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**REF: SHA/26394**

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**APPEAL AGAINST HAMPSHIRE AND ISLE OF WIGHT  
ICB DECISION TO GRANT AN APPLICATION BY  
HAMRO HEALTHCARE LTD FOR INCLUSION IN THE  
PHARMACEUTICAL LIST AT ROOM 4&6, 119 WREN  
WAY, FARNBOROUGH, GU14 8XJ UNDER  
REGULATION 25**

**1 Outcome**

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

A copy of this decision is being sent to:

Rushport Advisory LLP on behalf of Hamro Healthcare Ltd  
Day Lewis plc  
PCSE on behalf of Hampshire and Isle of Wight ICB

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## 1 The Application

By application dated 9 May 2024, Hamro Healthcare Ltd (“the Applicant”) applied to Hampshire and Isle of Wight ICB (“the Commissioner”) for inclusion in the pharmaceutical list at Room 4&6, 119 Wren Way, Farnborough, GU14 8XJ 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\*

1.1.2 \* 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 is not on the same site or in the same building as the premises of a provider of primary medical services with a patient list.”

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

- 1.4 The information contained within this document has been approved by the applicant prior to submission.

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

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

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

1.6 NHS England Premises Standards

1.7 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.

1.8 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.

1.9 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

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

1.11 The Applicant will have in place, prior to opening the following;

Risk Assessment

1.12 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 minimise risk.

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

Audit Procedures

1.14 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.

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

1.15.1 staffing levels and the training and skills within the team

1.15.2 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)

1.15.3 use of specialised equipment and new technology

1.15.4 records of decisions to make or refuse a sale

- 1.15.5 systems and processes for receiving prescriptions, including EPS records of decisions to make or refuse a sale (note that our pharmacy SOPs will require more frequent analysis of refusals to sell)
- 1.15.6 systems and processes for secure delivery to patients
- 1.15.7 any information about pharmacy services on the website
- 1.15.8 review of how the pharmacy adheres to the information security policy, Payment Card Industry Data Security Standard (PCI DSS) and data protection law
- 1.15.9 feedback from patients and people who use our pharmacy services
- 1.15.10 concerns or complaints received, and
- 1.15.11 activities of third parties, agents or contractors
- 1.16 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

- 1.17 A reactive review will take place if an audit identifies a problem, or if there is;
  - 1.17.1 a change in the law affecting any part of the pharmacy service
  - 1.17.2 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
  - 1.17.3 a data security breach
  - 1.17.4 a change in the technology the pharmacy uses
  - 1.17.5 concerns or negative feedback are received from patients or people who use the pharmacy services
  - 1.17.6 a review of near misses and error logs causes a concern about an activity

#### Accountability

- 1.18 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

- 1.19 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

- 1.20 We 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

- 1.21 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

- 1.22 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.

- 1.23 The website will display;

1.23.1 the GPhC pharmacy registration number

1.23.2 the name of the owner of the registered pharmacy

1.23.3 the name of the superintendent pharmacist

1.23.4 the name and address of the registered pharmacy that supplies the medicines

1.23.5 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)

1.23.6 information about how to check the registration status of the pharmacy and the superintendent pharmacist

1.23.7 details of specific services available and how to use them, i.e.

1.23.7.1 Return of unwanted medicines

1.23.7.2 Patient Lifestyle Questionnaire

1.23.7.3 How to register exemptions from NHS charges

1.23.7.4 Promotion of Health Lifestyles and details of campaigns being undertaken

1.23.7.5 Procedures for Emergency Supply

1.23.7.6 Explanation of rules on non face to face contact

1.23.7.7 Patient Information Leaflet

1.23.8 the email address and phone number of the pharmacy

1.23.9 details of how patients and users of pharmacy services can give feedback and raise concerns

1.23.10 GPhC internet logo (linked to register entry)

1.23.11 Where any medicines are sold online, the pharmacy will be registered with the appropriate agency for online pharmacies

1.23.12 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

1.24 The pharmacy will allow the public to access pharmaceutical services from the pharmacy premises via a website 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. NOTE - this is a new requirement under the Regulations and does not allow access to essential pharmaceutical services in a face to face manner at the premises and only applies to access via the website.

#### Transparency and Choice

1.25 Our website and materials will specify the nature and type of services we provide and who provides those services.

1.26 If any part of our pharmacy services is provided at different locations we will explain clearly to people who use pharmacy services where each part of the service is based.

#### Managing Medicines Safely

1.27 The pharmacy SOPs will provide the procedures for all staff to follow to ensure that the sale and supply of medicines is carried out in such a manner as to minimise risk to patients.

#### Supplying Medicines Safely

1.28 The SOPs for delivery of medicines will contain detailed information on the safe and effective supply of medicines via the pharmacy's own driver, Royal Mail and courier firms, including;

1.28.1 assess the suitability and timescale of the method of supply, dispatch, and delivery for all medicines and particularly refrigerated medicines and controlled drugs

1.28.2 ensuring that robust identity check processes are in place to ensure that the medicines dispensed are delivered to the correct person.

1.28.3 assess the suitability of packaging (for example, packaging that is tamperproof or temperature controlled)

1.29 The pharmacy will monitor third-party providers, including analysis of patient feedback about deliveries and delivery times and processes.

#### Equipment and Facilities

1.30 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.

1.31 All equipment will be subject to annual performance testing and review, with specialist equipment (such as temperature monitoring) subject to monthly checks.

- 1.32 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

- 1.33 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.

#### PHARMACY SYSTEMS AND PROCEDURES

- 1.34 All Essential Services will be delivered in accordance with:

1.34.1 Company Standard Operating Procedures

1.34.2 NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013

1.34.3 NHS Act 2006

1.34.4 Human Medicines Regulations 2012

1.34.5 GPhC – Professional Standards and Guidance on Distance Selling Pharmacies

1.34.6 Relevant Data Protection laws

- 1.35 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.

- 1.36 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.

- 1.37 Access to information about the provision of NHS Essential Services will be achieved by using:

1.37.1 Telephone

1.37.2 Live Video Call

1.37.3 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.

1.37.4 Email

1.37.5 Postal services

- 1.38 All NHS services will be delivered free of charge in accordance with the NHS Act 2006.

- 1.39 Essential Services may be delivered using:
- 1.39.1 Telephone, including text messaging where appropriate
  - 1.39.2 Electronic Prescription Service (EPS)
  - 1.39.3 Website
  - 1.39.4 Email
  - 1.39.5 Royal Mail postal service
  - 1.39.6 Courier service
  - 1.39.7 Specialist Waste Management Services
  - 1.39.8 Live video services.
  - 1.39.9 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.
- 1.40 Provision of NHS Essential Services
- Dispensing Services
- 1.41 Prescriptions will be received by the EPS, post, 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.
  - 1.42 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.
  - 1.43 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
- 1.44 The Terms of Service require pharmacy contractors to ensure that appropriate advice about the benefits of repeat dispensing is given to any patient who—
    - 1.44.1 (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
    - 1.44.2 (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.
  - 1.45 Such advice will be provided by the Pharmacy using its permissible methods of non face-to-face contact with patients.

- 1.46 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. 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.
- 1.47 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

- 1.48 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.
- 1.49 The request may be received from a Prescriber (Urgent Supply) or from a Patient (Emergency Supply).
- 1.50 The following conditions must apply to the request made by a prescriber:
- 1.50.1 The Pharmacist must be satisfied that the request is from the appropriate authorised prescriber, see list above.
  - 1.50.2 The Pharmacist is satisfied that a prescription cannot be supplied immediately due to an emergency.
  - 1.50.3 The Prescriber agrees to provide a written prescription within 72 hours.
  - 1.50.4 The medication is supplied in accordance with the prescriber's directions.
  - 1.50.5 The medication is permitted to be supplied on an Emergency Supply basis.
    - 1.50.5.1 An emergency supply cannot be provided for a Schedule 1, 2 or 3 CD except Phenobarbital for epilepsy by a UK registered prescriber.
  - 1.50.6 EEA prescribers cannot request an emergency supply of any Schedule 1 - 5 CD.
- 1.51 Full records of the supply will be kept as per the relevant SOP.
- 1.52 The following conditions must apply to the request made by a patient:
- 1.53 Interview
- 1.54 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.
- 1.55 Records
- 1.56 An entry must be made in the POM register on the day of supply and record all the relevant details. The label for the dispensed medicine must contain the words "Emergency Supply".
- 1.57 Faxed Prescriptions

- 1.58 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.
- 1.59 The pharmacist should not dispense against faxed prescriptions and instead should use the Emergency Supply procedures.

