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8 August 2024

REF: 26198

APPEAL AGAINST NORTH CENTRAL LONDON ICB DECISION TO REFUSE AN APPLICATION BY MEDICINE HOUSE LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT SUITE C278, CHASE ROAD, SOUTHGATE, GREATER LONDON N14 6HA 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 Medicine House Ltd
PCSE on behalf of North Central London ICB

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1 The Application

By application dated 7 July 2023, Medicine House Ltd ("the Applicant") applied to North Central London ICB ("the Commissioner") for inclusion in the pharmaceutical list at Suite C278, Chase Road, Southgate, Greater London N14 6HA 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 made no comment.

1.2 In response to why the application should not be refused pursuant to Regulation 31 the Applicant made no comment.

1.3 In response to why the application should not be refused pursuant to Regulation 25(2)(a) the Applicant made no comment.

1.4 The Applicant intends to provide the following services:

1.4.1 Essential services

1.4.2 Advanced and Enhanced services

1.4.2.1 New Medicines Service (NMS)

1.4.2.2 Community Pharmacist Consultation Service (CPCS)

1.4.2.3 Care Home Service

1.4.2.4 Home Delivery Service

1.4.2.5 Emergency Supply Service

1.5 The Applicant's proposed core opening hours are:

1.5.1	Mon to Fri	09.00 to 17.00
1.5.2	Sat	Closed
1.5.3	Sun	Closed
1.5.4	Total: 40 Hours	

1.6 The Applicant's total opening hours are:

1.6.1	Mon to Fri	09.00 to 17.00

1.6.2 Sat Closed

1.6.3 Sun Closed

1.6.4 Total: 40 Hours

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

1.7 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.

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

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

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

1.11 The applicant will register the premises with the GPhC and will thus abide by the Guidance for registered pharmacies providing pharmacy services at a distance, including on the internet” set out in 2019 and updated in March 2022.

1.12 Therefore, Medhouse Pharmacy has in place in abiding the above guidance from GPhc the following, specifically but not exhaustively:

Risk Assessment

1.13 Medhouse Pharmacy will ensure to gather information about the risks associated with each service, medicine, and medical device provided at a distance, including on the internet, before beginning to provide these services.

1.14 The sole proprietor is fully aware of the importance of risk assessment, which will be undergone to evaluate and minimise the potential risk associated towards patients and people who use pharmacy services provided by Medhouse Pharmacy.

1.15 The clinical governance lead [redacted] will manage the risk assessment, which will consider the following aspects:

1.15.1 How to identify and manage risks

1.15.2 Staff's communication with patients and the public about pharmacy services and obtaining their consent

1.15.3 Communication between staff across different locations

1.15.4 Supply of medicines, including counseling [sic] and delivery

1.15.5 Medhouse Pharmacy's ability to provide the proposed services

1.15.6 Business continuity plans, including website and data security and equipment

1.15.7 Record-keeping based on the nature of the provided pharmacy services

1.15.8 The behavior [sic] of both staff and individuals using pharmacy services

1.15.9 The integration of different technologies

1.15.10 Potential changes in the number or scale of services

1.16 Medhouse Pharmacy will ensure that staff are aware of the risk assessment results and are involved in managing the identified risks as appropriate. Risk register will also keep up to date and any measures taken will be documented.

1.17 The risk assessment will be reviewed every 3 months and when significant business or operational changes are made. Therefore, by doing so, Medhouse Pharmacy will be insured that the potential risks faced by patients is minimised at all times, by identifying the need for changes in regards to essential factors which could cause arise to potential risks.

1.18 Medhouse Pharmacy will eveluate [sic] how the systems operate together if parts of pharmacy service are the responsibility of several different pharmacies and staff. This evaluation will cover information flow and the IT systems used to share information among various locations. Additionally, Medhouse Pharmacy will assess the precision of these systems and how to handle any possible issues arise [sic].

1.19 To ensure patient safety throughout the healthcare sytem [sic] Medhouse Pharmacy will not work with online providers who attempt to bypass the regulatory oversight established in the UK. If our service involves legally working with prescribers or prescribing services outside the UK, Medhouse Pharmacy will make sure following taking in account:

1.19.1 Effectively manage any additional risks that may arise from this arrangement.

1.19.2 Will have sufficient indemnity insurance in place that covers our service when utilizing prescribers or prescribing services based outside the UK, as well as pharmacy staff who supply medications against prescriptions issued by such prescribers or services.

1.19.3 The prescriber is registered in their home country, where the prescription is issued, and is authorized [sic] to issue prescriptions online to individuals in the UK.

1.19.4 The prescriber adheres to national prescribing guidelines in the UK.

1.20 Medhouse Pharmacy will also make sure any cross-border arrangements within our service design are lawful under UK law.

Audit procedures

1.21 Regular audit procedures will be put in place, initially every 3 months. The audit will therefore ensures [sic] that Medhouse Pharmacy continues to provide safe pharmacy services to patients and people who use those services. Any issues of concern identified will ensure a reactive review is undertaken. Additionally, Medhouse Pharmacy will participate in clinical audits led by NHS England.

1.22 Regular Audit involves a range of tasks that are not limited to the following:

1.22.1 Reviewing standard operating procedures (SOPs), which should encompass all the services offered by Medhouse Pharmacy and be specific to our establishment.

1.22.2 Evaluating staffing levels, the proficiency and training of team [sic] and determining if any additional training is necessary to ensure that all employees possess the necessary skills and capabilities for their assigned tasks. Furthermore, the appropriateness of communication methods with individuals who use pharmacy services, as well as the communication methods used to provide services, such as between staff, third parties, agents or contractors, and other healthcare providers, including between hubs and spokes and with collection and delivery points, are also reviewed.

1.22.3 It will assess systems and processes for receiving prescriptions, including the electronic prescription service (EPS), as well as clinical decisions such as records of decisions to make or refuse a sale or supply of a medicine against a prescription.

1.22.4 The systems and processes for secure delivery to individuals receiving care, any information about pharmacy services on our website, and how to comply with information security policy, the Payment Card Industry Data Security Standard (PCI DSS), and data protection legislation will also be evaluated.

1.22.5 Feedback from individuals who use pharmacy services, including any concerns or grievances received, as well as the activities of third parties, agents or contractors, are also considered.

