patients and the public.
- 6.5.78 Therefore, these generic sops do not meet the requirements of Regulation 25(2)(b)(ii). [sic]
- 6.5.79 As all the requirements of Regulation 25(2) have not been met, Sai Dutt Ltd urge the committee to refuse the application.

6.6 TEMPLE BRIGHT ON BEHALF OF SANDRINGHAM ROAD PHARMACY

- 6.6.1 Temple Bright write further to [your] letter of 3 February enclosing a set of SOPs.
- 6.6.2 As anticipated in Sandringham Road Pharmacy Limited’s letter of appeal, it is clear that the SOPs which have been provided in support of this application are not those that would be used by the proposed pharmacy. The SOPs are self-evidently generic in nature and are not even stated as belonging to the Applicant (they are watermarked “Do not copy” and are stated to be the copyright of “Rushport Advisory LLP”). Given the watermarking and the purported copyright, it would appear that the Applicant would not even be

permitted to use the SOPs should the application be granted and the pharmacy open because to do so would appear to be in breach of Rushport Advisory's asserted copyright.

- 6.6.3 Indeed, the SOPs do not refer to the Applicant company at all, and do not even include details of the superintendent pharmacist. The "document control sheet" has not been completed, which would appear to suggest that they have been neither "authorised by" nor "approved by" the superintendent pharmacist.
- 6.6.4 Since the SOPs are generic in nature, make no reference to the proposed pharmacy and do not even purport to have been approved by the Applicant, the SOPs are not sufficient evidence to satisfy NHS Resolution that the requirements of Regulation 25 are met by the Applicant.

6.7 CO-OP

- 6.7.1 Thank you for your correspondence about the appeal raised by Cottingham Pharmacy as per the reference above.
- 6.7.2 Unless otherwise stated, any future reference to 'regulations' concern The National Health Service (Pharmaceutical and Local Pharmaceutical) Regulations 2013, as amended.
- 6.7.3 Regulation 31
31(2)(a)(i) and (ii)
- 6.7.4 Whilst the application is via a separate Limited Company and there is no mutuality between the Directors of Lincolnshire Co-op Chemists and those of the original Applicant, as the Co-op pharmacy is within the same parade of shops. [sic]
- 6.7.5 [See map at Appendix B]
- 6.7.6 In the absence of a formal definition within the regulations of 'adjacency' the Co-op will use the Oxford English Dictionary of adjacent which is "...Next to or very near something else; neighbouring; bordering, contiguous; adjoining". Additionally, NHS Resolution assess Regulation 31 via a broader definition than this, bringing in the phrase 'close-proximity' (Ref: SHA/24576).
- 6.7.7 The proposed site is unarguably within 'close-proximity' and therefore adjacent to the Co-op trading pharmacy and is classified as being within the same distinct retail area as the Co-op pharmacy in the suburbs of Cleethorpes, the Grimsby Road shopping area.
- 6.7.8 The application site and the Co-op site are within the same Lower-Layer Super Output Area (North East Lincolnshire 005C). This further reinforces the Co-op's stance that the sites are adjacent, and the Applicant should now provide comment on Regulation 31(2)(b) to satisfy the panel how they intend to manage the adjacency that the Co-op has proved.
31(2)(b)
- 6.7.9 The Co-op believe it is for the original Applicant to outline how they propose to manage the stated adjacency of the two premises from the perspective of the patient. Whilst it is a requirement that the NHSCB satisfy themselves as to there being no mutual interest between the directors of the Limited Companies, you must consider how a patient would understand the distinct difference between the two sites. The Co-op believe neither point was considered in making the decision to grant the DSP application and there is a real risk that

the patient will be confused between the two premises and not be able to make the distinction between the two, especially as the Co-op advertise that they provide NHS services. It is highly unlikely that the patient would interrogate Companies House WebCheck to learn who owns which trading entity, and nor should they be expected to.

Regulation 25 in general

25(2)(b)(i) and (ii)

- 6.7.10 The Applicant must supply suitable information to prove that they have procedures in place to satisfy the above.
- 6.7.11 Whilst it is not the place of NHS Resolution to ratify an Applicant's SOPs, simply sending an 'off-the-shelf' package of SOPs which considers nothing of how the actual service will be provided from the premises at 55 Grimsby Road, the Co-op find it difficult to understand how this regulation is satisfied. "...NHSCB is satisfied that the pharmacy procedures for the pharmacy premises are likely to secure" can therefore not be satisfied.
- 6.7.12 Regarding the urgent delivery of medication, the Applicant makes the following statement within their SOPs:

14.11 Delivery of Urgent and Emergency Supply items

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

Refer to relevant delivery SOP for further information on the delivery process.

- 6.7.13 Considering the word 'URGENT' for 'local' deliveries and in the absence of a definition of what 'local' means in the context of urgent deliveries, the Co-op believe the SOPs prove that there is the Applicant offering a two-tiered service. The acronym 'ASAP' meaning 'As Soon As Possible' is distinctly different than someone requesting something urgently.
- 6.7.14 The Applicant suggests they will use this phrase when communicating with their couriers who handle deliveries non-local patients. This procedure is clearly not going to satisfy the requirements of the regulations that are there to ensure there is an equitable service offered to patients on an England-wide basis.
- 6.7.15 There is no information as to how information provided to the patient during the provision of essential services is to be provided at a distance in a manner compliant with the Accessible Information Standard. The Co-op believe this is especially important as to explain the nuances of a Distance Selling Pharmacy to patients in a compliant manner with the Equalities Act 2010. Again, the Co-op question if a fair service can be truly provided by the Applicant to all patients.
- 6.7.16 Schedule 4 of the Regulations, notably part 2 prescribe to those providing pharmaceutical services what essential services are defined as being in the context of the regulations. In the Applicant's SOPs, on page 14 the Applicant suggests that the pharmacy staff will receive training in dispensing of appliances, if applicable. We take it from p123 of the SOPs that the Applicant will be supplying appliances:

“They are taking or using and likely to continue to take or use the medicine or appliance appropriately”

6.7.17 There is no indication within the SOPs that describes how they intend to deliver appliances inconspicuously as per Schedule 4, Part 2, 14 (2)(c) and (2)(d). The Applicant therefore cannot satisfy their Terms of Service and therefore the essential services.

6.7.18 On 20 October 2020, new NHS regulations were laid that introduced the latest changes to the Terms of Service.

6.7.19 This includes the following requirements:

“1.4 NHS Mail. NHS.uk Entry and the NHS Digital Directory of Services

It is common or secure communication from NHS bodies to now be received by NHS mail. This includes notification of Market Entry applications and referrals for services such as the Discharge Medicines Service. It is therefore important that the NHS mail system is accessible and accessed every day by staff.

At least two members of staff (unless fewer than two are working at the pharmacy) must have live, linked NHSmail accounts to the premises specific NHSmail account. NOTE – the NHSmail account is not the same as the email address that may be set up by the pharmacy themselves and is assigned by NHSmail directly.

When the NHSmail account details are received for the first time the Pharmacy must register the email address with the MHRA so that Central Alerting System emails can be received on product defects/recalls.”