#### Delivery of Urgent Supplies

- 1.60 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 procedures will apply.

#### Disposal of Unwanted Medicines

- 1.61 Patients will have a number of options for disposal of unwanted medicines.
- 1.61.1 A specialist waste management company will provide safe and secure disposal of unwanted medicines by collection of unwanted medicines from patients and residential homes.
- 1.61.2 Patients wishing to return unwanted medicines to the pharmacy may do so by courier, which will be provided and paid for by the pharmacy.
- 1.61.3 Patients in locality may contact pharmacy by phone or email to arrange collection of unwanted medicines from their home or work by pharmacy staff.
- 1.62 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.
- 1.63 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 and any marketing leaflets.

#### Promotion of Healthy Lifestyles

- 1.64 Identification of patients for promotion of healthy lifestyles can take two forms, namely, passive or active.
- 1.65 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.
- 1.66 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.
- 1.67 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.

- 1.68 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

- 1.69 The Pharmacy will take part in national health campaigns to promote health messages to our 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.
- 1.70 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.
- 1.71 Patients should also be assessed for participation in at least one clinical audit and whichever of the following that the NHSCB specifies—
- 1.71.1 (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
- 1.71.2 (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

- 1.72 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.
- 1.73 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.
- 1.74 If a patient;
- 1.74.1 (a) requires advice, treatment or support that the pharmacy cannot provide; but
- 1.74.2 (b) 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,
- 1.75 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

- 1.76 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—
- 1.76.1 (a) if the patient consents, refer the prescription form or repeatable prescription to another NHS pharmacist or to an NHS appliance contractor; and
- 1.76.2 (b) 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.
- 1.77 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

- 1.78 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.
- 1.79 The Applicant will conduct an initial assessment with the patient, care 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.
- 1.80 Compliance aid systems such as blister packs/dosette boxes will be provided in compliance with both service levels 1 & 2 respectively.
- 1.81 Clinical Governance
- 1.82 Note: Clinical Governance is not an 'essential service' and is therefore dealt with briefly in this submission.
- 1.83 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 Pharmacist and Pharmacy Technician CPD, conducting clinical audits, workforce survey and drug recalls.
- 1.84 '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.
- 1.85 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.
- 1.86 All staff will have an annual appraisal, receive and provide feedback.

## Information Governance

- 1.87 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.
- 1.88 The pharmacy will receive support from the PMR provide to ensure that continuous access to the Electronic Prescription System is maintained.
- 1.89 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")

- 1.90 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.
- 1.91 Under the DMS the pharmacy must provide assistance and support to, and in respect of, an NHS patient
- 1.91.1 (a) 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
- 1.91.2 (b) 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.
- 1.92 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.
- 1.93 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.
- 1.94 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.
- 1.95 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")

- 1.96 The pharmacy will provide medicines properly requested under any PTP arrangements.
- 1.97 The RP should (and if requested to do so by the person being supplied must)
- 1.97.1 Provide an estimate of the time the drug will be ready and delivered.
- 1.97.2 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.
- 1.97.3 Contact the patient to confirm dispatch of the medication.
- 1.98 In addition to the normal requirements, the dispensing label on the packaging of the product supplied must also contain the additional wording shown below;
- 1.99 And insert the name of the relevant protocol.

#### Refusal to Supply under PTP

- 1.100 The pharmacy may refuse to provide an order for a drug that is or is purportedly in accordance with a PTP where—
- 1.100.1 (a) 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;
- 1.100.2 (b) providing it would be contrary to the RP's clinical judgement; THIS PRODUCT IS BEING SUPPLIED IN ACCORDANCE WITH THE [INSERT NAME] PANDEMIC TREATMENT PROTOCOL
- 1.100.3 (c) 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
- 1.100.4 (d) the person who requests the provision of the drug, or any persona accompanying (see footnote re “accompanying”) that person, commits or threatens to commit a criminal offence.
- 1.101 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.
- 1.102 Any refusal to supply must be noted on the patient and / or pharmacy record system.

#### Delivering Medicines

- 1.103 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.
- 1.104 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.
- 1.105 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).

- 1.106 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.
- 1.107 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.
- 1.108 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.
- 1.109 Medicine for local delivery which is (A) not fragile and (B) is to be delivered by the delivery driver can be packaged in the using the normal pharmacy bags supplied for standard prescription items.
- 1.110 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 siftproof container (for solids). Must be tightly packed in strong outer packaging and must be secured or cushioned to prevent any damage.
- 1.111 This means that for postal / courier items, either:
- 1.112 At the very least - padded envelopes even for non-fragile items as this will help to ensure the integrity of the manufacturers packaging.
- 1.113 For most items - bubble wrap and where necessary, polystyrene filler, placed within a cardboard box. Cardboard boxes must be the re-enforced type.
- 1.114 Large or any fragile medicines should be packed into cardboard boxes with bubble packaging and filling material to protect from damage.
- 1.115 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.
- 1.116 A list of the approved cold chain couriers will be maintained within the Pharmacy. Coldchain items will 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. 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 will therefore not be used in direct contact with any medicine. The courier service will be a dedicated, fully monitored and temperature controlled delivery service. Any breach of the cold chain will be 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 will not be re-used.

## Controlled Drugs

### Delivery of Controlled Drugs

- 1.117 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.

#### Return and Destruction of CONTROLLED DRUGS

- 1.118 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.
- 1.119 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

- 1.120 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

- 1.121 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

- 1.122 The reverse of the prescription should be fully completed (other than age exempt patients) in black ink.
- 1.123 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 (ie for deliveries made other than by the pharmacy's delivery driver), the patient may scan 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.

- 1.124 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.
- 1.125 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. Scanned email copies of exemptions are also acceptable.
- 1.126 The nature of any exemption will be recorded on the PMR system with a copy attached to the patient's file.
- 1.127 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

- 1.128 The pharmacy profile will be properly maintained in the NHS Digital Directory of Services Central Alerting System.
- 1.129 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

- 1.130 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

- 1.131 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—
  - 1.131.1 (i) the essential services provided at or from the premises are only available to persons in particular areas of England, or
  - 1.131.2 (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

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

## 2 The Decision

The Commissioner considered and decided to grant the application. The decision letter dated 25 October 2024 states:

- 2.1 “Hampshire and Isle of Wight ICB has considered the above application and I am writing to confirm that it has been granted. Please see the enclosed report for the full reasoning.”

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

#### “The Application

- 2.2 An application from Hamro Healthcare Ltd for a Distance Selling Premises Application was received on 24 May 2024, from the address of 119 Wren Way, Farnborough, GU14 8XJ
- 2.3 The Committee was now required to consider the application in accordance with Regulation 25 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended.

#### Consideration

- 2.4 The Committee considered the following:
- 2.5 The NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended.
- 2.6 Department of Health guidance on Distance Selling Premises.
- 2.7 The application form provided by the Applicant.
- 2.8 Representations made by Boots UK Ltd, Day Lewis Plc, and Hampshire and Isle of Wight LPC. The Committee noted that Day Lewis Plc opposed the application.
- 2.9 The Applicant's response to the representations received during the consultation period.
- 2.10 The Committee decided it was not necessary to hold an oral hearing before determining the application.
- 2.11 A map of the locality showing the nearest community pharmacies and GP Surgeries, in relation to the proposed premises for the Distance Selling pharmacy.
- 2.12 The Committee noted that a site visit had not been undertaken as this application for a distance selling pharmacy is not visited by members of public.