1.23 Therefore, the audits will be part of an on-going improvement process to optimise overall patient care. Medhouse Pharmacy will also demonstrate active participation of staff in the audit process.

Reactive review:

1.24 If a regular audit identifies a problem or any of the following take place, a reactive review will be undertaken:

1.24.1 A change in the law affecting any part of pharmacy service

1.24.2 A significant change in any part of the pharmacy service provided, for example an increase in the number of patients services are provided to, or an increase in the range of services intended to be provided; or a change in a third party, agent or contractor used

1.24.3 A data security breach

1.24.4 A change in the technology used

1.24.5 If any concerns or negative feedback are received from patients or people who use pharmacy services

1.24.6 A review of near misses and error logs identifies a concern about an activity

1.25 Depending on services provided independent experts will audit security practises at Medhouse Pharmacy

Accountability

1.26 A responsible pharmacist will be appointed at all times during the opening hours. It will be ensured that clear lines of accountability will be set out within each area to allow

traceability and due diligence will be used when contracting couriers for delivery of medication.

Record keeping

1.27 Relevant records associated with but not limited to patient consent(s), complaints, sale refusals, audits, reactive reviews staff accountability, and complaints will be kept within the electronic IT system for a minimum of 7 years or unless longer legislations require longer periods.

Trained and competent staff

1.28 [Mr I] will ensure that all staff members are fully trained and competent to carry out their role in the safest and most appropriate manner to ensure patient safety and satisfaction. All staff will be fully and relevantly trained according to their job role, prior to being involved in providing any pharmacy services at a distance.

1.29 All Pharmacists will be encouraged and required to keep up to date CPD records.

1.30 In terms of staff training, the following will be ensured:

1.30.1 All staff will gain appropriate induction and full training within their specific role.

1.30.2 All staff must read and understand the SOPs, and training matrix must be signed to approve their understanding.

1.30.3 Medhouse Pharmacy will provide extra training for information security management – how data is protected; and cyber security and using specialised equipment and new technology

1.30.4 Medhouse Pharmacy will provide ongoing external training for staff members, with each member having individual development plans put in place.

1.30.5 All staff qualification(s) and professional registrations (if applicable) will be checked and they will also be ID checked.

The premises

1.31 The premises will be registered with the GPhC, therefore it will be inspected and kept safe and fit for purpose.

Website

1.32 The Medhouse Pharmacy will be registered with GPhC as a distance selling pharmacy and therefore, the website will be fully compliant. The website will be secure and follows information security management guidelines and data protection law. Secure facilities will be used to for collecting, [sic] using and storing patient information and processing card payments. All information will be made clear, accurate and updated regularly, and will not be misleading in any way.

1.33 The website prominently displays:

1.33.1 The GPhC pharmacy registration number

1.33.2 The name of the owner of the registered pharmacy

1.33.3 The name of the superintendent pharmacist

1.33.4 The name and address of the registered pharmacy that supplies the medicines with relevant phone number(s) and email address(es)

1.33.5 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)

1.33.6 Information about how to check the registration status of the pharmacy and the superintendent pharmacist

1.33.7 Once in the Pharmaceutical list, Details of specific services available and how to use them, i.e.

1.33.8 Return of unwanted medicines

1.33.9 Patient Lifestyle Questionnaire

1.33.10 How to register exemptions from NHS charges

1.33.11 Promotion of Health Lifestyles and details of campaigns being undertaken

1.33.12 Procedures for Emergency Supply

1.33.13 Explanation of rules on non face to face contact

1.33.14 Annual patient survey

1.33.15 Patient Information Leaflet

1.33.16 The email address and phone number of the pharmacy

1.33.17 Details of how patients and users of pharmacy services can give feedback and raise concerns

1.33.18 If an online consultation provided with prescribed medicines website will also have details of prescriber such as name, registration number, country registered, whether prescriber is a doctor or a nonmedical prescriber as well as information about how to check the registration status of the prescriber

Transparency and patient choice

1.34 Informed patient consent will be obtained prior to any pharmacy service(s) being provided. All patient consent information including forms will be stored on the secure IT system within their PMR record.

1.35 Pharmacy services transparently provided to people so that they will know who the responsible pharmacist is when their medicines or medical devices are supplied, have enough information about the service to make an informed decision and can raise concerns if they need to about the quality of service.

1.36 Additionally, it will be ensured and proven that any potential arrangements with medical or non-medical prescribers are transparent, and do not;

1.36.1 cause conflicts of interest

1.36.2 restrict a patient's choice of pharmacy, or

1.36.3 unduly influence or mislead patients deliberately or by mistake

1.37 Medhouse pharmacy will ensure to provide information about the indemnity and regulatory arrangements for those prescribers who are not based in the UK, especially if the prescriber is not regulated by a UK health professional regulator

Managing medicines safely

1.38 Medhouse Pharmacy will meet the standards of Principle 4, which involves minimising risks in the supply of medicines at a distance, including on the internet.

1.39 To be able to manage medicines safely Medhouse Pharmacy owner will take steps to minimise identified risks, such as deciding which medicines are appropriate for supplying at a distance, ensuring that pharmacy staff can verify the identity of the person receiving pharmacy services and assess their capacity, and identifying inappropriate requests for medicines. In addition, Medhouse Pharmacy will ensure that all prescribers, whether medical or non-medical, follow relevant remote consultation, assessment, and prescribing guidance and good practice guidance.