6.7.20 The language of this excerpt describes what the Terms of Service need from a pharmacy contractor to satisfy their Terms of Service and therefore their Essential Services regarding NHS.net email access. The Co-op believe these are not procedures that say what the Applicant will do, more just what they should do and therefore this doesn't prove that they will enable access to NHS.net mail. Their intentions are made more opaque by not differentiating between whether the individual's NHS.net email address is registered with the Central Alerting System or the individuals. [sic]

6.7.21 They make a similar statement on page 103:

4. Patient moves community pharmacy after stage 1 of the service has been provided. The situation may occur where stage 1 of the service has been delivered by a pharmacy contractor and that pharmacy contractor subsequently finds out that the patient wishes to use a different pharmacy contractor for the provision of the service. The first pharmacy contractor should contact the second pharmacy contractor and offer to send them, via a secure electronic message (eg to the pharmacy contractor's premises specific NHS mail account) and with the patient's consent, the referral information received from the NHS trust and any relevant information and/or findings identified during stage 1 of the service. The same approach could be taken if another pharmacy contractor contacts the first pharmacy contractor to inform them that the patient has asked them to dispense the first prescription post discharge.

6.7.22 Again, this describes what is needed to provide DMS, but not that they will apply for a branch NHS.net email account.

6.7.23 In summary, the Co-op believe that the Applicant has failed to address significant concerns that they have regarding their ability to reflect how they

will provide essential pharmaceutical services as per Regulation 25, equitably to all persons despite their varying information accessibility needs, to anywhere in England. They have merely supplied off the shelf SOPs and a good oversight of the regulations without articulating to the Co-op what their service will look like in accordance to the regulations themselves.

6.7.24 The Co-op also believe that the proposed premises are adjacent to the Co-op within the same shopping area, and the Applicant has also not reflected how they intend to ensure that the service does not appear as part of our service offering to the patients.

6.7.25 The Co-op feel the appeal should be upheld, and their comments considered when reconsidering the application. The Co-op are also happy to attend an oral hearing should there be an identified need

6.8 L ROWLAND & CO (RETAIL) LTD

6.8.1 Thank-you for the opportunity to comment on the above appeal. If NHS Resolution decide to convene an oral hearing L Rowland & Co (Retail) Ltd are willing to attend under the provisions of Paragraph 8 of schedule 3 of the regulations.

6.8.2 L Rowland & Co (Retail) Ltd have no further comments to make at this stage but remain concerned about the potential issue of direction of Prescriptions which they raised previously and if the application is allowed to open will this become evident.

6.8.3 L Rowland & Co (Retail) Ltd respectfully request that NHS Resolution inform them of the outcome in due course.

In a letter of 10 June 2021 to NHS England, Rowlands Pharmacy stated:

6.8.4 L Rowland & Co (Retail) Ltd note this is a Distance Selling excepted application and should one be required would be willing to attend any oral hearing in relation to the above application to express their written comments verbally.

6.8.5 L Rowland & Co (Retail) Ltd wishes to make the following comments:

6.8.6 As the application is in respect of distance selling premises, by virtue of regulation 64 (3) of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, approval is subject to the following conditions:

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

6.8.8 The means by which the Applicant provides pharmaceutical services must be such that any person receiving those services does so otherwise than at the proposed premises;

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

6.8.10 The pharmacy procedures for the premises must be such to secure –

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

- 6.8.10.2 The safe and effective provision of essential services without face-to-face contact between any person receiving the services, whether on their own or on someone else's behalf, and the Applicant or the Applicant's staff; and
- 6.8.11 Nothing in the Applicant's practice leaflet, in the Applicant's publicity material in respect of the proposed premises, in material published on behalf of the Applicant publicising services provided at or from the proposed premises or in any communication (written or oral) from the Applicant or the Applicant's staff to any person seeking the provision of essential services from the Applicant must represent, either expressly or impliedly, that –
- 6.8.11.1 The essential services provided at or from the premises are only available to persons in particular areas of England, or
- 6.8.11.2 The Applicant is likely to refuse, for reasons other than those provided for in the Applicant's terms of service, to provide drugs or appliances ordered on prescription forms or repeatable prescription forms which are presented by particular categories of patients (for example, because the availability of essential services from the Applicant is limited to other categories of patients).
- 6.8.12 L Rowland & Co (Retail) Ltd note that in SHA/24544, Primary Care Appeals refused a DSP application because they were not satisfied that items which require cold chain transport could be satisfactorily received by the patient. They state the following *"...there was nothing provided by the Applicant to demonstrate that an audit process or appropriate system is in place which would highlight any items, which might have ceased to be refrigerated in transit and therefore be compromised, and how these would be prevented from being given to the patient. In addition, Committee noted SOP 3 specifically defines a failed delivery as one where there has been no one there to accept delivery. It therefore does not include a situation where the cold chain has been compromised in transit, and the SOP does not set out how such a situation would be recognised and dealt with. The Committee was not therefore confident, as it is required to be, that all dispensed cold chain products would be delivered in a safe and effective manner"*. L Rowland & Co (Retail) Ltd trust that NHS England will consider this view when reaching their decision on this application.
- 6.8.13 NHS England will be aware that the Applicant, in this case, consists of a number of GPs of a local GP practice. Regulation 30 of Schedule 4 to the NHS Pharmaceutical and Local Pharmaceutical Regulations 2013 concerns inducements. L Rowland & Co (Retail) Ltd wish to be assured that NHS England has suitable processes in place to monitor changes to prescriptions nominations such that they are able to intervene should this regulation not be being complied with.
- 6.8.14 In addition, L Rowland & Co (Retail) Ltd note the 2015 guidance issued jointly by pharmacy bodies and the BMA regarding patient choice and note that patient choice is a fundamental part of NHS services. Again, L Rowland & Co (Retail) Ltd seek reassurance that NHSE has procedures in place to intervene should patient choice be affected in any way.
- 6.8.15 L Rowland & Co (Retail) Ltd furthermore wish to be assured that NHS England has sufficient governance procedures in place to ensure that the criteria for the expected application are fulfilled. L Rowland & Co (Retail) Ltd also request that NHS England keep them informed of the outcome in due course.

6.9 HUMBERSIDE LPC

- 6.9.1 The LPC committee has reviewed this appeal subject to its conflict of interest provisions.
- 6.9.2 It's unfortunate that another contractor has been needlessly brought into this through the LPC assume a misunderstanding of how DSPs are situated and the regulations at hand. As such the LPC will comment in the support of clarity as the LPC represents both current contractors mentioned in the appellants submission.
- 6.9.3 The LPC note that regulation 25 can only be appealed for very defined reasons, as NHS Resolution communicates itself, regulation 31 on co-location and regulation 25 itself around assurance that the pharmaceutical services can be provided in a non-face-to-face fashion as described in the regulations, often backed by SOPs as in this appeal.
- 6.9.4 Unfortunately, many of the 9 points raised by the appellant do not apply in a regulation 25 case and fail to provide evidence of things that will occur and only 'may', and even then, only in certain circumstances that are not definite occurrences. Many other points raised seem to apply more to a regulation 18 application and are therefore not relevant in this case even if they were evidenced.
- 6.9.5 Of the 9 points raised the LPC feel they can only pass comment on point 1 and point 5.
- 6.9.6 Point 1 – The LPC merely feel the need to clarify that Drugs4Delivery is not located at the address in question meaning regulation 31 cannot be used to deny the appeal. It's unfortunate that this contractor has been brought into this but as mentioned there seems to be a misunderstanding about how the regulations are applied and the term "existing service" does not apply here.
- 6.9.7 Point 5. While the fact that other DSP applications have failed through, in this example, inadequate cold chain SOPs, that has no automatic relevance to any other applications. That said, the LPC would hope the appeals Committee is assured that the Applicant meets the required parameters of its service delivery within Regulation 25.
- 6.9.8 Should this appeal go to an oral hearing the LPC would wish to be in attendance and kept up to date with the progression of the case.