#### Regulation 31 – Refusal: same or adjacent premises

- 2.13 The Committee noted that it was required to refuse an excepted application, if the two conditions under paragraph 31(2) applied. These conditions are –
- 2.13.1 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 the premises to which the application relates, or adjacent premises; and
- 2.13.2 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).

- 2.14 The Committee was satisfied there is no pharmacy providing pharmaceutical services at the same or adjacent premises. The application did not therefore need to be refused in accordance with Regulation 31.
- 2.15 The Committee noted that the Applicant stated on the application form that it does intend to provide the New Medicines Service advanced service remotely with consent where required.
- 2.16 The Committee noted that the pharmacy intends to open for 40 core hours per week.
- 2.17 The Committee went on to consider the reasons provided by the Applicant as to why the application should not be refused.
- Regulation 25(1)
- 2.18 The Committee noted that as this was a distance selling application Regulation 25(1) indicates that section 129(2A) of the National Health Service Act 2006 does not apply, provided that Regulation 25(2) does not require the application to be refused.
- Regulation 25(2)(a)
- 2.19 The Committee noted the proposed address and that it is not in the same site or building as a provider of primary medical services with a patient list. The Committee therefore did not have to refuse the application under Regulation 25(2)(a).
- 2.20 Regulation 25(2)(b)
- 2.21 The Committee noted that it had to be satisfied that services would be provided on an uninterrupted basis to patients anywhere in England who request those services and that essential services would be provided safely and effectively without face-to-face contact between any person receiving the services whether on their own or on someone else's behalf, and the applicant or the applicant's staff.
- 2.22 The Committee noted that the applicant had stated that: all essential services would be delivered in accordance with the relevant regulations, professional standards and company standard operating procedures and that provision would be uninterrupted to persons anywhere in England who request those services during the opening hours of the premises.
- 2.23 The Committee noted the proposed audit procedures and that there will always be a responsible pharmacist on site during opening hours with accountability set out by the superintendent pharmacist. The Committee noted the details relating to the website and the offer of services to patients via that means.
- 2.24 The Committee was satisfied that, based on the information provided, there would be uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services during the stated opening hours.
- 2.25 The Committee went on to consider whether essential services would be provided safely and effectively without face-to-face contact between any person receiving the services whether on their own or on someone else's behalf, and the applicant or the applicant's staff.
- 2.26 The Applicant had confirmed that 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. The 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. Access to information about Essential Services will be achieved by using telephone, Live Video Call, the website, email and postal services. Essential services would be delivered via a number of methods including telephone, EPS, website, email, postal services, courier services, specialist waste management services, video services and specialist cold chain courier services.

#### Schedule 4 Terms of service of NHS pharmacists

- 2.27 The Committee took the view that where compliance with the Terms of Service would ordinarily require face to face contact, the Applicant must explain how it is going to achieve compliance (and therefore safe and effective provision) without face-to-face contact.
- 2.28 The Committee considered Schedule 4 to the Regulations having regard to the additional information supplied by the Applicant in support of the application.
- 2.29 Schedule 4, paragraph 5(2) & (3) - the Committee considered whether the Applicant had explained how patients would present prescriptions. The Committee noted the Applicant's comments which stated that prescriptions will be received by the EPS, post, or where practicable, with the patient's informed consent, collected from a surgery. They had also described the means of supplying dispensed prescriptions.
- 2.30 The Committee was satisfied that paragraph 5(2) & (3) would be complied with effectively without face-to-face contact.
- 2.31 Schedule 4, paragraph 6 - the Committee considered whether the Applicant had explained how in a case of urgency at the request of a prescriber drug or appliance would be provided to a patient. The Committee noted the Applicant's supporting information which acknowledged that such requests would be unlikely to occur often in a distance selling pharmacy. However, they had gone on to describe the processes and had described the way the legal requirements would be met in terms of the patient interview and records.
- 2.32 They had also described that such requests would be prioritised for urgent local or courier delivery.
- 2.33 The Committee was satisfied that paragraph 6 would be complied with effectively.
- 2.34 Schedule 4, paragraph 7 – the Committee considered whether the Applicant had explained how evidence would be sought and provided about the patient's entitlement to exemption from NHS Charges. The Applicant had explained that for local patients, 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. Exemptions may also be sent to the pharmacy by post and the pharmacy will pay for postage and return the exemption to the patient free of charge. 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. In all instances. The PMR system would 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.
- 2.35 The Committee was satisfied that paragraph 7 would be complied with effectively.
- 2.36 Schedule 4, paragraph 8(1) – the Committee considered whether the applicant had explained how items would be provided to patients including protection of the cold chain

and requirements of the misuse of drugs act. The Committee noted the Applicant's comments which included information about deliveries. They stated that medicines will be packed, transported, and delivered in such a way that their integrity, quality and effectiveness is 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. They went on to describe management of the cold chain including packaging, labelling, and an appropriate courier service. Delivery of controlled drugs will be carried out by couriers with pharma grade specialist facilities to meet specific quality and validation requirements.

- 2.37 The Committee noted that in addition to the broader information provided as part of the application, that very specific details were also available in the SOPs that had been provided as part of their response to comments from interested parties.
- 2.38 The Committee was satisfied that paragraph 8(1) would be complied with effectively.
- 2.39 Schedule 4, paragraph 8(15) – the Committee considered whether the applicant had explained how drugs would be provided in a suitable container suitable for posted/delivered items. The Committee noted the Applicant's comments which confirmed that suitable package would be used for deliveries and that there would be differentiation in terms of the packaging used for different medicine types and delivery methods.
- 2.40 The Committee was satisfied that paragraph 8(15) would be complied with effectively.
- 2.41 Schedule 4, paragraph 9(4) – the Committee considered whether the applicant had explained how for repeatable prescriptions they would assess that the patient is taking/using the item(s) appropriately and is not suffering from any side effects. The Committee noted the Applicant's comments which stated that the advice required for repeat dispensing would be provided using its non-face to face methods for communication. The SOPs covered this in more detail, stating that the pharmacist would telephone the patient to ask the relevant questions and provide advice before issuing the prescription.
- 2.42 The Committee was satisfied that paragraph 9(4) would be complied with effectively.
- 2.43 Schedule 4, paragraph 10(1) – the Committee considered whether the applicant had explained how it would provide appropriate advice about the use of drugs/appliances, safe keeping of items and returning of unwanted items be given. How it would advise regarding importance of only ordering items actually needed (repeatable prescriptions and appliances). The Committee noted the Applicant's comments which stated that the advice required for repeat dispensing would be provided using its non-face to face methods for communication. The SOPs covered this in more detail, stating that the pharmacist would telephone the patient to ask the relevant questions and provide advice before issuing the prescription.
- 2.44 The Committee was satisfied that paragraph 8(1) would be complied with effectively.
- 2.45 Schedule 4, paragraph 14 - The Committee considered whether the Applicant had explained how it would accept unwanted drugs from patients and how patients will be advised on returning unwanted items. The Committee noted the Applicant's comments which outlined the options for disposal of unwanted medicines – i.e., a specialist waste management company for residential homes, return via a courier (paid for by the pharmacy) or local collection. Appropriate packaging will be made available, and the service will be advertised on the website/app and marketing leaflets.