1.40 As a pharmacy professional Medhouse Pharmacy staff will follow guidance on categories of medicines that are not suitable to be supplied online (such as non-surgical cosmetic products) and some categories of medicines should not be supplied unless further the safeguards have been put in place such as

1.40.1 Antimicrobials (taking into account antimicrobial steawardship [sic] guidelines)

1.40.2 Medicines liable to abuse, overuse or misuse, or when there is a risk of addiction and ongoing monitoring is important

1.40.3 Medicines that require ongoing monitoring or management (narrow therapeutic index medicines such as lithium and warfarin)

Supplying medicines safely

1.41 The SOPs will contain detailed information of providing secure delivery of medication through couriers, mainly Royal Mail and the pharmacy's delivery driver. The following will be considered to ensure the safe supply of medicines to patients:

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

1.41.2 The suitability of packaging (for example, packaging that is tamperproof or temperature controlled)

1.41.3 Secure methods of storing and accessing medicine

1.41.4 Monitor and track the package to ensure it reaches the right person as well as monitor any unexpected interruptions in delivery

1.41.5 Check the terms, conditions and restrictions of the carrier

1.41.6 Check the laws covering the export or import of medicines if the intended recipient is outside of UK

1.41.7 Train staff and monitor third-party providers

1.42 All third-party services regarding deliveries will be assessed based on patient feedback and satisfaction

Information for pharmacy users

1.43 Medhouse Pharmacy staff will consider to use effective communication methods which promote discussion between the pharmacy user and the pharmacy staff, including the pharmacist. Clear information will be provided to pharmacy service users about how they can contact the pharmacist or pharmacy staff for further advice or in case of any problems. Additionally, staff will provide advice on when to visit their GP or local pharmacist

Specialist equipment and facilities

1.44 All specialist equipment purchased to provide pharmacy services will be ensured that it is purchased from reputable manufacturers which ensures that they;

1.44.1 are of high specification, accuracy and security,

1.44.2 are calibrated, maintained and serviced regularly in line with the manufacturer's specifications, and the keeping of maintenance logs for as it can be can shown [sic] to be appropriate

1.45 To ensure patient safety, all equipment will be annually tested and specialist equipment (such as temperature-controlled equipment) will be tested monthly.

1.46 IT equipment will meet the latest security specifications and security of data will be protected. Fully encrypted networks are used. Only trained staff have access to this, being authorised by the Superintendent Pharmacist. Software and operating systems are robust enough to handle volume of work, have control system built in to help manage the risk and accessible therefore system can be audited regularly

Essential Services

1.47 All essential services will be conducted in a manner appropriate as a distance selling pharmacy contract encompasses. This therefore includes rigidly following relevant legislations and regulations including:

1.47.1 SOP's

1.47.2 NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013

1.47.3 PSNC distance selling pharmacy guidelines

1.48 It will therefore be ensured that the pharmacy's procedures and SOPs allow for the uninterrupted provision of essential services during the opening hours of the pharmacy to anyone in England who requests the service.

1.49 The premises is secured with secure entry and will be inspected and approved by GPhC. The premises is wholly distance selling and does not allow for the entry of the general public and no one other than qualified staff have access to the registered area. There are no signs indicating that it is a pharmacy. All NHS services will be provided free of charge.

Essential services 1- Dispensing

1.50 "*The supply of medicines and appliances ordered on NHS prescriptions, together with information and advice, to enable safe and effective use by patients and carers, and maintenance of appropriate records*."

1.51 Medhouse Pharmacy will ensure the above is met in a fully compliant and appropriate manner, through the following ways:

1.51.1 All new patients register online the pharmacy website [sic] with consent for receiving their prescriptions is gained (either through post, EPS or fax). A short questionnaire of their medical history is also obtained either online or through post which can be sent to them and returned with prepaid envelope.

1.51.2 A proof of exemption (if applicable) is obtained and retained on the PMR (including any expiry records). This can be obtained by fax or by post (the pharmacy will send a prepaid envelope to obtain their exemption and send it back free of charge)

1.51.3 A charge is obtained online (where applicable) via a secure method e.g. sagepay.

1.51.4 The responsible pharmacist will clinically and legally check prescriptions received.

1.51.5 If they are not legally or clinically appropriate, SOPs will be followed to resolve any potential issues, including contacting the prescriber to discuss and resolve any clinical or legal issues.

1.51.6 Every patient will be contacted and appropriately counselled (through email, telephone or SMS) with every prescription dispensed for them.

1.51.7 Their medication will be appropriately packaged and sent for delivery to their home address.

1.51.8 Royal mail will be the courier of choice to be used (all prescription items will be delivered free of charge) and once delivered a signature is obtained to complete the dispensing audit of each prescription.

1.52 Additionally, if any owing's are owed to the patient, this would be clearly communicated and identified whether the part dispensed medication is needed and if so will be delivered to the patient.

Emergency Supply

1.53 In many instances, emergency supply may be required either at the request of a patient or prescriber. The responsible pharmacist will follow procedures as set out within the SOP's, which is written abiding to the Medicines, Ethics and Practice (MEP) guidelines for emergency supply. Due to the distances selling [sic] nature however, medication may not be able to be urgently delivered as required and in such instances patients will be signposted to an appropriate supplier who can cater to the patients need in a timely manner.

1.54 If the request is that of a patient, the pharmacist must interview the patient (through means other than face to face contact e.g. telephone) requesting the supply and must be satisfied that there is an urgent need for the medication and that it is impractical to obtain a prescription without undue delays as well as following guidelines set out within the SOPs following Medicines, Ethics and Practice (MEP) guidelines for emergency supply.

Delivery

1.55 For the delivery of all medication, it will be ensured that they are fully protected so that the medications' integrity, quality and efficacy are fully preserved. This is done in such a way that they packaging offers [sic] full protection, by the use of padded envelope (small, non-fragile items), bubble wrap, re-enforced cardboard box, polystyrene filler etc. depending on the size and fragility of the items being transported. The recipient, confirming delivery, must sign for all items delivered.

1.56 Cold chain items and controlled drugs must be ensured that they are delivered in a safe and appropriate manner. The following logistics are to be used for the delivery of cold chain medication and controlled drugs:

1.56.1 Secure controlled drug delivery: (www.citysprinthealthcare.co.uk) City Sprint provide medical courier services nationwide to a range of clients including NHS Foundation Trusts, Acute Trusts, Teaching Hospitals and the private hospital and diagnostic sectors. They are MHRA accredited with GDP trained couriers to ensure the safe delivery of controlled drugs which is required to be utilised at Medhouse Pharmacy to ensure optimal patient safety and adhering to all legalities surrounding the transfer of controlled drugs from one authorised person to another authorised person.

1.56.2 Igloo- thermo logistics will provide cold chain deliveries when required. They have MHRA accredited facilities and are ISO9001 certified and therefore follow Good Distribution Practice to ensure the safe transfer of temperature sensitive medication to patients. Igloo logistics have systems in place whereby if there is a breach in the cold chain, while being delivered, the driver is delivered and subsequently the Pharmacy. The driver will therefore follow the failed delivery procedure and re-delivery will be arranged. Whereby the cold chain has been breached, these products will not be re-used.