7 Summary of Observations

This is summary of observations received.

- 7.1 RUSHPORT ADVISORY LLP ON BEHALF OF KARMA MEDICAL SOLUTIONS LTD
 - 7.1.1 Thank you for your letter of 8 March 2022. Rushport Advisory LLP act for Karma Medical Solutions Limited in the above application and have been instructed by the Applicant to submit the following reply to the comments submitted by various interested parties to the appeal.

Rowlands, DMB, LPC, Boots
 - 7.1.2 The Applicant has no further comments to make on these representations.

Co-op
 - 7.1.3 Co-op has simply misunderstood Regulation 31 and Rushport Advisory LLP trust that the Committee will note that regulation 31 does not apply in this case

and there is no other pharmacy in either the same or adjacent premises and nor is there any link between Co-op and the Applicant.

- 7.1.4 Rushport Advisory LLP believe the use of words such as “urgent” and “ASAP by the quickest route possible” have clear meaning that the Committee will understand.
- 7.1.5 Co-op references the Accessible Information Standard but appears to be unaware that the requirements are covered within the section of the SOPs that deals with reasonable adjustments to be made under the Equality Act.
- 7.1.6 Co-op is correct that appliances will be provided, but has failed to appreciate that many items are listed in Part IX of the Drug Tariff as appliances which would be considered “normal” dispensary items such as tape, dressing, eye drops etc and which do not require measuring or fitting. Appliances that require measuring or fitting will not be dispensed by the Applicant and all packaging used for all items will be inconspicuous in any event.
- 7.1.7 Co-op’s comments in relation to NHSmail are difficult to understand. For example, how could the Applicant have members of staff who regularly check the NHSmail account if the Applicant had not applied for one?

Temple Bright

- 7.1.8 Temple Bright has misunderstood the law relating to copyright and Rushport Advisory LLP trust it is clear to the Committee that the Applicant does have consent to use the SOPs they have provided as part of their application. Copyright is an important right that helps to prevent unauthorised reproduction of works.
- 7.1.9 The “Document Control Sheet” referred to by Temple Bright has not been filled in because the Applicant is yet to make changes to the SOPs.
- 7.1.10 It is disappointing that Temple Bright has accused Rushport of dishonesty and Rushport Advisory LLP simply confirm again that the SOPs have been authorised and approved by the superintendent pharmacist for use in this application.

Sai Dutt Limited

- 7.1.11 The majority of the lengthy submission from the Appellant is either vexatious or frivolous and Rushport Advisory LLP trust the Committee will understand their not replying to each and every point. For the sake of completeness the Applicant denies all the points made by the Appellant.
- 7.1.12 Rushport Advisory LLP note that the Appellant repeatedly refers to “risk assessments” but appears to confuse these with SOPs. The two are not the same as the Committee will be aware and Risk Assessments are a tool that is used to manage risk when the pharmacy is operating and are not part of the NHS application process. It is the GPhC that monitors use of appropriate Risk Assessments (and potentially NHS England as part of contract monitoring).
- 7.1.13 Dealing with some points raised by the Appellant.

Patients Accessing the Premises

- 7.1.14 The Appellant has misunderstood regulation 25. Whilst it would in fact be lawful for the Applicant to allow patients to access the premises to purchase GSL or P meds, they do not intend to operate this way and patients can only purchase such medicines online or over the phone. The purchase of GSL or P

medicines is not an essential service and is not covered further as part of this application. The pharmacy will operate a controlled entry system (as has been stated multiple times) and patients will not be able to simply walk in as suggested by the Appellant.

Exemption Checking

- 7.1.15 The Applicant has provided significant amounts of detail relating to exemption checks and this includes explanatory notes from both NHSBSA and the PSNC. Rushport Advisory LLP trust that these will be sufficient for the Committee.

Falsified Medicines Directive

- 7.1.16 The Applicant is of course aware that FMD no longer applies to the UK but as the SOPs make clear, the Applicant will follow any falsified medicines rules that are enacted in the UK.

Palliative Care and Urgent Controlled Drug Deliveries

- 7.1.17 All distance selling pharmacies deliver medication to patients and the time taken to carry out a delivery will be affected by a number of factors that are not within the control of the pharmacist, eg extreme weather. The pharmacy will always use procedures that mean dispensed medicines are delivered with “reasonable promptness” and prioritise deliveries that are urgent (eg use a same day courier). For obvious reasons it is unlikely that a patient who requires medication immediately would use the postal system to post a controlled drug prescription to the pharmacy. In any event, the pharmacy SOPs state that the patient will be contacted with an estimate for delivery time and that time will be updated as required. For prescriptions received via EPS the prescription can be returned to the NHS spine electronically if delivery times do not suit the patient.

7.2 TEMPLE BRIGHT ON BEHALF OF SANDRINGHAM ROAD PHARMACY

- 7.2.1 Temple Bright write further to [your] letter of 8 March 2022 and in order to respond to representations received in respect of Sandringham Road Pharmacy Limited’s appeal against the above application.
- 7.2.2 In relation to the letter from NHS England dated 14 February 2022, Temple Bright note that NHS England states that SOPs were not initially provided by the Applicant but that “the Committee were happy to support the application without seeing these”.
- 7.2.3 It is not at all clear why a Committee of NHS England should be “happy” to “support” an application. NHS England has a statutory function to assess applications and to determine whether the application meets the relevant regulatory test. It is inappropriate for NHS England to determine applications by considering whether it is “happy” to “support” them. This statement by NHS England provides further evidence that NHS England did not properly determine the application.
- 7.2.4 In relation to the response from Rushport, Sandringham Road Pharmacy Limited maintains that the SOPs which have been provided by the Applicant are insufficient to demonstrate that the requirements of regulation 25 are met by this application.
- 7.2.5 The Applicant’s representative states that “On page 2 the Appellant repeats arguments about procedures being provided by third parties (in this case Rushport Advisory LLP) that the Committee has rejected on many occasions. As the Committee will be aware, almost all pharmacies use SOPs sourced from

third parties and this includes “normal” 40 hour retail pharmacies and distance selling pharmacies.”

- 7.2.6 This statement is flawed for two reasons. Firstly, each application must be determined on its own facts. Whether or not NHS Resolution has accepted the SOPs provided by the Applicant’s representative “on many occasions” does not require NHS Resolution to grant the current application. Indeed, this statement simply underlines Sandringham Road Pharmacy Limited’s ground of appeal that the SOPs that have been provided are generic in nature and are self-evidently not those which are intended to be used by the proposed pharmacy. They are therefore incapable of satisfying NHS Resolution in respect of the matters contained within regulation 25.
- 7.2.7 Secondly, whilst it is not unusual for pharmacies to “use” SOPs that have been sourced from third parties, it is, of course, in the very nature of SOPs that they must be adapted to the particular pharmacy and should be regularly reviewed and updated as required. It is quite clear from the SOPs provided by the Applicant’s representatives that the Applicant would not lawfully be in a position to adapt the SOPs from time to time as may be required or, indeed, to use them in the ordinary course of the operation of its pharmacy. The SOPs are watermarked “do not copy” (and so copies could not be made for distribution to members of staff for learning and training purposes, for example) and are stated to be the “copyright” of Rushport Advisory LLP.
- 7.2.8 Whilst the Applicant’s representative has finally added the Applicant’s details into the SOPs, the SOPs clearly do not belong to the Applicant in any meaningful sense and cannot be used as a living document by the Applicant. The SOPs provided therefore cannot satisfy NHS Resolution that the Applicant has in place procedures to secure the safe and effective provision of pharmaceutical services by the proposed pharmacy.
- 7.2.9 Given Sandringham Road Pharmacy Limited’s primary submission that the SOPs provided by the Applicant’s representative are fundamentally flawed, Sandringham Road Pharmacy Limited makes no comment on the contents of the SOPs themselves.