- 2.46 The Committee concluded that it was satisfied that the requirement of paragraph 14 would be complied with safely and effectively.
- 2.47 Schedule 4, paragraph 17 – The Committee considered whether the Applicant had explained or otherwise demonstrated 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.
- 2.48 The Committee noted information provided in the application which states that there will be “active” and “passive” approaches. A questionnaire will be available via the website which would identify whether further information was required. In some cases, patients will choose to complete the questionnaire without being asked to and others will be identified and asked to complete the questionnaire. Leaflets will be delivered with medication and there will also be targeted campaigns.
- 2.49 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.
- 2.50 Schedule 4, paragraph 18 – The Committee considered whether the Applicant had explained how it would participate in health campaigns. The Committee noted the Applicant’s comments which confirmed that the pharmacy would participate in the national health campaigns and that this would be done by sending out leaflets during the period of the campaign and providing additional advice and learning resources via the website.
- 2.51 Patients would be directed to the resources via email, text and other non-face to face communication so that they are aware of the campaign.
- 2.52 The Committee considered it had been provided with sufficient information and was satisfied that paragraph 18 would be complied with safely and effectively.
- 2.53 Schedule 4, paragraph 20 – The Committee considered whether the Applicant had demonstrated how it would assess patients’ needs before signposting them in order to minimise inappropriate use of health or social care services. The Committee noted the Applicant’s comments which stated that the same active and passive assessment tool (as set out above) would be used. If the pharmacy is not able to provide the appropriate advice, treatment, or support, they will provide contact details of another suitable provider and in some cases refer the patient to that provider. Advice would be provided via non face to face methods.
- 2.54 The Committee concluded the Applicant had demonstrated how it would assess patients’ need before signposting them to minimise inappropriate use of health or social care services.
- 2.55 Schedule 4, paragraph 21 – The Committee considered whether the Applicant had demonstrated how it would provide advice or support for people caring for themselves or their families. The Committee noted the Applicant’s comments which also referred to the active and passive assessment tool and advice on treatment options, non-prescription medicines and lifestyle - that would be offered via non face to face methods. The Committee noted that the SOPs went into more detail about requests for advice and included recording advice on self-care.
- 2.56 The Committee concluded the Applicant had demonstrated how it would provide advice or support for people caring for themselves or their families.

- 2.57 Schedule 4, paragraph 22(b) & 22(c) - 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
- 2.57.1 recently discharged from hospital who is referred to P for advice, advice and support in respect of the patient's medication regimen by the staff of the hospital in which the patient stayed;
- 2.57.2 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 arrangement linked to the transfer of care between different providers of NHS services.
- 2.58 Further the Committee considered whether the Applicant had explained what procedures it had in place for checking referrals for the discharge medicines services.
- 2.59 The Committee noted that the information received as part of the application sets out the requirements for the service. However, from the information that has been provided regarding how the applicant will deal with patients via the internet and by telephone, the Committee had no reason to believe they would not deliver the Discharge Medicines Service in this way. The SOPs that were submitted in response to comments from interested parties included further detail including that a live video or audio call would be arranged.
- 2.60 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 22(b) and 22(c) of Schedule 4.
- 2.61 Schedule 4, paragraph 28 – The Committee considered whether the Applicant had demonstrated how it would comply with all components of clinical governance element of the Terms of Service. The Committee noted the Applicant's comments which stated:
- "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 Pharmacist and Pharmacy Technician CPD, conducting clinical audits, workforce survey and drug recalls. '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. 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. All staff will have an annual appraisal, receive and provide feedback."*
- 2.62 The Committee concluded the Applicant had demonstrated how it would comply with all components of clinical governance element of the Terms of Service (paragraph 28).
- 2.63 Schedule 4, paragraph 28(c) - The Committee considered whether the Applicant had explained how it will ensure that it has a website for the 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.
- 2.64 The Committee noted information provided in the application which states:
- "The pharmacy will allow the public to access pharmaceutical services from the pharmacy premises via a website 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. NOTE - this is a new requirement under the Regulations and does not allow access to essential pharmaceutical services in a face-to-face manner at the premises and only applies to access via the website."*

- 2.65 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 28(c) of Schedule 4.
- 2.66 In relation to all other essential services, the Committee was, on balance, satisfied that procedures adopted by the pharmacy (and general adherence to the Terms of Service) would be "likely to secure" safe and effective provision.
- 2.67 The Committee concluded that essential services would be provided safely and effectively without face-to-face contact between any person receiving the services whether on their own or on someone else's behalf, and the applicant or the applicant's staff.

#### Decision

- 2.68 The Committee concluded that it was not required to refuse the application under the provisions of Regulation 31.
- 2.69 The Committee determined the application as follows –
- 2.69.1 the Committee was satisfied that the proposed premises were not adjacent to or in close proximity to other chemist premises.
- 2.69.2 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.
- 2.69.3 the Committee was satisfied that all essential services were likely to be secured without interruption during the stated opening hours.
- 2.69.4 the Committee was satisfied that all essential services were likely to be secured for persons anywhere in England.
- 2.69.5 the Committee was satisfied that all essential services were likely to be secured in a safe and effective manner.
- 2.69.6 the Committee was satisfied that all essential services were likely to be secured without face-to-face contact.

- 2.70 The Committee determined to grant the application.

#### Regulation 64(3)

- 2.71 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, as amended, if the applicant is subsequently included in the pharmaceutical list for the area of Hampshire Health and Wellbeing board in respect of the premises included in the application that inclusion will be subject to the following conditions:
- 2.71.1 The applicant must not offer to provide pharmaceutical services to persons who are present at (which includes in the vicinity of) the proposed premises.

- 2.71.2 the means by which the applicant provides pharmaceutical services must be such that any person receiving those services does so otherwise than at the proposed premises.
- 2.71.3 the proposed premises must not be on the same site or in the same building as the premises of a provider of primary medical services with a patient list.
- 2.71.4 the pharmacy procedures for the premises must be such as to secure:
  - 2.71.4.1 the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services, and
  - 2.71.4.2 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
- 2.71.5 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:
  - 2.71.5.1 the essential services provided at or from the premises are only available to persons in particular areas of England, or
  - 2.71.5.2 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)

#### Third Party Rights Of Appeal

- 2.72 The application is granted so the applicant does not have appeal rights.
- 2.73 The Committee decided that the following parties that should have third party rights of appeal as they had expressed their grounds for opposing the application adequately in their representations.
  - 2.73.1 Day Lewis Plc t/a Day Lewis Pharmacy FH527, 15 Churchill Crescent, Hawley Estate, Hampshire, GU14 8EL."

### 3 The Appeal

In a letter dated 21 November 2024, Day Lewis plc ("the Appellant") appealed against the Commissioner's decision. The grounds of appeal are:

- 3.1 "We have been notified by NHS England, in a letter dated 25<sup>th</sup> October 2024, that the above application has been approved. I enclose a copy of that letter for your information.
- 3.2 On behalf of Day Lewis Plc I wish to appeal this decision for the following reasons:

- 3.3 We raised several points of objection in our letter to NHS England on 9<sup>th</sup> July 2024. I have enclosed a copy of that letter.
- 3.4 We believe that the reasons for approving this application are flawed. On behalf of our client, therefore, we appeal against the decision to approve this application for the following reasons:
- 3.5 To our knowledge the applicant did not respond to the objections we raised and therefore NHS England was not in receipt of the information it needed to be satisfied that the requirements of Regulation 25 have been met.
- 3.6 Furthermore, the decision report provided by NHS England makes no reference to having considered the legitimate concerns of objectors in making its decision to approve the application.
- 3.7 Our grounds of appeal are therefore that the application does not meet the regulatory tests for the reasons we have raised previously and should therefore have been refused. Namely:
- 3.7.1 Without the provision of a full set of Standard Operating Procedures NHS England was not in possession of sufficient information to approve the application.
- 3.7.2 There is no information provide [sic] on measures that will be in place to ensure the continuity of service in the case of unplanned pharmacist absences.
- 3.7.3 There is no information is respect of how patients with impaired vision or other disabilities will be able to access essential pharmaceutical services without face to face contact.
- 3.7.4 There is other information within the application (referred to in our letter of objection) that would suggest that services may not be provided safely.
- 3.8 In summary, we believe that NHS England has failed to properly consider regulation 25 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 in determining this application and that its decision to approve the application is flawed.
- 3.9 Should Primary Care Appeals decide to hold an oral hearing to consider this matter we would wish to attend.”