1.57 Medhouse pharmacy's SOP's outline the safe and secure delivery of medication to patients which is underpinned by the use of city sprint and igloo services.

Urgent Delivery (also in the case of an emergency supply)

1.58 Whereby it has been established that the patient requires urgent medication, this will be sent via an expediated form of delivery. The pharmacy will not charge the patient any delivery fees for this.

Essential service 2- Repeat dispensing/eRD

1.59 *"The management and dispensing of repeatable NHS prescriptions for medicines and appliances, in partnership with the patient and the prescriber.*

1.60 *This service specification covers the requirements additional to those for dispensing, such that the pharmacist ascertains the patient's need for a repeat supply and communicates any clinically significant issues to the prescriber."*

1.61 It will be ensured that patients receive their repeat medication safely by the following measures:

1.61.1 They will be asked to send their repeat authorisation and repeat dispensing prescriptions if they are paper versions. New patients will be asked to complete service consent form confirming that Medhouse Pharmacy has their permission to dispense repeat prescriptions and that they have the permission to retain repeat authorisation.

1.61.2 The patient will be contacted 10 days prior to their course of medication finishing to confirm that the patient is still taking the medication as on the repeat prescriptions and confirming that their next repeat prescription is to be made up.

1.61.3 Any clinical issues and comments will be relayed with patient consent to the prescriber and recorded in the patients PMR.

1.62 Where necessary, as identified by the pharmacist, the patient may be contacted by means of non face-to-face contact and given advice in addition to information delivered with the repeat prescription.

Essential service 3- Disposal of unwanted medicines

1.63 Patients wishing to dispose their unwanted medicine can do after informing Medhouse Pharmacy of their intention, contacting through telephone, email or other appropriate non face-to-face contact. Medication disposal service will be advertised on the pharmacy leaflet and website. After it is identified that there are no needles, sharps or chemicals (if there is, patients will be signposted for safe disposal), their collection will be arranged. It is intended to contract with PHS group upon inclusion in pharmaceutical list, which will collect unwanted or out of date medication from patients home [sic].

1.64 Where the patient requires disposal of Controlled Drug (CD), appropriate prepaid packaging with instructions will be sent to the patient. Appropriate method of collection will be outlined by the Superintendent Pharmacist and where couriers are used, only approved couriers will be used. Patients may also be signposted if they prefer to make this return to another pharmacy. Any returned CD medicine must not be re-used or entered into the CD register. It must be destroyed (destruction must be witnessed by another member of staff and record of this kept) as soon as reasonably possible and must be stored segregated from other stock and labelled as 'patient return' in the CD cabinet.

Essential service 4- Public health (promotion of healthy lifestyles)

1.65 Public health will be promoted through numerous methods as follows:

1.65.1 The website will have a dedicated page for promotion of public health which within it will be general health information as well as information on specific health promotion national campaigns. This will be updated with new information from NHSE and regulated health and wellbeing boards throughout the UK.

1.65.2 Medhouse Pharmacy will have social media presence (Facebook and Twitter) and will regularly post health promotion information and will also link the health promotion website page to their social media accounts.

1.65.3 Patients upon signing up to Medhouse Pharmacy's services will complete health questionnaire. The questionnaire will help utilise to identify patients' risk to allow for tailored healthy living advice and targeted recommendations.

1.65.4 Leaflets will be sent to patients who are identified to be at a higher risk of health complication, for example those having medical conditions such as high blood pressure, diabetes, coronary heart disease, smoke or are overweight, etc with information on how to reduce their risks and health promotion.

1.66 Medhouse Pharmacy will be heavily involved in public health campaigns and patients will be signposted to relevant campaigns within the website and NHS marketing material will also be delivered alongside their medication.

Essential service 5- Signposting

1.67 Patients will be appropriately signposted when they require advice, relevant support or treatment which the pharmacy cannot provide, and which another health or social service provider is able to give, they will be signposted in numerous appropriate ways as follows

1.67.1 The website will have details to signpost patients. For example it will include links to NHS website so patients can find further information regarding their ailments and important contact information, for example NHS111 service and NHS emergency services and when it is appropriate to use these services.

1.67.2 Patients will be encouraged to contact the pharmacist during core opening hours through non face to face contact so that they can be appropriately signposted.

1.67.3 Patients will also be able to contact the pharmacist through the website, through chat log or video call if required, by clicking on 'ask a pharmacist' function which will have a webpage within the website where they can book a non face-to-face consultation with the pharmacist.

1.67.4 The pharmacist may also request to video call the patient to see visual/physical symptoms to appropriately advise and signpost where deemed necessary.

1.67.5 Out of core hours, if patients request to 'ask a pharmacist' they will be signposted to NHS website or NHS111 to receive further assistance.

1.68 Additionally, when signposting is required when the pharmacy is unable to provide a particular appliance or stoma, their prescription or repeatable authorisation and repeatable dispensing prescriptions will be passed onto an appropriate pharmacy or NHS appliance contractor, with their consent, or the information of two appropriate pharmacies or NHS appliance contractors will be communicated to them.

1.69 Where deemed appropriate by pharmacist professional judgement, a record will be kept of referral to aid auditing and potential follow up care.

1.70 All pharmacists working for Medhouse Pharmacy will be required to undergo required levels of Continued Professional Development (CPD's) to ensure they are up to date with relevant practices and they are able to appropriately signpost patients. This will be in accordance of SOP's where they must be up to date with their CPD's.

Essential service 6- Support for self-care

1.71 Self care will be promoted by Medhouse Pharmacy by aiding patients where deemed necessary, through the following aids as set out:

1.71.1 The responsible pharmacist will be contactable at all times of core opening hours for advice and signposting where necessary.

1.71.2 All sales of medication will be overseen by the pharmacist which will allow for appropriate intervention when deemed necessary.

1.71.3 Information on the treatment of minor ailments, common illnesses and management of long term conditions will be set at in the website with appropriate signposting also given as previously discussed

1.71.4 The 'ask a pharmacist' function will be available to make an appointment within core opening hours at all times so the pharmacist can appropriately advice and/or signpost patients.