7.3 SAI DUTT

- 7.3.1 Sai Dutt Ltd’s comment is that approval of this application will definitely increase inequalities in the area. Please refer to the Department of Health suggestions with regards to DSP.
- 7.3.2 There are no need of the DSP as per PNA.
- 7.3.3 Verbal reassurance is not enough. Approval to this DSP will significantly increase practices like prescription direction & conflict of interest in the NHS.
- 7.3.4 Sai Dutt Ltd would urge the NHS resolution to reject this application.

7.4 CO-OP

- 7.4.1 Thank you for the opportunity to make final observations on the appeal SHA/24675 (Distance Selling Pharmacy Cleethorpes).
- 7.4.2 The Co-op will in turn go through the key points raised in each communication and state their observations.

Boots UK response dated 4th March 2022

- 7.4.3 The Co-op has no further observations on the comments raised by Boots UK.

7.4.4 The Co-op understand that the team had made the assertion that Regulation 31(2)(a) (adjacency) was satisfied but did not show what their rationale was. The Co-op would be keen for [yourselves] to have visibility of the committee minutes to reinforce their decision made rather than sharing a graph and photos of an empty retail unit.

7.4.5 As you will know, in the absence of a definition from within the Regulations themselves, we rely on the common definition of adjacency. NHS England are therefore fortunate that in the Department of Health Guidance Document (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/255959/nhs_pharm_servs_market_entry_chpt_11.pdf) contains practical advice of what is classed as adjacent or otherwise:

81. Where the premises within an excepted application for distance-selling premises are:

already included in a pharmaceutical list; or

adjacent to or in close proximity to premises that are already included in a pharmaceutical list,

the applicant will have had to explain why their application should not be refused pursuant to regulation 31.

7.4.6 The Applicant never did, and the Co-op don't believe this was considered any more than a mere formality to acknowledge.

7.4.7 When the Co-op raised this with Nick Speight of PCSE on the 13 January 2022 via email, the following comment was made:

"No statement was made to the effect that the application should be refused. In specific regard to Regulation 25 it was stated that there were no comments to make and although reference was made to Regulation 31 the wording was a statement that NHS England should be mindful of the regulations. The representations did not state that the application should be refused under regulation 31 merely that consideration should be given to the issue raised."

7.4.8 In the absence of any substantive comment by the Applicant to outline why their application should not be refused, this should have compelled the committee to consider the Co-op's evidence supplied, which they didn't.

7.4.9 The Co-op believe that the premises are, by definition, adjacent.

7.4.10 The Co-op also believe that the committee in making their decision to dismiss their concerns have deduced that 55 Grimsby Road is instead not adjoining. They have two distinctly different meanings.

7.4.11 According to the Oxford English Dictionary, adjacent as an adjective is defined as being "*Next to or very near something else; neighbouring; bordering, contiguous*". Adjoining is defined as being "*...contiguous; neighbouring; (also) joined, attached, connected*".

7.4.12 The Co-op do not contest that the application is not adjoining, but they believe that it is within the same neighbourhood, shares the same utility supplies and therefore, by definition, adjacent, and therefore the regulation should be considered, and the application should not pass through the preliminary considerations of adjacency.

- 7.4.13 Cadent Gas Networks have kindly shared the diagram (Appendix C) of the adjacent properties, showing the fact that they share an LP (Low Pressure) Gas supply - this is the tertiary pressure-rated gas main in the UK, and shows that the infrastructure serves the same premises, adjacent to one another.
- 7.4.14 The Co-op have also included plans from Northern Power Grid (Appendix C) which suggest that the site shares mutual power infrastructure, which again shows that the Co-op property and that of the Applicant would meet the definition of being adjacent to one another.
- 7.4.15 In the letter from the NHS England team dated 14 February 2022, it suggested the below:

Standard Operating Procedures (SOP)

In relation to the issue raised by Sandringham Pharmacy in relation to the Standard Operating Procedures (SOPs) not being submitted as part of the process. It is not necessary for them to be submitted as part of the application and the Committee were happy to support the application without seeing these. However, a full set of SOPs were submitted as part of the initial response to Sandringham, and other interested parties, to provide assurance in relation to the issues raised.

- 7.4.16 Of course, it is not the position of anybody to ratify the suitability of an Applicant's SOPs, but the points raised by the Co-op and the other applicants doubting the integrity of the SOPs provided, the Co-op wonders how the group were able to satisfy themselves of the Applicant's desire or ability to remain compliant to the NHS Terms of Service for a Distance Selling Pharmacy.

Appellant Reps dated 4 January 2022

- 7.4.17 The appellant has made considerable effort in outlining the flaws with the suite of SOPs that have been provided. The Co-op agree with all points raised that both require clarification and cite the correct regulations. The Co-op ask that particular attention is made to the lack of information around the sale of GSL medicines (which could be considered as support for self-care, one of a pharmacist's essential services) that are not to be provided face-to-face. The Co-op also strongly agree with the concerns around handling of cytotoxic medicines that require cold-chain transport and the handling of failed delivery controlled drugs.

Humber LPC reps dated 28 January 2022

- 7.4.18 The Co-op has no further observations on the comments raised by Humber LPC.

Rowlands Pharmacy reps dated 10 January 2022

- 7.4.19 The Co-op has no further observations on the comments raised by Rowlands Pharmacy.

Temple Bright reps dated 11 February 2022

- 7.4.20 The Co-op agree with the comments that Temple Bright had made regarding the lack of assurance that the SOPs, which are used to outline how the Applicant intends to provide services compliant with the requirements of a pharmacy trading at a distance, are what the pharmacy intend to offer, and have not actually been made specific to the nuances of the pharmacy nor have been signed off by the Superintendent pharmacist. They should hold no validity to the course of the decision making because, as Temple Bright points out, the

intellectual property rights do not belong to the Applicant themselves. It would be akin to the Co-op applying for a pharmacy and using another contractor's SOPs to provide assurance to the panel which they believe would not be satisfactory.

Rushport Advisory reps dated 7 January 2022

- 7.4.21 The Co-op wish not to comment on the SOPs provided, other than to question the validity of the SOPs as a body of documents that belong to someone else purporting to reflect how the operators of the proposed pharmacy will operate.
- 7.4.22 The Co-op agree that the grounds of appeal should be considered against Regulations 31 and 25 only.
- 7.4.23 Should there be any requirement to attend an oral hearing, the Co-op would be happy to attend this to further reinforce their comments and response to the first appeal.