In a letter dated 9 July 2024 addressed to the Commissioner, the Appellant stated:

- 3.10 “Thank you for your letter dated 19<sup>th</sup> June informing us of the above application. On behalf of Day Lewis Plc, who provide pharmaceutical services from premises at Access House, Strawberry Hill, Newbury RG14 I would like to object to this application for the following reasons:
- 3.11 Firstly, we note that the applicant does not appear to have provided a full set of detailed Standard Operating Procedures (“SOPs”). This is apparent from the front page of the SOP document provided which states:
- [Note: This is not a complete list of SOPs for the operation of the pharmacy. These SOPs are provided to demonstrate how essential services will be provided in a safe and effective manner without face-to-face contact with the patient.]*
- 3.12 The applicant lists various Advanced and other services it intends to provide but does not provide SOPs for these. Whilst the applicant states on the application form that it

does not intend to provide these services face to face (notwithstanding that the regulations do not prevent it from doing so), as SOPs have not been provided the mechanism for delivering these services is not clear.

- 3.13 This leaves significant doubt in respect of the applicant's compliance with the requirements of an application made under Regulation 25.
- 3.14 We would suggest that the ICB will not be in a position to grant this application if it is not in possession of this information in full. Whilst the applicant has provided some limited supporting information in respect of this application there are many gaps in the information provided.
- 3.15 The ICB is being asked to determine whether the application meets the regulatory tests and can therefore be approved. This can only be determined by reviewing each and every SOP in detail to ensure that:
- 3.15.1 (a) all essential services will be provided without interruption during the proposed opening hours of the pharmacy;
  - 3.15.2 (b) all essential services will be made available to anybody in England who wishes to access them;
  - 3.15.3 (c) all essential services are likely to be secured in a safe and effective manner;
  - 3.15.4 (d) all essential services will be provided without the face to face contact between any person receiving the services, whether on their own or on someone else's behalf, and the applicant or the applicant's staff.
- 3.16 In the absence of a full set of SOPs we do not believe that the ICB can be confident that the requirements of Regulation 25(2)(b) will be met. For example:
- (b) all essential services will be made available to anybody in England who wishes to access them;
- 3.17 From the information provided, it is not clear how certain patient groups such as those with severe disabilities, sight loss or hearing loss will have equal access to the services offered by this pharmacy. Where services require internet or telephone access they may discriminate against patients who are not able to make use of these communication methods for any reason.
- 3.18 The ICB will be unable to satisfy themselves that all patients will be able to access essential services unless communication methods (in the absence of face to face contact) are explained in detail.
- 3.19 The nature of distance selling pharmacies is that the model relies heavily on the use of either websites or apps. Whilst telephone services may be provided, many of the services referred to by the applicant appear to rely on access to the internet. This naturally excludes patients who do not have such access, through choice or lack of availability.
- 3.20 Where these patients are discriminated against, through lack of access to the pharmaceutical services provided by this pharmacy, it cannot be said that services are available to anyone in England who wants to use them.
- (d) all essential services will be provided without the face to face contact between any person receiving the services, whether on their own or on someone else's behalf, and the applicant or the applicant's staff.

- 3.21 The applicant has provided floor plans that show a consultation area and the plan provided shows a door with the wording 'restricted access' next to it. These features suggest that the applicant expects patients to visit the premises.
- 3.22 It is clear that the applicant intends to provide 'face to face' advanced and enhanced services, but it is not clear what protections will be in place to prevent the inadvertent provision of 'essential' services on a face to face basis.
- 3.23 For example, a patient attending the pharmacy for the New Medicines service may well require signposting to other services or the provision of public health support. As both of these are 'essential' pharmacy services, providing them on a face to face basis does not meet the requirements of regulation 25. In our opinion, where a patient is present in person at the premises and in conversation with the staff it will be impossible to avoid the provision of face to face essential pharmacy services, even where this is unintentional.
- 3.24 The applicant has failed to provide sufficient information to enable the ICB to be confident that the application meets the requirements of Regulation 25. In fact, the information provided clearly demonstrates that those requirements will not be met. That being the case the application must be refused.
- 3.25 Should the ICB decide to hold an oral hearing I can confirm that we would wish to attend."

#### 4 **Summary of Representations**

This is a summary of representations received on the appeal.

##### 4.1 RUSHPORT ADVISORY LLP ON BEHALF OF THE APPLICANT

- 4.1.1 "I act for Hamro Healthcare Limited in the above application and have been instructed to submit this reply to the appeal submitted by Day Lewis against the decision of the Commissioner to approve me [sic] client's application.
- 4.1.2 As the Committee will note, the letter of appeal raises the same issues that Day Lewis has raised in multiple other appeals. None of the issues raised has ever been sustained as valid point of appeal. We nevertheless addressed each point that was raised in our 5 August 2024 reply to initial consultation comments which is attached with this letter.
- 4.1.3 Day Lewis raises one additional point about the provision of NMS. My client has been clear on their application form that NMS will be provided remotely and the point made by Day Lewis is therefore not relevant.
- 4.1.4 The additional letter sent by Day Lewis refers to a different application from my client's, nevertheless, the points raised are the same.
- 4.1.5 I attach a slightly updated copy of my client's SOPs which replace the previous version that was circulated with the letter of appeal and have been approved by my client."

In a letter to the Commissioner dated 5 August 2024 Rushport Advisory LLP on behalf of the Applicant stated:

- 4.1.6 "Thank you for your letter of 5 August 2024. I act for Hamro Healthcare Ltd in the above application and have been instructed by my client to submit the following reply to the consultation comments received.

- 4.1.7 Each interested party asks the ICB applies the correct legal test when determining the application. In addition, the interested parties ask the ICB to be satisfied that proper procedures are in place.
- 4.1.8 Day Lewis suggests that the lack of complete SOPs leaves “significant doubt” as to whether the legal test will be complied with.
- 4.1.9 Whilst we submit that the evidence already provided is sufficient to satisfy the ICB that the legal test has been met, my client has nevertheless instructed me to attach their SOPs for the Committee’s attention that have been approved by the Superintendent Pharmacist for use in the pharmacy once it opens.
- 4.1.10 The SOPs answer the questions raised by Day Lewis elsewhere in their letter. In addition, Day Lewis raises the same objections that they submit to all DSP applications and which have been rejected by ICBs and the Appeal Unit on multiple occasions.

#### Interruption in Services

- 4.1.11 Any absence of the responsible pharmacist to be covered by another pharmacist and my client has access to either a second pharmacist or to locums (via personal knowledge or through agencies) to cover any absence of the RP.

#### Accessing Services

- 4.1.12 As with any pharmacy, my client will communicate with patients in the manner that is most suitable for them, except that my client will not use face to face contact at the premises to provide essential services.
- 4.1.13 It must be remembered that the patient will have chosen to use a distance selling pharmacy and will therefore have considered that the communication methods available are appropriate for their needs.
- 4.1.14 It is not clear what Day Lewis is referring to when they refer to patients having “equal access to the services offered”. No such requirement for “equal access” is found in the Regulations or the Equality Act and it is not possible or practical to offer “equal access” in many cases. For example, a person who is blind may not find a Zoom call as beneficial as a patient who can see perfectly.
- 4.1.15 Primary Care Appeals has dealt with this argument in previous applications and found

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

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

#### Controlled Drugs Delivery

- 4.1.17 My client has set out how controlled drugs will be delivered to patients. Patients will be provided with estimated delivery times and these will be updated as required. As with any other delivery of this type, if a patient is not in when the

delivery is attempted then a card will be left for the patient with instructions on how to rearrange delivery.

#### Face to Face Contact

- 4.1.18 As NHS Resolution has ruled on many occasions, face to face contact with a delivery driver at a patient's home is permitted under the Regulations as the restriction relates only to the Applicant's premises. Similarly, it is perfectly lawful for pharmacy staff to deliver to and collect unwanted medication from premises that are not the pharmacy premises such as a patient's home.