1.72 Furthermore, patients with disabilities will appropriately be aided, which will ensure Medhouse Pharmacy can meet their requirements under the Disability Discrimination Act (DDA). Pharmaceutical adjustments will be made, such as the use of compliance aid systems (e.g. blister packs/dosette boxes) to comply with essential services 1 & 2 for such patients. With such patients, an assessment will be made on a case by case

basis to determine the level of pharmaceutical adjustment required to suit their needs and improved medical compliance. This is done via non face to face means.

Clinical Governance

1.73 [Mr I] (GPhC no: [redacted]), will be the clinical governance lead and information governance lead and will oversee deliverance of such required standard. He will ensure that all staff undergoes nationally accredited training appropriately so that they deliver the highest level of clinical governance. All staff performance will be audited against key performance indicators, and will have annual appraisals and regular feedback of their work.

1.74 Additionally Medhouse Pharmacy will collect structured feedback from patients by using more than one method such as postal, email or web-based submission which accessible to range of patients [sic] and public using the pharmacy services and that they reasonably reflect the pharmacy's business profile.

1.75 Whatever method is used to capture structured feedback, it will be free from advertisements. Collected feedback will be considered and potential adjustment will be carried out appropriately within appropriate limits to provide better service for patient and public. The summary of the feedback will be displayed on pharmacy's website

1.76 Medhouse Pharmacy will take patient complaints with the highest regard. We will have a page on the website which is dedicated to such concerns, which can also be communicated over the phone or through the post if requested.

1.77 Complaints will be managed by [Mr I], considering the root cause, and if necessary, further advise will be gained from professionals such as the National Pharmacy Association (which Medhouse Pharmacy will be a member of) and each outcome will be appropriately agreed upon with further agreed improvement will be considered. If complaints are of a more serious nature, they will be appropriately dealt with by taking it up with appropriate authorities.

Information Governance

1.78 Medhouse Pharmacy will fully comply with General Data Protection Regulation (GDPR) and UK Data Protection act (2018). Additionally it will fully comply with access to Health records Act. All patient data will be subject to Freedom of Information act [sic] and this will be published on the website transparently and details of how to gain access to the information we hold of them. All patient data will be stored in fully secure IT database, and will be kept private and confidential in accordance to NHS and legal obligations on data security, protection and confidentiality.

1.79 The website will be designed and made by approved and reputable company which ensures that it is compliant with all legal obligations of data protection and confidentiality.

1.80 All staff will be fully aware of laws and regulation surrounding data protection and patient confidentiality and will be appropriately trained within the training provided to them. All confidential waste will be separated and disposed of by a certified confidential waste disposal agency, which will be contracted to regularly carry out such duties.

1.81 A validated PMR system will be used which is compliant to N3 spine and stores patient and NHS information confidentially. The system will be fully maintained with only authorised access of trained staff being permissible.

Cover for Responsible Pharmacist break

1.82 Any breaks by the RP will be covered by a second pharmacist who will assume responsibility of the RP.

Practice leaflet

1.83 The Practice Leaflet will fully and clearly set out that the Pharmacy is distance selling in nature. Additionally, the practice leaflet will set out that the services provided are accessible by anyone in the UK and no staff , anyone representing the pharmacy or the practice leaflet will imply that the essential services are for only available to people in a particular area.

Summary

1.84 The above information will help justify that Medhouse Pharmacy is competent to function in a compliant manner which abides by all regulations distance selling pharmacy's are expected to abide by."

2 **The Decision**

The Commissioner considered and decided to refuse the application. The decision letter dated 24 April 2024 states:

Covering letter

2.1 "North Central London ICB has considered the above application and I am writing to confirm that it has been refused. Please see the enclosed report for the full reasoning.

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

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

Decision report

2.3	"CAS reference number	CAS-223703-Z7N3J2
2.4	Name of applicant	Medicine House Ltd
2.5	Fitness to practise	Cleared for inclusion
2.6	Address of proposed premises	Suite C 278 Chase Road Southgate Greater London N14 6HA
2.7	Status of location	Non-controlled locality.
2.8	Relevant regulations and guidance Regulations	25 – distance selling premises.

Regulation 31 – refusal: same or adjacent premises.

DH market entry guidance chapter 11.

Additional information

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

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

2.11 None identified.

2.12 Interested parties notified of the application – Representation Submitted

2.13 [Names and addresses of the parties listed]

2.14 Interested Parties notified of the application – Representations not submitted

2.15 [Names and addresses of the parties listed]

Additional information

2.16 The PCRC have determined that there is enough information to deal with this application without holding an oral hearing.

2.17 The comments received from parties is available to the PSRC panel to review.

Boots Comments

2.18 Boots request that all the criteria and conditions have been satisfied.

2.19 With regard to Regulation 31 (Refusal: same or adjacent premises) and to the provisions of Schedule 2 to the Regulations:

2.20 "Applications seeking the listing of premises that are already, or are in close proximity to, listed chemist premises.

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

Distance Selling premises applications.

2.22 Regulation 25 *(1) Section 129(2A) of the 2006 Act(c) (regulations as to pharmaceutical services) does not apply to an application—*

(a) for inclusion in a pharmaceutical list by a person not already included; or

(b) by a person already included in a pharmaceutical list for inclusion in that list also in respect of premises other than those already listed in relation to that person,

in respect of pharmacy premises that are distance selling premises.

(2) The ICB must refuse an application to which paragraph (1) applies—

(a) if the premises in respect of which the application is made are on the same site or in the same building as the premises of a provider of primary medical services with a patient list; and

(a) The premises in respect of which the application is made are not on the same site or in the same building as the premises of a provider of primary medical services with a patient list.

(b) unless the ICB is satisfied that the pharmacy procedures for the pharmacy premises are likely to secure—

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

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

(b) The applicant provided information via their application and additional information.

2.23 This has been reviewed by the ICB.

2.24 Whilst the applicant has covered most of the required information, there is unfortunately some information that is missing regarding how some parts of the essential service will be provided via non face to face methods.

2.25 There is no information regarding Paragraph 10(1) of schedule 4.

2.26 There is no information regarding Paragraph 22B & 22C of schedule 4.

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

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

2.29 Therefore, the recommendation is that the ICB is not satisfied that the pharmacy procedures for the pharmacy premises are likely to secure the safe and effective provision of essential services without face to face contact between any person receiving the services, whether on their own or on someone else's behalf, and the applicant or the applicant's staff.

