

24 May 2024

REF: SHA/26163

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APPEAL AGAINST NHS LEICESTER, LEICESTERSHIRE AND RUTLAND ICB DECISION TO REFUSE AN APPLICATION BY KINGS PHARMACY LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT 146 KING STREET, LOUGHBOROUGH LE11 1SD 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:

Schedule Four Consultancy LLP – on behalf of the Applicant
Leicester, Leicestershire and Rutland ICB

Advise / Resolve / Learn

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1 The Application

By application dated 20 May 2023, Kings Pharmacy Ltd (“the Applicant”) applied to Leicester, Leicestershire and Rutland ICB (“the Commissioner”) for inclusion in the pharmaceutical list at 146 King Street, Loughborough LE11 1SD under Regulation 25. In support of the application it was stated:

- 1.1 In response to “If you are undertaking to provide appliances, specify the appliances that you undertake to provide (or write ‘none’ if it is intended that the pharmacy will not provide appliances)” the Applicant stated: *“Drug Tariff part IX” and “EXCEPT items that require measuring or fitting”*
- 1.2 In response to why the application should not be refused pursuant to Regulation 31 the Applicant stated: *“Not applicable as no other pharmacy in same or adjacent premises”*
- 1.3 In response to why the application should not be refused pursuant to Regulation 25(2)(a) the Applicant stated: *“Application is not on the same site or in the same building as the premises of a provider of primary medical services with a patient list.”*

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

- 1.4 Please find below information to explain how the pharmacy procedures used within the premises will secure:
 - (a) the uninterrupted provision of essential services during the opening hours of the premises, to persons anywhere in England who request those services, and
 - (b) the safe and effective provision of essential services without face to face contact between any person receiving the services, whether on their own or someone else's behalf, and the applicant or the applicant's staff.
- 1.5 The Applicant provided no further information other than floor plans for the proposed pharmacy.
- 1.6 The Applicant intends to provide the following services at these premises:
 - 1.6.1 Essential services;
 - 1.6.2 Appliances [already referred to above];
 - 1.6.3 Advanced and Enhanced services - NMS (remotely with consent where required).
- 1.7 The Applicant's proposed core opening hours are:

Mon to Fri 9am to 1pm
 2pm to 6pm

Sat -

Sun -

Total 40 hours

1.8 The Applicant's proposed total opening hours are as follows:

Mon to Fri 9am to 1pm
 2pm to 6pm

Sat -

Sun -

Total 40 hours

2 **The Decision**

The ICB considered and decided to refuse the application. The decision letter dated 17 January 2024 states:

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

Covering letter

2.1 "NHS Leicester, Leicestershire and Rutland 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 NHS Leicester, Leicestershire and Rutland 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 **"Kings Pharmacy Ltd, Distance Selling Premises at 146 King Street, Loughborough, LE11 1SD (2013 Regulations – Regulation 25 (Leicestershire))**

2.4 **Re: CAS-236957-G4C9V3**

Regulation 25

2.5 The applicant meets the criteria of Regulation 25(2)(a):

2.5.1 The proposed premises are not listed on the same site or in the same building as a GP practice.

2.6 The applicant has failed to provide assurance that the criteria of Regulation 25 (2)(b) will be met as the commissioner cannot be satisfied that the Pharmacy procedures for the pharmacy premises are likely to secure:

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

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

Regulation 31

2.7 Regulation 31 does not apply as the proposed pharmacy will not be adjacent or in close proximity to an existing pharmacy premises.

2.8 There are no existing pharmacies operating from the proposed best estimate location and therefore, under this provision, Regulation 31 would not cause the application to be refused.

Regulation 64

2.9 The applicant has not provided any additional information or Standard Operating Procedures to confirm that all the points within Regulation 64 will be met.

Fitness to practise

2.10 The fitness to practise criteria has been reviewed and approved by NHS England's Clinical Adviser (or whichever area team has approved the FTP).

2.11 The Committee agreed that the approval of the application will have no impact on those with protected characteristics or on NHS England's duty on health inequality.

2.12 The Committee was not satisfied that the applicant meets all of the criteria for opening a wholly, internet/mail order-based distance selling premises and therefore determined to **decline** this application, on the grounds that the applicant has failed to provide sufficient evidence to satisfy all elements of Regulation 25 and Regulation 64.