#### Website

- 4.1.19 My client is fully aware of their obligation to provide such a website prior to the pharmacy commencing trading and is similarly aware of the requirements for the website to contain a health promotion zone. Any failure of any distance selling pharmacy to provide such a website would be dealt with as part of routine contract monitoring by NHSE.

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

## 5 Summary of Observations

No observations were received by NHS Resolution in response to the representations received on appeal.

## 6 Additional comments

### 6.1 RUSHPORT ADVISORY ON BEHALF OF THE APPLICANT

- 6.1.1 "I act for Hamro Healthcare Limited in the above application and have been instructed to submit these comments for the attention of the Committee following the recent decisions issued in SHA/26376, SHA/26374 and SHA/26364 (the "Recent Decisions").
- 6.1.2 This letter and the update to the attached SOPs [Appendix A] is not new evidence, rather it provides clarification to existing evidence that should be helpful to the Committee in determining my client's application.
- 6.1.3 The Recent Decisions were refusals of applications where the Applicant had used identical wording in their SOPs to the wording used in my client's application. The Recent Decisions refused the applications on two grounds which are dealt with in turn below.
- 6.1.4 The uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services.
- 6.1.5 In the Recent Decisions the Committee found as follows;

"5.22

*The above extract at 5.21 raised some concerns for the Committee as it contradicted 5.20.1 and 5.20.2. The Committee noted SOP 31 states "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 to (for up to 2 hours per day) unless another pharmacist*

*is present". Whereas SOP 32 states "Monitor the time that the RP has been absent... If the absence exceeds 2 hours... The second pharmacist must assume the role of RP and the Superintendent Pharmacist should be contacted and informed that there is only one pharmacist on duty". SOP 31 suggested to the Committee that the Responsible Pharmacist must not leave the premises unless another pharmacist is present to assume that role.*

*However, SOP 32 outlines what would happen in the event that the Responsible Pharmacist is absent. This suggested to the Committee that during a two hour period, a Responsible Pharmacist would not be present, meaning the Applicant would be unable to provide all essential services in line with the Regulations."*

- 6.1.6 The wording of the SOPs makes it clear that if the RP were to be away from the premises for more than 2 hours then the second pharmacist must sign in as the RP. In other words, whilst the RP might have left the premises, the second pharmacist was still on the premises and services would therefore have been uninterrupted. The SOPs correctly identified that a pharmacist must remain on the premises and that services must be uninterrupted. The Terms of Service make no reference to the RP being absent and instead refer to services being uninterrupted and this is exactly what happens when an RP is absent but a second pharmacist remains at the premises.

- 6.1.7 Delivery of Cold Chain Medicines

- 6.1.8 In the Recent Decisions the Committee found as follows;

*"...The Committee was concerned that the statement "Ensure that any deliveries for fridge items and CDs are taken out of storage when appropriate" indicated that the local delivery driver would be handling and delivering cold chain items. As the Committee must be satisfied that the Applicant had explained how drugs/appliances will be provided to the patient (including to ensure that the 'cold chain' is maintained), the Committee considered that the wording creates sufficient ambiguity as to the Applicant's intentions. The Committee noted that the Applicant had not provided any information on the process that would be followed for deliveries of cold chain items by its own driver."*

- 6.1.9 The Committee had previously acknowledged that

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

- 6.1.10 In addition to this the SOP "Cold Chain Delivery via Courier" stated (but it was not noted in the decision letters);

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

6.1.11 We submit that it is clear from the SOPs that Fridge Lines are to be delivered via courier. It is not appropriate to remove fridge lines from the fridge until they are to be handed to the courier. This is why the relevant SOP states the CD and fridge lines should only be removed from the fridge “when appropriate”. This would apply if some items on a prescription were fridge lines and others were not.

6.1.12 Clarification to SOPs

6.1.13 The Committee is required to be satisfied on the balance of probabilities that the procedures used are safe and effective. Irrespective of our views on the approach adopted by the Committee in the Recent Decisions, we and the clients we act for must strive to ensure that there is no ambiguity in the evidence provided to the Committee. For this reason, we have updated the attached SOPs in order to ensure that there is no ambiguity about the procedures to be followed. These SOPs go beyond the requirements of the Terms of Service. We ask the Committee to note again that this is not new evidence and simply clarifies the position of our client on each of the points raised in the Recent Decisions.”

## 7 Further observations

In the interests of transparency and fairness, NHS Resolution sought to rely on the discretion afforded in paragraph 7 of Schedule 3 of the Regulations to vary the normal procedures and to circulate the additional submission from Rushport Advisory LLP and seek observations on it. No further observations were received by NHS Resolution in response to the additional submission from Rushport Advisory LLP.

## 8 Consideration

8.1 The Pharmacy Appeals Committee (“Committee”) appointed by NHS Resolution, had before it the papers considered by the Commissioner.

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”).

### **Regulation 31**

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

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

*(2) This paragraph applies where -*

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

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

*(ii) adjacent premises; and*

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

- 8.6 The Committee noted that the Applicant had stated on the application form “*not applicable as no other pharmacy in same or adjacent premises*” in response to why the application should not be refused pursuant to Regulation 31. The Committee noted that the Commissioner had stated that it “*was satisfied that there is no pharmacy providing pharmaceutical services at the same or adjacent premises*” and had concluded that the application did not need to be refused in accordance with Regulation 31. The Committee noted that no party, either on appeal or in subsequent correspondence had sought to argue that Regulation 31 required the application to be refused. Based on the information before it, the Committee determined that it was not required to refused the application under the provisions of Regulation 31.

#### **Regulation 25**

- 8.7 The Committee had regard to Regulation 25 of the Regulations which reads as follows:

*“(1) Section 129(2A) and (2B) of the 2006 Act (regulations as to pharmaceutical services) does not apply to an application—*

- (a) for inclusion in a pharmaceutical list by a person not already included; or*
- (b) by a person already included in a pharmaceutical list for inclusion in that list in respect of premises other than those already listed in relation to that person,*

*in respect of pharmacy premises that are distance selling premises.*

*(2) NHS England must refuse an application to which paragraph (1) applies—*

- (a) if the premises in respect of which the application is made are on the same site or in the same building as the premises of a provider of primary medical services with a patient list; and*
- (b) unless NHS England is satisfied that the pharmacy procedures for the pharmacy premises are likely to secure—*
  - (i) the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services, and*
  - (ii) the safe and effective provision of 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.”*

- 8.8 The Committee also had regard to the provisions of Schedule 2 to the Regulations shown below:

#### ***Additional information to be included with excepted applications***

- 8.** *If the applicant (A) is making an excepted application, A must include in that application details that explain—*

- (a) *A's belief that the application satisfies the criteria included in one of the regulations in Part 4 which need to be satisfied if section 129(2A) and (2B) of the 2006 Act (regulations as to pharmaceutical services) are not to apply in relation to that application; and*
- (b) *if the regulation includes reasons for which the application must be refused, why the application should not be refused for those reasons.*

**Nature of details to be supplied**

- 10.** *Where, pursuant to this Part, a person is required to provide details, that obligation is only discharged if the information or documentation provided is sufficient to satisfy NHS England in receipt of it, with good cause, that no relevant information or documentation is missing, having regard to the uses that NHS England may need to make of the information or documentation when carrying out its functions.*

**Regulation 25(1)**

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

**Regulation 25(2)(a)**

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

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

- 8.11 As far as Regulation 25(2)(b) is concerned, the Committee considered the information which had been provided by the Applicant in relation to its procedures for the provision of essential services, including its Standard Operating Procedures (SOPs) that it intends to use at the proposed pharmacy premises.
- 8.12 The Regulations require the Committee to be satisfied as to a number of matters, including that essential services will be provided on an uninterrupted basis, in a safe and effective way, across England, and without face to face contact.
- 8.13 Paragraph 8 of Schedule 2 requires an applicant to provide details in relation to an application, and paragraph 10 of Schedule 2 indicates that the obligation is only discharged if the information or documentation provided is sufficient to satisfy the Commissioner in receipt of it, with good cause, that no relevant information or documentation is missing, having regard to the uses that the Commissioner may need to make of the information or documentation when carrying out its functions.
- 8.14 The Committee has asked itself whether it has sufficient information and documentation which would address the criteria in Regulation 25(2)(b). If the Committee is to be satisfied of the matters in that paragraph, the Committee must be provided with evidence to demonstrate these matters. In this case, that evidence put

forward has taken the form of the original application and the SOPs which the Applicant has prepared or commissioned.