8 Consideration

- 8.1 The Pharmacy Appeals Committee ("Committee") appointed by NHS Resolution, had before it the papers considered by NHS England.
- 8.2 It also had before it the responses to NHS Resolution's own statutory consultations.
- 8.3 On the basis of this information, the Committee considered it was not necessary to hold an Oral Hearing.
- 8.4 The Committee had regard to the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 ("the Regulations").
- 8.5 The Committee noted the various regulations quoted by Sai Dutt Ltd in their appeal including Regulation 18 (Unforeseen Benefits) and Regulation 24 (No significant change relocation) as well as reference to the PNA. The Committee was mindful that this is an application made under the provisions of Regulation 25 and therefore it is the criteria as set out in Regulation 25 to which it has to have regard. The Committee noted that Regulation 25 is an "excepted application" and as such the application and subsequent consideration of such is not based on the Pharmaceutical Needs Assessment. The Committee was of the view that the comments from Sai Dutt Ltd regarding reducing inequalities was not relevant. The Committee also noted the comments with regard to a "Duty to promote innovation". The Committee was mindful that innovation was not a relevant criteria for a distance selling premises application and took no view on whether or not the Applicant was proposing or promoting innovation.
- 8.6 The Committee took no view on the matters raised by Sai Dutt Ltd which did not fall within the criteria as set out in Regulation 25.

Regulation 31

- 8.7 The Committee first considered Regulation 31 of the Regulations which states:
 - (1) *A routine or excepted application, other than a consolidation application, must be refused where paragraph (2) applies.*
 - (2) *This paragraph applies where -*

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

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

(ii) adjacent premises; and

(b) the NHSCB 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).

- 8.8 The Committee noted that the Applicant had stated that Regulation 31 was not applicable as there is no other pharmacy in the same or adjacent premises. The Committee noted that NHS England had concluded, at 2.2 above, that the proposed site is not on the same site or adjacent to an existing pharmacy.
- 8.9 The Committee noted the information provided by other parties in which they sought to argue that the application should be refused under Regulation 31.
- 8.10 The Committee noted the comments from the Co-op with regard to another pharmacy being located in the same parade of shops. The Committee noted that there was no dispute that there was another pharmacy in the same parade of shops and accepted that they might share the same amenities (as shown in the supporting information from the Co-op). The Committee noted that the address given for the Co-op Pharmacy was 121 Grimsby Road and the address on the instant application was for 55 Grimsby Road.
- 8.11 The Committee was of the view that whilst the premises may be close to each other, Regulation 31, as quoted above, states "the premises to which the application relates or adjacent premises". The Committee was of the view that the two pharmacies in question were not the same premises and, given the addresses of both, were not in adjacent premises.
- 8.12 The Committee went on to consider Regulation 31(2)(b).
- 8.13 The Committee noted that the instant application was made in the name of Karma Medical Solutions Ltd. The Committee noted the assurances from the Applicant that they did not already have a pharmacy operating in the area and further that none of the directors of this pharmacy had any connection to any of the other pharmacies in the area, most notably Lincolnshire Co-op ("the Co-op") or Drugs4Delivery. The Committee further noted that neither Sai Dutt Ltd nor the Co-op had sought to argue that the Applicant was the same legal entity as a pharmacy already included in the pharmaceutical list.
- 8.14 The Committee noted the comments from Sai Dutt Ltd with regard to Drugs4Delivery operating a distance selling pharmacy in the area, though not at the same site as the instant application, and that this could be considered to be part of the same services as the Applicant was offering to provide. The Committee noted that there was no commonality between the Applicant and Drugs4Delivery.
- 8.15 The Committee noted that NHS England did not consider there to be any issues relating to Regulation 31.
- 8.16 The Committee considered, based on the information before it, that it was reasonable to consider that the pharmacies would be running separate businesses and providing separate services from their respective premises (if the instant application was to be granted) and therefore Regulation 31(2)(b) did not apply.

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

Regulation 25

- 8.18 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) The NHSCB 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 the NHSCB is satisfied that the pharmacy procedures for the pharmacy premises are likely to secure—
 - (i) the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services, and
 - (ii) the safe and effective provision of essential services without face to face contact between any person receiving the services, whether on their own or on someone else's behalf, and the applicant or the applicant's staff."

- 8.19 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 the NHSCB in receipt of it, with good cause, that no relevant information or documentation is missing, having regard to the uses that the

NHSCB may need to make of the information or documentation when carrying out its functions.

- 8.20 Pursuant to paragraph 9(1)(a) of Schedule 3 to the Regulations, the Committee may:
- 8.20.1 confirm NHS England's decision;
 - 8.20.2 quash NHS England's decision and redetermine the application;
 - 8.20.3 quash NHS England's decision and, if it considers that there should be a further notification to the parties to make representations, remit the matter to NHS England.

Regulation 25(1)

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

Regulation 25(2)(a)

- 8.22 As far as Regulation 25(2)(a) is concerned, the Committee had regard to the application form in which the Applicant states "Application not on the same site or in the same building as the premises of a provider of primary medical services with a patient list."
- 8.23 The Committee noted that this had not been disputed and that it had not been provided with any information to persuade it otherwise.
- 8.24 The Committee did note the comments from Sai Dutt Ltd with regard to the owners of the pharmacy and that they were all medical practitioners who worked in a surgery in the vicinity of the proposed location. The Committee noted that there was nothing in the Regulations which prohibited doctors from owning and running a pharmacy. The Committee noted the various comments from parties with regard to the potential for direction of prescriptions.
- 8.25 The Committee noted guidance published by the Department of Health (paragraph 85 of chapter 11 of "Regulations under the Health and Social Care Act 2012: Market entry by means of Pharmaceutical Needs Assessments") which states:
- "[Regulation 25(2)(a)] is one of the safeguards previously promised in connection with this type of application to avoid circumstances arising where patients of the provider of primary medical services inadvertently present prescriptions for dispensing at the pharmacy, even though such dispensing to patients on the site is not permitted".*
- 8.26 The Committee considered that, having regard to the guidance, the intent of Regulation 25(2)(a) is to prevent patients of a provider of primary medical services inadvertently accessing the pharmacy. Where premises are not used for the delivery of primary medical services, there will be no patients. The Committee was satisfied that the information provided to it did not indicate that the Applicant's proposed premises are used for the delivery of primary medical services and therefore should not be regarded as 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 determined that the application did not need to be refused by virtue of regulation 25(2)(a).

Regulation 25(2)(b)

- 8.27 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, including its Standard Operating Procedures (SOPs) that it intends to use at the proposed pharmacy premises.
- 8.28 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.
- 8.29 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 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.
- 8.30 The Committee has asked itself whether it has sufficient information and documentation which would address the criteria in Regulation 25(2)(b). If the Committee is to be satisfied of the matters in that paragraph, the Committee must be provided with evidence to demonstrate these matters. In this case, that evidence put forward has taken the form of the original application and the SOPs which the Applicant has prepared or commissioned.
- 8.31 The Committee noted the comments from the Appellants and parties with regard to the generic nature of the SOPs and that there was no information contained in the SOPs to demonstrate that they were commissioned for use in the Applicant's pharmacy. The SOPs as provided in representations by the Applicant's representative, are clearly marked showing the Applicant's pharmacy name and details on the cover sheet as well as in the footers. The Committee noted that the "Document Control Sheet" was not fully completed, which parties had said showed that they were generic SOPs, however the Committee noted the comments from the Applicant that there had been no revisions as yet to the SOPs and further that some of this information was unable to be completed until a grant was received and the premises had been registered with the GPhC.
- 8.32 The Committee was of the view that the details given on the SOPs should have the potential to re-assure parties that the SOPs were intended to be used by the Applicant. The Committee further noted that the Applicant's representative had indicated that the SOPs have been approved by the Applicant's superintendent pharmacist and no party was disputing this. The Committee considered that the above points supported the position that the Applicant intended to use these SOPs. The Committee did not consider that the "Do Not Copy" indications on the SOPs and that there are references to "Rushport Advisory" on the SOPs meant that the Applicant was not intending to use the SOPs. As such, the Committee considered that the evidence pointed towards the SOPs intending to be used by the Applicant.
- 8.33 It is not for the Committee to 'approve' or 'disapprove' of these SOPs (as they may contain matters not relevant to the Committee's consideration, and there are many ways an applicant can choose to organise itself in order to comply with the various requirements of the Regulations) and the Committee has not sought to do so. The Committee has sought evidence within the SOPs and application in order to satisfy itself that it is appropriate to grant the application, the absence of which would require it to reject it.
- 8.34 The Committee noted in the SOPs provided by the Applicant with their appeal that SOP 1 'Introduction and Background to SOPs' states that the pharmacy must provide:
- 8.34.1 *"the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services."*