Decision

Regulation 31.

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

Regulation 25(2)(1)(a)

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

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

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

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

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

2.34 The ICB is not satisfied that the pharmacy procedures for the pharmacy premises are likely to secure the safe and effective provision of essential services without face to face contact between any person receiving the services, whether on their own or on someone else's behalf, and the applicant or the applicant's staff. Therefore, the application has been refused.

2.35 Determination made by NHS North East London ICB on behalf of NHS West London ICB

Conditions of approval for a Distance Selling Pharmacy

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

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

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

2.36.3 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;

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

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

2.36.4.2 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 you or your staff; and

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

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

2.36.5.2 or you are likely to refuse, for reasons other than those provided for in your terms of service, to provide drugs or appliances ordered on

prescription forms or repeatable prescription forms which are presented by particular categories of patients (for example, because the availability of essential services from you is limited to other categories of patients)."

3 **The Appeal**

In a letter dated 2 May 2024 addressed to NHS Resolution, Rushport Advisory LLP on behalf of the Applicant appealed against the Commissioner's decision. The grounds of appeal are:

3.1 "I act for Medicine House Limited and have been instructed by my client to submit this appeal against the decision of the ICB to refuse the above application.

3.2 My client acknowledges that there was some information missing from their initial application and has therefore taken this opportunity to provide their full SOPs with this appeal as these address all the matters raised by the ICB in their letter of refusal.

3.3 In addition, my client notes that at part 4 of their application is blank in relation to the provision of appliances. For clarification we ask Primary Care Appeals to note that my client will provide appliances as listed in Part IX of the Drug Tariff, but not those that require measuring or fitting and we provide this information under Sch 2, Part 1, paragraph 9(a)(ii) of the relevant Regulations.

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

4 **Summary of Representations**

This is a summary of representations received on the appeal.

THE COMMISSIONER

4.1 "I am writing with reference to the above application appeal.

4.2 The application was refused as there were two elements of the essential service that the applicant had not covered in their application. We have now reviewed the additional documentation that they have sent with the appeal and this additional information has been reviewed.

4.3 Had this additional information been available at the time of the decision, this application would have been granted.

4.4 We, therefore, now have no further comments to make regarding this application."

5 **Summary of Observations**

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

6 **Consideration**

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

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

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

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

Regulation 31

6.5 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).

6.6 The Committee noted that the Applicant had not provided any information in the application form on this point. However, the Committee was aware that the wording of the application form only required the Applicant to include information in the relevant section if the proposed premises were adjacent to, or in close proximity to, another pharmacy or dispensing appliance contractor premises. The Committee considered it reasonable to determine that the lack of information in the application form on this point when read with the wording of the application form allowed it to be reasonably satisfied that the Applicant considered that the proposed premises were not adjacent to, or in close proximity to, another pharmacy or dispensing appliance contractor premises. Further the Committee noted the Commissioner's decision letter includes: *"There are no current pharmacies listed at the proposed premises or adjacent to the proposed premises. Therefore regulation 31 does not apply for this application."*

6.7 The Committee having regard to the above information and noting that there had been no challenge to it on appeal, determined that it was not required to refuse the application under the provisions of Regulation 31.

Regulation 25

6.8 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."

6.9 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)

6.10 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)

6.11 The Committee noted that the Applicant had not included any information in the relevant section of the application form. The Committee also noted that the application form states that the relevant section should only be completed if the proposed premises are on the same site or in the same building as the premises of a provider of primary medical services with a patient list. The Committee considered that, where the Applicant did not include any information in this section, it was reasonable to consider

that the Applicant was indicating that the proposed premises were not on the same site or in the same building as the premises of a provider of primary medical services with a patient list. The Commissioner in its decision report also stated that *"The proposed site is not on the same site or in the same building as the premises of a provider of Primary Medical Services with a patient list. Therefore, this regulation does not apply for this application."* Based on the information available to it, the Committee therefore determined that the proposed premises were not on the same site as, or in the same building as the premises of a provider of primary medical services with a patient list.

Regulation 25(2)(b)

6.12 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.

6.13 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.

6.14 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.

6.15 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.

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

6.17 The Committee noted in the SOPs provided by the Applicant that SOP 1 'Introduction and Background to SOPs' point 1.3 states that the pharmacy must provide: "*The uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services*." Also; "*The safe and effective provision of essential service 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."*

6.18 Further, SOP 3 'Procedures for NHS Essential Services' states: *"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."*

6.19 In its SOP 31 'The Responsible Pharmacist' point 31.9, the Applicant 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 a RP at a non-Distance Selling pharmacy is allowed to*

(for up to 2 hours per day) ***unless another pharmacist is present.*** [Emphasis added by Applicant.]

6.20 *The Pharmacy will have a second pharmacist available during the core and any additional hours that it operates. If, for any reason, the RP is required to leave the premises or wishes to take a break (as per Working Time Directive) then the second pharmacist must sign in as the RP."*

6.21 The Committee further noted point 32.1 of the Applicant's SOPS under the heading 'During the absence of the RP' states:

6.22 *"All of the pharmacy team must adhere to the pharmacy procedures set down by the RP.*

6.23 *Monitor the time that the RP has been absent.*

6.24 *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.*

6.25 *The pharmacy must contact the RP for additional instructions and the estimated time of return.*

6.26 The Committee considered that there was some confusion between points 31.9 and 32.1 of the SOPs. The Committee considered whether the second pharmacist signs in as RP immediately (even if the RP is taking only a short break) or whether the second pharmacist signed in only after an absence of 2 hours. The Committee was satisfied however that the Applicant had shown that there is a procedure to cover the absence of an RP and there would be at least one pharmacist on duty throughout the opening hours of the pharmacy.

6.27 The Committee noted that throughout the SOPs the Applicant states that essential services will be provided without face to face contact between any patient and the pharmacy staff. SOP 1 'Introduction and Background to SOPs' point 1.3 states:

6.27.1 "*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*.

6.27.2 *Face to face contact with patients or their representatives either on or in the vicinity of the premises is <u>only</u> allowed in respect of the provision of services other than Essential Services*.

6.27.1 *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*."