- 8.15 The Committee noted the comments from the Appellant that without full SOPs being provided to the Commissioner, they were not in a position to approve the application. The Committee was mindful that there are many ways an applicant can choose to organise itself in order to comply with the various requirements of the Regulations. The Committee noted that SOPs had been provided to the Commissioner, which had not been provided to parties, however they had been circulated to parties as part of the appeal process and parties had had the opportunity to comment on them.
- 8.16 The Committee was of the view that it is not for it to 'approve' or 'disapprove' of these SOPs (as they may contain matters not relevant to the Committee's consideration) and the Committee has not sought to do so. The Committee has however 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.
- 8.17 The Committee noted in the SOPs provided by the Applicant in response to the appeal that SOP 1 "Introduction and Background to SOPs" states that the pharmacy must provide:
- 8.17.1 *"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."*
- 8.18 Further SOP 3 "Procedures for NHS Essential Services" states:
- 8.18.1 *"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. Patients who wish to send paper prescriptions to the pharmacy by post should be sent stamped addressed envelopes to enable them to do so."*
- 8.19 In its SOP 31, "Responsible Pharmacist" the Applicant states:
- 8.19.1 *"As a Distance Selling pharmacy, we must provide uninterrupted service throughout the opening hours of the pharmacy. Whilst the GPhC permits the absence of the RP from the pharmacy in particular situations, the NHS Terms of Service still require a pharmacist to be present so that services are not interrupted."* [emphasis in SOPs].
- 8.20 SOP 31 goes on to state:
- 8.20.1 *"If, for any reason, the RP wishes to leave the premises or wishes to take a break then the second pharmacist must sign in as the RP and arrangements must be made for this prior to one RP leaving the premises and another RP signing in."*
- 8.21 The Committee noted the revised wording of the SOPs as provided by the Applicant with regard to the absence of the Responsible Pharmacist as well as confirmation from the Applicant's representative that a second pharmacist would be present at the pharmacy and therefore there would be no interruption of services.

- 8.22 Based on the revised information before it, including the updated SOPs, the Committee was satisfied that the provision of services would be without interruption.
- 8.23 The Committee went on to consider whether services would be available to persons anywhere in England and without face to face contact.
- 8.24 The Committee noted that throughout the SOPs the Applicant states that essential services will be provided without face to face contact between the patient and the pharmacy staff. SOP 1 "Introduction and Background to SOPs" paragraph 1.3 states:
- 8.24.1 *"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 representatives either at 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."*
- 8.25 The Committee noted SOP 3 "Procedures for NHS Essential Services" that patients would be able to utilise multiple methods to contact the pharmacy that did not result in face to face communication. The SOP, under the heading "Communication Channels" paragraph 3.1 states:
- 8.25.1 *"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 communications such as text messages.*
- 8.26 The Committee noted that patients would be able to contact the pharmacy by telephone, via video link, through the website as well as by email and postal services.
- 8.27 The Committee noted references throughout the SOPs and the application form to services being provided other than by face to face and that "contact" would also not be face to face either on or in the vicinity of the premises. The Committee noted the information with regard to the premises and that there would be a controlled entry system which would ensure that patients would not be able to enter the premises to receive essential services. The Committee further noted the references to the local delivery driver in the SOPs and application form, but also noted reference is made throughout the SOPs to the provision of services to all of England. In addition the Committee noted references in the SOPs and application form to the use of Royal Mail and couriers. The Committee was satisfied, based on the information before it that the provision of services would be available to persons anywhere in England and would be without face to face contact.
- 8.28 The Committee was aware that when the pharmacy opens, it will be the responsibility of the Commissioner, in keeping with Regulation 64, to ensure that services are provided other than with face to face contact.
- 8.29 The Committee noted the comments from the Appellant that the floor plans provided show a consultation area, which the Appellant states *"suggests that the Applicant expects patients to visit the premises"*. The Committee noted that in SOP 3, it states

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

8.30 The Committee was of the view that the presence of a consultation area did not necessarily mean that the pharmacy was going to be providing essential services face to face. The Committee noted that there are various reasons why a consultation area might be required, in particular for conversations which the pharmacist may be having with patients using the permissible means of communication i.e. telephone or video chat. The Committee also noted that the Applicant is proposing to carry out Advanced and Enhanced services, some of which would require a private consultation. The Committee further noted the comments from the Appellant that SOPs for the Advanced and Enhanced services had not been provided. The Committee accepted this but was mindful that it is the essential services as listed in paragraphs 3 to 22 of Schedule 4 of the Regulations which it has to have specific regard to.

8.31 The Committee was satisfied that the provision of essential 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.

8.32 The Committee went on to consider each essential service in paragraphs 3 to 22 of Schedule 4 of the Regulations (“Terms of Service”) in turn.

Dispensing of drugs and appliances

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

8.34 From the information contained in the SOPs, “Online Order Receipt and Exemption Checking” in SOP 6 states:

8.34.1 *“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.”*

8.35 The Committee also had regard to SOP 17 “Order Delivery” which under the heading “Choice of Delivery method” states:

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

8.36 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 using a local delivery driver.

8.37 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

- 8.38 The Committee considered whether the Applicant had explained how it proposes to safely and effectively receive requests from prescribers for urgent supplies of drug and appliances.
- 8.39 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.
- 8.40 The Committee was therefore satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 6 of Schedule 4.

#### Preliminary matters before providing ordered drugs or appliances

- 8.41 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.
- 8.42 The Committee noted SOP 6 “Online Order Receipt and Exemption Checking” and in particular “Exempt NHS Prescriptions” which states:

8.42.1 *“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, but see NOTE below) and the pharmacy can note that the evidence provided was not in original format. It is for the pharmacist in charge to determine if the evidence is satisfactory or not and, if not, then cross the ‘Evidence not Seen’ box.”*

- 8.43 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.
- 8.44 The Committee considered whether the Applicant had explained how charges will be paid.
- 8.45 The Committee noted SOP 6 under the heading “Paid NHS Prescription” states:

8.45.1 *“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.”*

- 8.46 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

- 8.47 The Committee considered whether the Applicant had explained how drugs/appliances will be provided to the patient (including to ensure that (1) 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).

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

- 8.49 The Committee noted SOP 17 "Order Deliver" under the heading "Transfer to the Delivery Driver" states:

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

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

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

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

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

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

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

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

- 8.50 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 CD's) states:

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

*...*

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

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

*5. Confirm details of all prescriptions to be delivered.*

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

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

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

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

8.51 The Committee noted the SOP went on to state, under the heading 'Cold Chain delivery via courier':

8.51.1 "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 must include a note to explain that fridge items will be delivered separately to the rest of their items to enable the cold chain to be maintained.*

...