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

8.35 Further SOP 3 "Procedures for NHS Essential Services" states:

8.35.1 *"NHS Essential services will be provided to any patient living in England who requests such services, this is made clear on the website and in the practice leaflet."*

8.36 The Committee noted the comment from Sai Dutt Ltd and Temple Bright on behalf of Sandringham Road Pharmacy Ltd that it is intended to only operate the pharmacy as a local dispensing service rather than a national service. The Committee were of the view that this was a subjective view and that there was nothing within the application form, SOPs or subsequent representations from the Applicant's representative that would lead it to the conclusion that the Applicant was only offering a local dispensing service. The Committee noted the references to the local delivery driver in the SOPs, but also noted that reference is made through the SOPs to the provision of services to all of England. In addition the Committee noted the references in the SOPs to the use of Royal Mail and of couriers. The Committee was satisfied, based on the information before it, that the provision of services would be available to persons anywhere in England.

8.37 In its SOP 31 'The Responsible Pharmacist' the Applicant states:

8.37.1 *"As a distance selling pharmacy, we must provide uninterrupted service throughout the opening hours of the pharmacy. For this reason the RP is not allowed to leave the premises in the same way as an RP at a non - Distance Selling pharmacy is allowed (for up to 2 hours per day) unless another pharmacist is present."*

8.38 And goes on to state:

8.38.1 *"The pharmacy will have a second pharmacist available during the core and any additional hours that it operates. If, for any reason, the RP is required to leave the premises or wishes to take a break ... then the second pharmacist must sign in as the RP".*

8.39 The Committee noted the comments from Sai Dutt Ltd with regard to the absence of the pharmacist and the opening hours of the pharmacy. the Committee noted the SOPs dealing with the absence of the responsible pharmacist as well as cover for breaks and further noted that the proposed hours provided a break for the pharmacist in accordance with the working time directive. Based on the information provided, the Committee was satisfied that the provision of services would be uninterrupted.

8.40 The Committee noted that throughout the SOPs the Applicant states that essential services will be provided without face to face contact between anyone receiving the services and the pharmacy staff. SOP 1 "Introduction and Background to SOPs" states:

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

Face to face contact with patients or their representative either on or in the vicinity of the premises is only allowed in respect of the provision of services other than Essential Services.

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

- 8.41 The Committee also noted SOP 3 "Procedures for NHS Essential Services" under "Communication channels" states:
- 8.41.1 *"All communication regarding NHS Essential Services should be carried out using the most suitable non face to face method for the patient and the service being provided with particular consideration to maintaining confidentiality. This may be telephone, email, video-conferencing or other types of non-face to face communication such as text messages."*
- 8.42 The Committee noted that patients would be able to contact the pharmacy by telephone, through the website as well as by email and postal services.
- 8.43 The Committee noted the comments from the Appellants with regard to the location of the pharmacy being in a parade of shops and how the Applicant would ensure that there would be no face to face contact.
- 8.44 The Committee noted the comments with regard to the sale of GSL and P medicines on-line and over the phone and further noted the comments from the Applicant that these are not essential services and therefore this service may be provided from the pharmacy.
- 8.45 The Committee noted that throughout the SOP there was reference to non-face to face communication for all essential services. The Committee also noted the comments from the Applicant that the pharmacy will operate from *"secure premises with a controlled entry system, to which members of the public will not have access. A patient that requests essential services to be provided at the premises will be informed that the pharmacy is not permitted to provide those services at the premises."*
- 8.46 Whilst noting the Appellants concerns about the nature of the SOPs provided and their lack of specificity about the circumstances of the particular pharmacy and its location, the Committee had noted that the SOPs had been approved by the superintendent pharmacist and that, in relation to face to face contact, a controlled entry system was proposed. On balance, the Committee was satisfied that the provision of services would be without face to face contact. The Committee was aware that when the pharmacy opens, it will be the responsibility of NHS England, in keeping with Regulation 64, to ensure that services are provided other than with face to face contact.
- 8.47 The Committee was satisfied that the provision of services would be without interruption, would be without face to face contact and would be available to persons anywhere in England. The Committee went on to consider whether safe and effective provision of essential services was likely to be secured.
- 8.48 The Committee considered each essential service in paragraphs 3 to 28 of schedule 4 of the Regulations ("Terms of Service") in turn.
- 8.49 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:

Dispensing of drugs and appliances

- 8.50 The Committee considered whether the Applicant had explained how none electronic prescriptions will be presented by the patient and how products will be provided.
- 8.51 From the information contained in the SOPs, provided on appeal, SOP 6 'Online Order Receipt & Exemption Checking' states:

8.51.1 *“Requests to collect and dispense NHS Prescriptions*

Requests to dispense a prescription received in the post.

Any requests from the “contact us” section of the website.”

- 8.52 The Committee also had regard to SOP 17 ‘Order Delivery’ which under the heading ‘Choice of Delivery Method’ states:

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

- 8.53 The Committee noted the comments with regard to the name of the courier firm(s) to be used not being given. The Committee was of the view that the names of the firms to be used was not relevant as part of its consideration as to whether the Applicant had provided it with evidence to demonstrate how products will be provided to patients requesting them.

- 8.54 The Committee was again satisfied that the Applicant was proposing to offer the service to all of England and, given the information in the SOPs, was of the view that the Applicant would not just be serving the immediate locality using a local delivery driver.

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

Urgent supply without a prescription

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

- 8.57 The Committee had regard to SOP 14 ‘Emergency Supply and Urgent Supply’ which describes how the Applicant will process such a request. The Committee noted that the SOPs refer to Essential Services being delivered by several methods of non-face-to-face communication including telephone and email, and considered that it was reasonable to infer that these methods would be used to receive requests from prescribers for the urgent supply of drugs.

- 8.58 The Committee noted the comments from the Co-op with regard to some patients receiving “urgent” delivery and how this would be achieved “ASAP” for those less local and further noted the response from the Applicant to this. The Committee was of the view that by its very nature the use of a distance selling pharmacy will always mean that there is a slight delay between the dispensing and receipt of medication opposed to a standard “bricks and mortar” pharmacy whereby the dispensing and receipt of the medication can happen almost simultaneously. The Committee consider the SOP before it and was of the view that the Applicant was not operating a “two tier” system for those that required an urgent supply without a prescription but was offering this in line with the procedures as set out in the terms of service.

- 8.59 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.