6.28 The Committee noted, as per 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' point 3.1 states: *"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."*

6.29 *"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."*

6.30 The Committee considered the information provided in the SOPs, alongside the information submitted with the application, were sufficient to provide assurance that the Applicant, if granted, would be offering pharmaceutical services without face to face contact.

6.31 The Committee was aware that when the pharmacy opens, it will be the responsibility of the Commissioner, in keeping with Regulation 64, to ensure that services are provided other than with face to face contact.

6.32 The Committee was satisfied that the provision of services would be without interruption, would be without face to face contact and would be available to persons anywhere in England. The Committee went on to consider whether safe and effective provision of essential services was likely to be secured.

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

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

Dispensing of drugs and appliances

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

6.36 From the information contained in the SOPs provided by the Applicant, SOP 3 'Procedures for NHS Essential Services' in the first paragraph states:

6.36.1 *"Patients who wish to send paper prescriptions to the pharmacy by post should be sent stamped addressed envelopes to enable them to do so."*

6.37 SOP 6 'Online Order Receipt & Exemption Checking', point 6.2 under the heading 'Scope' states:

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

6.37.2 *Requests to dispense a prescription received in the post.*

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

6.38 The Committee had regard to SOP 17 'Order Delivery' which under the heading 'Choice of Delivery Method' at point 17.6 states:

6.38.1 *"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 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."*

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

6.40 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

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

6.42 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 means 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.

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

Preliminary matters before providing ordered drugs and appliances

6.44 The Committee considered whether the Applicant had explained how evidence will be sought and obtained about the patients' entitlement to exemption or remissions from NHS Charges.

6.45 The Committee noted SOP 6 'Online Order Receipt & Exemption Checking' and in particular the heading 'Exempt NHS Prescriptions' point 6.11 which states:

6.45.1 *"…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."*

6.46 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.

6.47 The Committee then considered whether the Applicant had explained how charges will be paid.

6.48 The Committee noted SOP 6 'Online Order Receipt & Exemption Checking' under the heading 'Paid NHS Prescription' point 6.14 which states:

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

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

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

6.49 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 order drugs and appliances

6.50 The Committee considered whether the Applicant had explained how drugs/appliances will be provided to the patient (including to ensure that (i) the 'cold chain' is maintained, where relevant, and (ii) that the requirements of the Misuse of Drugs Regulations 2001 and, in particular, Regulations 14 and 16, are met). The Committee noted that SOP 17 'Order Delivery' under the heading 'Transfer to the Delivery Driver' at point 17.10 states:

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

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

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

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

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

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

6.50.7 *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.*

6.51 *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."*

6.51.1 Further SOP 17 at point 17.14, under the heading 'Delivery of a prescription via Royal Mail (Not for cold chain or CDs) states:

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

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

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

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

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

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

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

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

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

6.52 The Committee noted that the SOP then, under the heading 'Cold chain delivery via courier', at point 17.16 states:

6.52.1 *"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.*

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

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

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

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

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

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

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

6.53 The Committee noted SOP 17.7 under the heading '*Unsuccessful cold chain delivery via courier'* states:

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

6.53.2 *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."

6.54 The Committee noted SOP 17.8 under the heading 'Breach of Integrity of Cold Chain' states:

6.54.1 *"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.*

6.54.2 *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."*

6.55 The Committee noted that SOP 21 'Controlled Drugs: Delivery' under the heading 'Delivery of Schedule 2 & 3 CDs' at point 21.5 states:

6.55.1 *"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.*

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

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

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

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

6.55.6 *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.*

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

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

6.55.9 *The prescription should be retained in the pharmacy until the delivery driver returns the appropriate paperwork signed by the patient or representative to*

confirm successful delivery or the patient signature is confirmed online if delivered by courier."

6.56 The Committee noted SOP 21.6 under the heading 'Successful Schedule 2 & 3 Delivery' states*:*

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

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

6.57 The Committee noted SOP 21.7 under the heading 'Unsuccessful Schedule 2 & 3 Delivery via pharmacy driver' states:

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

6.58 The Committee noted SOP 21.8 under the heading 'Unsuccessful Schedule 2 & 3 Delivery via courier' states:

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

6.58.2 *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."*

6.59 The Committee noted SOP 21.9 under the heading 'Note re Use of Couriers for Controlled Drugs Deliveries' states:

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

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

6.61 The Committee considered whether the Applicant had explained the arrangement which would ensure that, for appliances which require fitting/measuring, a registered pharmacist measures/fits them.

6.62 In relation to appliances, the Committee noted that in its appeal the Applicant had stated: *"In addition my client notes that at part 4 of their application is blank in relation to the provision of appliances. For clarification we ask Primary Care Appeals to note that my client will provide appliances as listed in Part IX of the Drug Tariff but <u>not</u> those that require measuring or fitting and we provide this information under Sch 2 Part 1 paragraph 9(a)(ii) of the relevant regulations."*

6.63 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' point 7.9 where the Applicant states:

6.63.1 "*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)."*

6.64 SOP 24 'Support for Self-Care, Signposting and Heath Promotion' under the heading 'Items Requiring Measuring and Fitting' point 24.14 states:

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

6.65 In the event that the application is granted, the Applicant would therefore not be able to provide appliances to patients which require fitting/measuring.

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

6.67 The Committee next considered whether the Applicant had explained what containers would be suitable for posted/delivered items.

6.68 The Committee noted that SOP 16 'Bagging Up' under the heading 'Choice of Packaging' at point 16.7 states:

6.68.1 *"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.*

6.68.2 *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.*

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

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

6.68.5 *For postal items, either:*

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

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

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

6.68.9 *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 by the Applicant.]

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

Refusal to provide drugs or appliances ordered

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

6.71 The Committee noted that SOP 33 'Repeat Dispensing' states under the heading 'Pharmaceutical & Legal Assessment' at point 33.11:

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

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

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

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

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

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

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

6.71.2 *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."

6.72 The Committee further noted SOP 33 under the heading 'Prescription Reception' at point 33.10 states:

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

6.72.2 *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."*

6.73 The Committee was therefore satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 9(4) of Schedule 4.

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

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

6.75 The Committee noted SOP 33 'Repeat Dispensing' under the heading 'Prescription Reception' at point 33.10 states:

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

6.75.1.1has a long term, stable medical condition (that is, a medical condition that is unlikely to change in the short to medium term); and,

6.75.1.2*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*

6.75.1.3*the provider of primary medical services whose patient list the patient is on*.