Appeal Rights

2.13 Kings Pharmacy Ltd"

3 The Appeal

By email dated 14 February 2024, Schedule Four Consultancy LLP on behalf of the Applicant, appealed against the Commissioner's decision. The grounds of appeal are:

- 3.1 Please provide below a concise and reasoned statement of your grounds of appeal. Please include an explanation of any supporting information that you are submitting to support your appeal.
- 3.2 "The original application form did not contain information so that the NHS Leicester, Leicestershire, and Rutland ICB could be assured that:
 - 3.2.1 The criteria of Regulation 25(2)(b) could be met
 - 3.2.2 That the points within Regulation 64 would be met
 - 3.2.3 This was an oversight by the applicant and the applicant unreservedly apologises for this.
- 3.3 It is submitted that the committee:
 - 3.3.1.1 failed to contact the applicant to provide the information that was omitted so that it could make a fully grounded assessment of the application
and / or
 - 3.3.1.2 failed to direct that the applicant be contacted by the ICB to provide the information that was omitted so that it could make a fully grounded assessment of the application
and / or
 - 3.3.1.3 failed to adjourn the decision-making hearing so that the applicant could be contacted by the ICB to provide the information that was omitted so that it could make a fully grounded assessment of the application
and / or
 - 3.3.1.4 failed to adjourn the decision-making hearing so that the applicant could be contacted by the committee to provide the information that was omitted so that it could make a fully grounded assessment of the application.
- 3.4 The application is now presented again with the information that was omitted.
- 3.5 The applicant requests that the committee hear the appeal in light of the new information provided."

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

- 3.7 The pharmacy will have SOPs in place for the provision of essential services. It is pertinent to know that only some of the SOPs have been provided to help facilitate the application, any specific SOP can be provided if requested.
- 3.8 Kings Pharmacy Ltd will have a website which facilitates the following:
- 3.8.1 Patient accesses website via a secure log-in procedure;
 - 3.8.2 Patient provides details of prescription;
 - 3.8.3 Patient will be contacted by the pharmacy and medical history assessed;
 - 3.8.4 Patient posts prescription to pharmacy and/or prescription received via EPS;
 - 3.8.5 Item is dispensed and details added to PMR;
 - 3.8.6 The medication is delivered nationwide via a tracked delivery service. There will be no charge to the patient for delivery of medication dispensed against NHS prescriptions. Any costs incurred for delivery will be met by the pharmacy.
- 3.9 The website will be built by a company called the 'Dash Media' (<https://dashmedia.co.uk>) who are web developers that have experience within the pharmacy web development market. Each patient will have their own personal login account once registered which will include their own personalised password for added security. Upon patient consent the pharmacy will then nominate them for EPS. This will then enable us to deliver a service safely and effectively to anyone in England without face to face contact.
- 3.10 Communication between the pharmacy and patients will be facilitated by phone, fax, email and webcam. Records of all patient interactions will be maintained on the PMR in use at the pharmacy. Kings Pharmacy Ltd has decided to use Titan PMR (<https://www.titanpmr.com>) as the software provider which will be a key tool in providing a safe and effective provision of service.
- 3.11 Kings Pharmacy Ltd is committed to having all staff trained by the National Pharmaceutical Association at a level suitable to their role. All training will need to be recognised and accredited by the GPhC and all staff will hold NVQ qualifications in Pharmacy Services. Staff and Responsible Pharmacists will also be provided with training on the SOPs relevant to their role. By following a set of SOPs, the pharmacy will be able to provide a safe and effective service that is patient-centric and outcome focussed.
- 3.12 The Superintendent Pharmacist will train all the staff members on the conditions of being a distance selling contractor. They will receive specific training on design patients [sic] without face-to-face contact, an example being how to elicit a comprehensive medical history by telephone or webcam.
- 3.13 Kings Pharmacy Ltd is comprised of two directors, Abu Taher and Dr Joynal Abedin. Mr Taher is the nominated superintendent and has suitable pharmacy experience. Mr Taher will act in overseeing the operations of the pharmacy and will maintain role of the Information Governance Lead, Clinical Governance Lead and Smartcard Sponsor. A full-time Responsible Pharmacist will be employed to be in attendance during the opening hours. He/she will be supported by a staff team of one full-time and one part-time dispenser. This level of staff will be able to cover initial trade levels once the pharmacy is open and will ensure an uninterrupted provision of essential services during the opening hours. The team is expected to grow with the business and new members will be added as and when required.
- 3.14 The premises have been carefully chosen to prevent face to face contact for any person seeking the provision of essential services, in, or within the vicinity of the premises. No