Preliminary matters before providing ordered drugs or appliances

- 8.60 The Committee considered whether the Applicant had explained how evidence will be sought and provided about the patients' entitlement to exemption or remissions from NHS Charges.
- 8.61 The Committee noted SOP 6 'Online Order Receipt & Exemption Checking' and in particular 'Exempt NHS Prescriptions' which states:
- 8.61.1 *"Where evidence of exemption is required or provided by the patient it can be sent to the pharmacy for verification via the delivery driver and then returned to the patient. The PMR system should be updated to reflect that necessary check has been carried out and a note of when the next check is required should be entered onto the system. The Regulations require a patient to produce 'satisfactory evidence' to confirm exemption. Where appropriate (i.e. for deliveries made other than by the pharmacy's delivery driver), the patient may scan or fax copies of the evidence to the pharmacy (or use the postal / courier service, ...) and the pharmacy can note that the evidence provided was not in original format. It is for the pharmacist in charge to determine if the evidence is satisfactory or not and, if not, then cross the 'Evidence not Seen' box."*
- 8.62 In response to the point raised by Sai Dutt Ltd, the Committee noted that the SOP went on to state:
- 8.62.1 *"Where a patient uses the postal system to provide evidence of exempt status then the patient should be advised to use Special Delivery Postal Services or our own courier service. The pharmacy should cover the cost of any postal/courier for the patient and return documents the same way"*.
- 8.63 The Committee was mindful that they were looking for evidence within the SOPs or application form in order to satisfy itself that it is appropriate to grant the application. The Committee was mindful that it is not looking at risk assessments but that there was evidence provided by the Applicant to demonstrate that the Applicant would be compliant with its Terms of Service.
- 8.64 The Committee was therefore satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 7(3) of Schedule 4.
- 8.65 The Committee considered whether the Applicant had explained how charges will be paid.
- 8.66 The Committee noted SOP 6 under the heading 'Paid NHS Prescription' it states:
- 8.66.1 *"Check to see if any fees have been paid and if so, was the correct amount paid?"*
- Contact the patient to arrange payment using the secure payments system using the "customer not present" option.*
- If no fees have been paid or there is a discrepancy between fees paid and those due, the patient should be contacted and directed to pay the appropriate fees via the online payment system."*
- 8.67 The Committee noted the comments from Sai Dutt Ltd with regard to what would happen if payment was not received. The Committee noted that the SOPs dealt with this situation, as set out above, and that the patient would be contacted by the pharmacy to arrange payment.
- 8.68 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 7(5)(b) of Schedule 4.

Providing ordered drugs or appliances

8.69 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).

8.70 The Committee considered the information before it contained in the SOPs as submitted by the Applicant.

8.71 The Committee noted SOP 17 'Order Delivery' under the heading 'Transfer to the Delivery Driver' states:

8.71.1 *"Ensure that any special instructions for the delivery are included within the packaging.*

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

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

Ensure that any deliveries for fridge items and CDs are taken out of storage when appropriate.

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

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

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

8.72 The Committee noted within the SOPs provided, SOP 17 'Order Delivery' under the heading 'Delivery of a prescription via Royal Mail (Not for Cold chain or CDs)' states:

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

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

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

Confirm details of all prescriptions to be delivered.

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

Ensure Royal Mail driver signs Delivery Log sheet for all prescriptions being accepted for delivery. ...

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

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

8.73 The Committee noted the SOP went on to state, under the heading ‘Cold chain delivery via courier’,:

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

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

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

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

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

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

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

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

Unsuccessful cold chain delivery via courier

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

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

Breach of Integrity of Cold Chain ...

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

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

8.74 The Committee noted that SOP 21 'Controlled Drugs: Delivery' under the heading 'Delivery of Schedule 2 & 3 CD's' states:

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

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

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

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

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

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

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

Successful Schedule 2 & 3 Delivery ...

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

Unsuccessful Schedule 2 & 3 Delivery via pharmacy driver

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

Unsuccessful Schedule 2 & 3 Delivery via courier

Unsuccessful deliveries sent with a courier should be returned to the pharmacy on the same day and entered back into the CD register where appropriate with an explanation. These must then be secured in the CD cabinet where appropriate. Where the time of attempted delivery means that the return cannot

be made on the same day, the courier will store the drugs at their approved warehouse overnight.

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

Note re Use of Couriers for Controlled Drug Deliveries

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

Controlled Drugs will be delivered by the pharmacy driver or courier services with tracked and verifiable audit trails.”

- 8.75 The Committee noted the comment from Sai Dutt Ltd with regard to the local delivery driver and the delivery of medicines using “unknown couriers”. The Committee noted the delivery process as set out in the SOPs by the Applicant for delivery of controlled drugs by both the local delivery driver as well as by couriers. The Committee noted that there was no name provided as to which national courier was to be used, however the Committee was mindful that this is not a requirement of the Regulations. The Committee was of the view that there was sufficient information contained in the SOPs to demonstrate that there would be compliance with the Regulations.
- 8.76 The Committee noted the comments from Sai Dutt Ltd and other parties with regard to reference to a different application for a distance selling pharmacy. The Committee considers each case based on the merits of that particular case and the information which is before it. The Committee further noted that the case referred to was for a completely different applicant who submitted information which they thought was relevant for their application. The Committee took no view on the previous application referred to as it was not relevant to the instant application which was before it.
- 8.77 The Committee has sought evidence within the SOPs and subsequent representations based on this application in order to satisfy itself that it is appropriate to grant the application, the absence of which would require it to reject it.
- 8.78 Based on the information before it, the Committee was satisfied that the Applicant had provided information sufficient to show that there would be compliance with paragraph 8(1) of Schedule 4.
- 8.79 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.
- 8.80 In relation to appliances, the Applicant in its application form stated that it will undertake to provide:
- 8.80.1 “Drug Tariff part IX* (*except items that require measuring or fitting)”.
- 8.81 The Committee noted the relevant SOPs with regard to Appliances which were contained within the information provided by the Applicant and in particular, SOP 7 “Pharmaceutical and Legal Assessment” under ‘Items requiring measuring and fitting’ the Applicant states:
- 8.81.1 “Where a prescription is received for an item that requires measuring or fitting the patient should be contacted and informed that these items are not available from this pharmacy as we do not provide a measuring and fitting service. Patients should be signposted to at least two other providers of the service in their area (see signposting SOP).”

8.82 SOP 24 'Support for Self-Care, Signposting and Health Promotion' under the heading 'Items Requiring Measuring and Fitting' states:

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

8.83 The Committee noted the comment from the Co-op with regard to appliances and the response provided by the Applicant. The Committee noted that some of the appliances listed in Part IX of the Drug Tariff could be considered "normal" dispensary items and the Applicant gave the example of "tape, dressing, eye drop" which would not require measuring or fitting before being dispensed. The Committee noted that the Applicant did not intend to provide appliances which require measuring or fitting.

8.84 In the event that the application is granted, the Applicant would not therefore, be able to provide those appliances as listed in the application form to patients.

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

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

8.87 The Committee noted SOP 16 'Bagging-Up' under the heading 'Choice of Packaging' states:

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

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

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

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

For postal items, either:

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

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

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

Cold chain items should be bubble wrapped and placed in Styrofoam filled re-enforced cardboard boxes and kept in the DELIVERIES FRIDGE (rather than the storage fridge) with the "FRAGILE" and "FRIDGE LINE" stickers attached.

The courier company will transport the boxes in vans with cold chain sections that protect the integrity of the box ("cold ship" packaging) and are fully monitored (see delivery SOP). Pharmacy staff should be aware that some thermolabile products can be damaged by excessive cold as well as heat. Items such as ice packs can cause freezing in medicines which is damaging to them and such items must not be used."