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

6.76 Further, the Committee noted SOP 33 goes on under 'Pharmaceutical and Legal Assessment' at point 33.11 to states:

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

6.77 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

6.78 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.

6.79 For the return of controlled drugs, the Committee noted that in SOP 22 'Controlled Drugs: Collection and Disposal of Patient Returns', particularly under the heading 'Patient Returned Medication', at point 22.5 states:

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

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

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

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

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

6.79.6 *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 ending the appropriate packaging to the patient to arrange for return by Royal Mail…"*

6.80 The Committee notes that SOP 22 goes on under the heading 'Return by Royal Mail' to state at point 22.7:

6.80.1 *"The pharmacist must*:

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

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

6.80.1.3 *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)*

6.80.1.4 *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*.

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

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

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

6.81 The Committee noted that SOP 22 under the heading 'Handling Patient-Returned CDs from Delivery Driver' states at point 22.8:

6.81.1 *"Drivers need to*:

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

6.81.1.2 *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.*"

6.82 The Committee noted that SOP 23 'The Safe and Effective Receipt and Disposal of Medicines' under the heading 'Process for Patients to Return Medication' at point 23.6 states:

"Patient Returned Medication

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

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

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

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

Patients may

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

6.82.6 *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*,

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

6.82.8 *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)*."

6.83 The Committee noted that SOP 23 goes on under the heading 'Process for accepting patient returns by the Driver' at point 23.7 to state:

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

6.83.2 *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*.

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

6.83.4 *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'*.

6.83.5 *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*.

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

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

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

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

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

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

6.84 The Committee noted SOP23 under 'Disposal of returned medicines' at point 23.10, states:

6.84.1 *"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*.

6.84.2 *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*."

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

Promotion of healthy lifestyles

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

6.87 The Committee noted that SOP 25 'Promotion of Healthy Living, Lifestyles & Health Campaigns' under the heading 'Health Campaigns and Community Engagement Exercise' states at point 25.4:

6.87.1 *"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*.

6.87.2 *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*.

6.87.3 *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*.

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

6.87.4.1*a clinical audit carried out in a manner which is compatible with the NHSCB's* [sic] *arrangements for the receiving and processing of data from the audit, or*

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

6.87.5 *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*."

6.88 Further, in SOP 25, under the heading 'Identification of patients for promotion of healthy lifestyles' states at point 25.3):

6.88.1 *"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*."

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

Prescription linked intervention

6.90 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.

6.91 The Committee noted SOP 25 'Promotion of Healthy Living, Lifestyle & Health Campaigns' at point 25.3 under the heading 'Identification of patients for promotion of Healthy Lifestyles' states:

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

6.91.2 *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*.

6.91.3 *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*.

6.91.4 *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*.

6.91.5 *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*."

6.92 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

6.93 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.

6.94 The Committee noted that in SOP 25 'Promotion of Healthy Living, Lifestyle & Health Campaigns' under the heading 'Health Campaigns and Community Engagement Exercise', at point 25.4 states:

6.94.1 "*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*.

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

6.94.3 *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. …..*

6.94.4 *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*.

6.94.5 *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*."

6.95 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

6.96 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.

6.97 The Committee noted that in SOP 24 'Support for Self-Care, Signposting and Health Promotion' under the heading 'Patient Identification' at point 24.13, states:

6.97.1 "*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*.

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

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

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

6.97.3 *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*."

6.98 The Committee noted that in SOP 24 under the heading 'Other Provider Organisations and Support Details' at point 24.10 states:

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

6.99 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

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

6.101 The Committee noted SOP 24 'Support for Self-care, Signposting and Health Promotion' under the heading 'Service Outline' at point 24.9 states:

6.101.1 *"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.*

6.101.2 *If appropriate, access the patient's Summary Care Record to see if it assists in delivery of the service."*

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

Discharge medicines service

6.103 The Committee considered whether the Applicant had explained how it will provide advice, assistance and support to and in respect of a health service patient – (a) recently discharged from hospital who is referred to P for advice, assistance and support in respect of the patient's medication regimen by the staff of the hospital in which the patient stayed; or (b) who is otherwise referred to P for advice, assistance and support in respect of the patient's medication regiment by the staff of an NHS trust and NHS foundation trust as part of arrangements linked to the transfer of care between different providers of NHS services.

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

6.105 The Committee noted SOP 26 'Discharge Medicines Service ("DMS").

6.106 The Committee noted point 26.3 states:

"Process

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

6.107 The Committee noted point 26.5 states:

"DMS Stages

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

6.108 The Committee noted point 26.10 states:

"Additional advice, assistance and support

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

6.108.1.1 *Summary Care Record ….. - If appropriate, access the patient's*

6.108.1.2 *Summary Care Record ….. to see if it assists in providing the service*

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

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

6.108.1.5 *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.*

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

6.108.1.7 *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.*

6.108.1.8 *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

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

6.108.1.10 *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

6.108.1.11 *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.*

6.108.1.1 *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

6.108.1.2 *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.*

6.108.1.1 *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."*

6.109 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

6.110 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.

6.111 The Committee noted SOP 24 'Support for Self-care, signposting and health promotion' states under the heading 'Health Promotion Zone on our website' at point 24.11:

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

Explaining the Interactive Page to Patients

6.111.2 *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.*

6.111.3 *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.*

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

6.112 The Committee also noted further mention of health promotion zones is made in SOP 25 'Promotion of Healthy Living, Lifestyle & Health Campaigns' under the heading 'Identification of patients for promotion of healthy lifestyles' at point 25.3 which states:

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

6.113 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.

Summary

6.114 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).

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

6.115.1 confirm the Commissioner's decision;

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

6.115.3 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.

6.116 The Committee has reached a different conclusion from the Commissioner regarding the application. In those circumstances the Committee determined that the decision of the Commissioner must be quashed.

6.117 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.

6.118 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.

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

7 Decision

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

7.2 Accordingly, the Committee:

7.2.1 quashes the decision of the Commissioner; and

7.2.2 redetermines the application as follows -

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

7.2.2.2 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,

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

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

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

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

7.2.3 The application is granted.

Case Manager
Primary Care Appeals