person who is seeking essential services under the NHS contract will be allowed entry to the premises and this will be made clear by the positioning of posters on any outward facing window and door of the premises. The poster will inform any persons seeking to have essential services provided of the ways in which they can contact the pharmacy so that essential services can be provided to them. All entrances and exits will remain inaccessible to members of the public who are seeking the provision of essential services. An alarm system will cover the pharmacy premises which will notify the owner of unauthorised access when the premises are closed. All access routes will always be secured and kept locked when the premises not in use. Keys to the pharmacy premises will only be kept with authorised persons employed by the company. Schedule 1, 2 and relevant 3 drugs will always be stored in a locked CD cabinet. Security of premises will be reviewed regularly. A chosen member of staff will be available for emergency outcall in case of a breach.

Essential Service – Dispensing

Uninterrupted service

- 3.15 Provision of service through the opening hours of the pharmacy will be maintained by having a Responsible Pharmacist present at all times during the pharmacy opening hours and having sufficient support staff at all times. The pharmacy website will run throughout these hours together with a phone, fax, email and webcam service. If the responsible pharmacist is required to leave the premises, a further pharmacist will be on hand to ensure that there is no break in pharmacist cover during the opening hours. Persons anywhere in England.
- 3.16 Patients anywhere in England can access these services via our pharmacy website a direct phone line to the pharmacy, fax, email as well as webcam. Internet connections at the pharmacy will be provided by the NHS N3 network via BT.
- 3.17 All prescriptions dispensed will be delivered using a dedicated courier service provided by City Sprint (www.citysprinthealth.co.uk). This will include the delivery of prescriptions received via post, fax and EPS release 2. City Sprint will also be delivering cold chain items and CDs. This is addressed in the SOPs which have been included.

Safe and effectively

- 3.18 The service will be delivered safe and effectively by using SOPs to manage the process. Please see the attached SOPs provided to show examples of how the pharmacy will be managed safely and efficiently at all times.
- 3.19 We will have a suitable number of staff who will be trained to a minimum of an NVQ level 2 (www.npa.co.uk)
- 3.20 Requests from patients to show the Pharmacist visual symptoms of conditions will be done via a secure video link. All conversations will be recorded on the PMR in detail.
- 3.21 If patient counselling is required for any dispensed medication, the pharmacy will have procedures so this can be done via the telephone or email before dispatch of medication. The pharmacy will require acknowledgment from the patient or another person that the counselling points have been understood. Patient interactions will be recorded on the PMR. A label will also be attached to the packaging asking the patient to contact the pharmacy for further details.
- 3.22 Prior to medication being delivered, staff will contact patient to confirm delivery address, date and time. Deliveries will be monitored with the online courier tracking service which will give real-time information and is also available as an app for smart phone and tablets.