- 8.88 Based on the information before it, the Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 8(15) of Schedule 4.

Refusal to provide drugs or appliances ordered

- 8.89 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.

- 8.90 The Committee noted SOP 33 'Repeat Dispensing' under the heading 'Pharmaceutical & Legal Assessment' states:

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

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

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

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

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

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

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

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

- 8.91 The Committee further noted SOP 33 under the heading 'Prescription Reception' states:

8.91.1 "The pharmacy record card must be completed and attached to a RA and an entry made on each occasion a dispensing takes place. Any amendments to the RD, e.g. items not issued or change to expected interval must be recorded in the comment section of the pharmacy copy of the card."

- 8.92 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

8.93 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.

8.94 The Committee noted in the SOPs provided with the appeal, SOP 33 'Repeat Dispensing' under the heading 'Prescription Reception' states:

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

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

and,

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

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

8.95 In addition the Committee noted that SOP 33 under the heading 'Pharmaceutical and Legal Assessment' states:

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

8.96 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

8.97 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.

8.98 For the return of controlled drugs, the Committee noted SOP 22 'Controlled Drugs: Collection and Disposal of Patient Returns' and in particular the section 'Patient Returned Medication' which states:

8.98.1 *"This service is available to all patients living in England.*

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

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

To arrange the return of unwanted medicines to the Pharmacy the patient must telephone and speak to a member of the dispensary team.

For controlled drugs this should always be the pharmacist on duty.

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

Each return will be made by booking an appointment for the pharmacy's driver to visit the patient's home to collect the returned medication or by sending the appropriate packaging to the patient to arrange for return by Royal Mail...".

- 8.99 The Committee noted that SOP 22 goes on to state, under the heading 'Return by Royal Mail':

8.99.1 *"The pharmacist must*

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

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

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

Contact the patient to ensure that the package has been received

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

- 8.100 The Committee further noted SOP 22 goes on to state, under the heading 'Handling Patient – Returned CDs from Delivery Driver':

8.100.1 "Drivers need to:

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

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

- 8.101 The Committee noted SOP 23 'The Safe and Effective Receipt and Disposal of Medicines' under the heading 'Process for Patients to Return Medication' states:

8.101.1 *"Patient Returned Medication*

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

This service is available to all patients living in England.

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

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

Patients may

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

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

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

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

8.102 The Committee noted that SOP 23 under 'Process for accepting patient returns by the Driver', states:

8.102.1 *"Confirm that a collection of unwanted medication for disposal has been booked. Returns without a booking should only happen in exceptional circumstances....*

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

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

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

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

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

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

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

8.103 The Committee noted that the SOP went on, under the heading 'Disposal of returned medicines', to state:

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

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

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

Promotion of healthy lifestyles

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

- 8.106 The Committee noted SOP 25 'Promotion of Healthy Living, Lifestyle & Health Campaigns' under the heading 'Health Campaigns and Community Engagement Exercise' states:

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

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

- 8.107 Further, in SOP 25 under the heading 'Identification of patients for promotion of Healthy Lifestyles' it states:

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

- 8.108 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.

Prescription linked intervention

- 8.109 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.

- 8.110 The Committee noted SOP 25 'Promotion of Healthy Living, Lifestyle & Health Campaigns' under the heading 'Identification of patients for promotion of Healthy Lifestyles' states:

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

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

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

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

patient' and the appropriate information that is relevant to them should be provided.

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

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

Health campaigns

- 8.112 The Committee considered whether the Applicant had explained how it will safely and effectively participate in health campaigns, if and to the extent required by NHS England.

- 8.113 The Committee noted under SOP 25 'Promotion of Healthy Living, Lifestyle & Health Campaigns' under the heading 'Health Campaigns and Community Engagement Exercise' it states:

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

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

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

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

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

Signposting

- 8.115 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.

- 8.116 The Committee noted in SOP 24 'Support for Self-Care, Signposting and Health Promotion' under the heading 'Signposting' and what appears to be intended as a sub heading 'Patient Identification' it states:

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

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

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

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

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

8.117 The Committee noted that in SOP 24 under the heading ‘Other Provider Organisations and Support Details’ it states:

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

8.118 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 19 – 20 of Schedule 4.

Support for self-care

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

8.120 The Committee noted SOP 24 ‘Support for Self-Care, Signposting and Health Promotion’ under the heading ‘Support for self-care’ ‘Service outline’ states:

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

Advice should be backed up, as appropriate, by the provision of written material such as leaflets.

When such a request is received, the pharmacist should be informed and a record kept of the request.

Advice (and requests for advice) must operate without face-to face interaction (e.g. telephone, Live video, via the website).”

8.121 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.

Discharge medicines service

8.122 The Committee considered whether the Applicant had explained how it will provide advice, assistance and support to and in respect of a health service patient – (a) recently discharged from hospital who is referred to P for advice, assistance and support in respect of the patient's medication regimen by the staff of the hospital in

which the patient stayed; or (b) who is otherwise referred to P for advice, assistance and support in respect of the patient's medication regimen by the staff of an NHS trust or NHS foundation trust as part of arrangements linked to the transfer of care between different providers of NHS services.

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

8.124 The Committee noted SOP 26 "Discharge Medicines Service ("DMS") states:

8.124.1 "Process

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

DMS Stages

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

Additional advice, assistance and support

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

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

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

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

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

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

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

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

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

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

Inform the patient / carer about

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

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

Follow up

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

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

- 8.125 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 22B and 22C of Schedule 4.

Websites and health promotion zones

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

- 8.127 The Committee noted SOP 24 "Support for Self-care, signposting and health promotion, under the heading "Health promotion zone on our website" it states:

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

Explaining the Interactive Page to Patients

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

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

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

8.128 The Committee noted further reference is made to health promotion zones in SOP 25 'Promotion of Health Living, Lifestyle & Health Campaigns' under 'Identification of patients for promotion of Health Lifestyles' which states:

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

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

8.130 The Committee noted the comments from the Co-op with regard to the NHS mail email address. The Committee noted that the Applicant had stated that they would be applying for NHS mail email accounts if the application was granted. The Committee was of the view that, for instances where a NHS mail account is required, the Applicant had set out that they would have one in place and that it would be checked by staff. The Committee took no view on whether parties were seeking a higher level of assurance than was required. The Committee was mindful that it had to be satisfied that, based on the information provided by the Applicant, there would be compliance with the relevant Terms of Service as set out in the Regulations and, based on the information before it, the Committee was satisfied.

Summary

8.131 On the information before it, the Committee could be satisfied that there are procedures likely to secure safe and effective provision of essential services as required by Regulation 25(2)(b).

8.132 In those circumstances, given that the Committee has provided full reasoning as to why the application should be granted rather than stating that Regulation 25 was met the Committee determined that the decision of NHS England must be quashed.

8.133 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 NHS England) or whether it was preferable for the Committee to reconsider the application.

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

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

9 Decision

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

9.2 Accordingly, the Committee:

9.2.1 quashes the decision of NHS England; and

9.2.2 redetermines the application as follows -

9.2.2.1 the Committee was satisfied that the proposed premises were not adjacent to or in close proximity to other chemist premises and further

that it was not reasonable to treat the proposed services as part of the same services as the existing services,

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

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

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

9.2.2.5 the Committee was satisfied that all essential services were likely to be secured in a safe and effective manner,

9.2.2.6 the Committee was satisfied that all essential services were likely to be secured without face to face contact;

9.2.3 The application is granted.

**Case Manager
Primary Care Appeals**