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

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

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

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

*Confirm details of all prescriptions to be delivered.*

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

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

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

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

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

*Give all fridge line deliveries to the courier.*

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

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

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

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

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

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

- 8.52 The Committee noted SOP 21 "Controlled drugs: Delivery" under the heading "Delivery of Schedule 2 & 3 CD's" it states:

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

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

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

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

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

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

*Any falsified medicines rules introduced by the UK must be followed*

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

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

#### *Successful Schedule 2 & 3 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.*

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

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

*Note re Use of Couriers for Controlled Drugs 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.”*

- 8.53 The Committee noted the comments from the Applicant’s representative in subsequent representations with regard to the delivery of cold chain and that they had reiterated that all cold chain items would be delivered by a specialist courier thereby ensuring that the integrity is maintained both up to the point of the item being transferred to the courier all the way up to the receipt of the medication by the patient. The Committee was of the view that the additional information from the Applicant’s representative clarified the position with regard to the delivery of cold chain items by specialist courier only.
- 8.54 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(1) of Schedule 4.
- 8.55 The Committee considered whether the Applicant had explained the arrangements which ensure that, for appliances which require fitting/measuring, a registered pharmacies measures/fits them.
- 8.56 In relation to appliances, the Applicant in its application form stated that it will undertake to provide:
- 8.56.1 *“Drug Tariff part IX\* (\*except items that require measuring or fitting).*
- 8.57 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:
- 8.57.1 *“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).”*
- 8.58 SOP 24 “Support for Self-care, signposting and Health promotion” under the heading “Items Requiring measuring and fitting” states:
- 8.58.1 *“Where a prescription is received for an appliance or stoma appliance customisation or any item that requires measuring or fitting the patient must be contacted and informed that these items are not available from this pharmacy as we do not provide a measuring and fitting service. Patients must be*

*signposted to at least two other providers of the service in their area. (see signposting SOP)."*

- 8.59 The Committee noted that the Applicant did not intend to provide appliances which require measuring or fitting. In the event that the application is granted, the Applicant would not therefore, be able to provide these appliances as listed in the application form, to patients.
- 8.60 Based on the information before it the Committee was satisfied that the Applicant had provided with information sufficient to show that there would be compliance with paragraph 8(4) of Schedule 4.
- 8.61 The Committee considered whether the Applicant had explained what containers would be suitable for posted/delivered items.
- 8.62 The Committee noted SOP 16 "Bagging up" under the heading "Choice of packaging" states:
- 8.62.1 *"Choice of packaging will depend on the nature of the items being delivered and the appropriate level of protection must be used to ensure that the item can withstand the normal rigours of the delivery process.*

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

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

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

*For postal items, either:*

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

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

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

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

- 8.63 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

- 8.64 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 to review the patients treatment.

- 8.65 The Committee noted SOP 32 "Repeat Dispensing" under the heading "Pharmaceutical and Legal Assessment" states:

- 8.65.1 *"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."*

- 8.66 The Committee further noted SOP 32 under the heading "Prescription reception" states:

- 8.66.1 *"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."*

- 8.67 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.

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

- 8.69 The Committee noted in the SOPs as provided, SOP 32 “Repeat Dispensing” under the heading “Prescription Reception” states:

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

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

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

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

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

- 8.70 In addition, the Committee noted under the heading “Pharmaceutical and Legal Assessment” in SOP 32 it states:

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

- 8.71 Given the above, 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

- 8.72 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.

- 8.73 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:

8.73.1 *“This service is available to all patients living in England.*

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

*Patients should be referred to the ‘Returning unwanted medication’ page on the website for information.*

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

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

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

- 8.74 The Committee noted that SOP 22 goes on to state, under the heading "Returned by Royal Mail":

8.74.1 *"The pharmacist must*

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

*Assess the items for suitability for return by Royal Mail*

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

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

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

*Contact the patient to ensure that the packaging has been received.*

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

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

8.75.1 *"Drivers need to:*

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

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

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

8.76.1 *"Patient Returned Medication*

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

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

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

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

*Patients may*

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

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

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

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

- 8.77 The Committee noted that SOP 23 under "Process for accepting patient returns by the driver" goes on to state:

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

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

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

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

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

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

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

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

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

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

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

*Ensure medicines are not visible in the vehicle at all times.”*

- 8.78 The Committee noted that the SOP under the heading “Disposal of Returned Medicines” went on to state:

8.78.1 *“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.”*

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

#### Promotion of Healthy Lifestyles

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

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

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

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

*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.”*

- 8.82 Further in SOP 25 under the heading “Identification of patients for promotion of Healthy Lifestyles” it states:

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

- 8.83 Based on the information before it, the Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 16 - 18 of Schedule 4.

#### Prescription Linked Intervention

8.84 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.

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

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

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

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

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

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

*Summary Care Record / National Care Records Service Access - If appropriate, access the patient’s Summary Care Record / National Care Records Service to see if it assists in identifying what areas to provide advice on.”*

8.86 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

8.87 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 the Commissioner.

8.88 The Committee noted under SOP 25 “Promotion of Healthy Living, Lifestyle & Health Campaigns” under the heading “Health Campaigns and Community Engagement Exercise” it stated:

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

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

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

...

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

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

- 8.89 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

- 8.90 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.

- 8.91 The Committee noted in SOP 24 "Support for Self-care, Signposting and Health Promotion" under the heading "Signposting" and then the sub heading "Patient identification" it states:

- 8.91.1 *"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.”*

- 8.92 The Committee noted that in SOP 2 under the heading “Other Provider Organisations and Support Details” it states:

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

- 8.93 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

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

- 8.95 The Committee noted SOP 24 “Support for Self-care, Signposting and Health Promotion” under the heading “Support for Self-care” “Service outline” it states:

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

...

*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).”*

- 8.96 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

- 8.97 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.

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

- 8.99 The Committee noted SOP 26 “Discharge Medicine Services (“DMS”) states:

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

*Arrange a live video call or audio call with the patient (or where appropriate and bearing in mind the duty of confidentiality their carer to; Assess the patient / carer understanding of the medicines that the patient should be taking.*

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

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

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

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

*Discuss common or expected side effects.*

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

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

*Inform the patient / carer about*

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

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

*Follow up*

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

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

- 8.100 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.

Website and health promotion zones

- 8.101 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.

- 8.102 The Committee noted SOP 2 "Our Healthy Living Pharmacy" states:

8.102.1 *"We have a "Health Promotion Zone" on our website and also provide healthy living advice on an opportunistic basis to patients."*

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

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

*Explaining the Interactive Page to Patients*

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

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

*The health promotion zone may also includes 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."*

- 8.104 The Committee further noted that reference is made to health promotion zones in SOP 25 “Promotion of Healthy Living, Lifestyle and Health Campaigns” under “Identification of patients for promotion of Healthy Lifestyles” which states:

8.104.1 “...*The website, app and email newsletters will also be used to promote healthy lifestyles via the health promotion zone.*”

- 8.105 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.

- 8.106 The Committee noted the Appellant’s comment that the Applicant had not made clear how certain patient groups such as those with severe disabilities, sight loss or hearing loss will have equal access to services offered by the Applicant. The Committee noted the Applicant’s comment that whilst the Appellant had suggested some patients may have unequal access to its proposed pharmaceutical services, there is no such requirement within the Regulations for “equal access”. The Committee noted SOP 4 entitled “The Equality Act” which sets out what the pharmacy needed to consider as well as “Practical ways of supporting patients” and “Patients who have care workers”. The Committee considered that the patient or a person authorised on their behalf, will have decided to use a distance selling pharmacy in the knowledge of how it operates and therefore accepts the methods of communication between themselves and the pharmacy. The Committee has already declared itself satisfied that the Applicant has demonstrated various means of non face to face communication with patients.

#### *Summary*

- 8.107 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).

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

8.108.1 confirm the Commissioner’s decision;

8.108.2 quash the Commissioner’s decision and redetermine the application;

8.108.3 quash the Commissioner’s decision and, if it considers that there should be a further notification to the parties to make representations, remit the matter to the Commissioner.

- 8.109 In those circumstances, although the Committee agreed with the decision reached by the Commissioner it had additional information available to it in the form of revised SOPs which were not available to all parties when the Commissioner made its decision. The Committee determined that the decision of the Commissioner must be quashed.

- 8.110 The Committee considered whether there should be a further notification to the parties detailed at paragraph 19 of Schedule 2 of the Regulations to allow them to make representations if they so wished (in which case it would be appropriate to quash the original decision and remit the matter to the Commissioner) or whether it was preferable for the Committee to reconsider the application.

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

- 8.112 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 the Commissioner; and

- 9.2.2 redetermines the application as follows -

- 9.2.2.1 the Committee was satisfied that the proposed premises were adjacent to or in close proximity to other chemist premises,

- 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**