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

Without face-to-face contact

- 3.24 This service will be delivered without face-to-face contact via the pharmacy website as a communication link as well as telephone post/email/fax/webcam. A courier service will provide a third-party delivery if this is required when it would not be practicable to use the in-house delivery service.
- 3.25 If needed, Controlled Drug (CD) deliveries will be undertaken by City Sprint who are accredited to handle and transport CDs. Their drivers will deliver to patients at a pre-determined time and the CD's must be signed for on receipt. Their drivers will only deliver the CD to the named recipient and they will ask for photographic proof of ID. In the instance of a failed delivery attempt, City Sprint will return any CDs to their overnight safe storage facility and the pharmacy will be contacted to arrange alternative delivery date to patient.
- 3.26 City Sprint is approved by the MHRA and has fully trained couriers to deal with all pharmacy deliveries including controlled drugs and fridge items. As well as collecting prescriptions from surgeries and collection of unwanted waste medication from patients. This will ensure there is no face to face contact.
- 3.27 Delivery of Refrigerated Medicinal Products - For cold chain products, delivery times will always be pre-arranged with the patient to minimise the risk of failed delivery. The patient's contact number will be given to the City Sprint delivery driver so they can again call the patient approximately 15-30 minutes prior to so they can check that somebody will be at the address to receive the medication.
- 3.28 Cold chain products will be packed in such a way as to ensure that the required temperatures are maintained throughout the journey and the medicines are transported in accordance with their labelling requirements to maintain product integrity.
- 3.29 For delivery of medication with short journey times of less than 3 hours, validated medical cool boxes will be used as recommended by the MHRA. For extended journeys, gels/ ice packs will be added to the packaging to maintain appropriate temperatures throughout. Extra caution will be taken with regards to the positioning of these packs within the consignments as this would be deemed extremely important as they must not be allowed to come into direct contact with the medicines being delivered. Temperatures will be strictly controlled and monitored with calibrated temperature probes to provide temperature data for the entire journey. This will be done by the courier driver. Temperatures will be recorded at the beginning of the journey and again at the point of delivery to ensure it stays between 2-8°C. If the temperature is outside of the required range, then the product will be deemed unsafe to deliver, marked as waste and returned to the pharmacy for destruction.
- 3.30 Thermometer(s) will be calibrated annually against a certified standard to ensure safe and effective use. When used to deliver medication, the City Sprint delivery driver must only remove the item from cold storage once the patient has answered the door and verified their identity. In the event of failed delivery, the cold storage item must be returned to the pharmacy as soon as possible, with the maximum and minimum temperatures again being recorded at the point of return. Once again, if temperature monitoring suggests that the medication may have been transported outside of the required range, then the product will be destroyed by the pharmacy and then item will be re-dispensed by the pharmacy. Once again, a new delivery will be agreed with the patient prior to redelivery.

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

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

Essential Service - Disposal of Unwanted Medication

Uninterrupted Service

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

Persons anywhere in England

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

Safe and Effectively

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

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

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

Without face-to-face contact

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

Essential Service – Signposting

Uninterrupted Service

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

Persons anywhere in England

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

Safe and Effectively

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

Without face-to-face contact.

- 3.40 Signposting will be delivered without face-to-face contact via the website email phone, post fax or webcam. All patients will communicate with the pharmacy via these methods and as such there will be no face-to-face patient interaction. The SOPs in place ensure we can deliver the service without face to face contact in a distance selling model.

Essential Service - Repeat Dispensing

Uninterrupted Service

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

Persons anywhere in England

- 3.42 Patients anywhere in England can access the Repeat Dispensing service by signing consent form which is available on the website for anyone wishing to use the service. This consent form can be emailed, faxed or posted directly to the pharmacy. Patients from surgeries that are ETP 2 compliant will have their prescriptions sent and received at the pharmacy electronically almost instantly after the Doctor signs off the electronic

prescription. The prescriptions medicines will be dispensed and despatched for delivery by our in-house delivery service or the courier without any delay.

Safe and Effectively

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

Without face-to-face contact

- 3.44 All repeat dispensing patients will be communicated without face-to-face contact via phone, email, post, fax or webcam. All medications will be delivered using our in-house delivery service or the City Sprint courier service and will maintain service delivery without face-to-face contact. We have SOPs in place to manage these services without face-to-face contact.
- 3.45 For patients who request our service and who are NOT signed up to the repeat dispensing service, we will request that they contact the pharmacy so that we can discuss their suitability for the service but also provide further information on the benefits of the service. The initial contact with the patient will be via a leaflet which will be included within their dispensed medication. Benefits will include saving time for the patient and the prescriber due to a decreased workload on both parties. A further benefit will include an improvement of medication safety as the pharmacy will check each and every request to ensure that the medication is still suitable before dispensing. During these checks, if a medication is flagged as being unsuitable or there are side effects, then the patient will be referred to the prescriber for discussion.

Essential Service – Discharge Medicine Service

Uninterrupted Service

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

Persons anywhere in England

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

Safe and Effectively

- 3.48 Discharge Medicine service will be delivered safe and effectively via the staff completing sufficient clinical and legal training to provide the service. Hospitals will identify patients who will benefit from discharge medicine service and will send a referral to the patient's pharmacy via secure electronic system. When a referral is received, the pharmacist will review the information in the referral, including comparing the revised medicines prescribed to those the patient used before being admitted to hospital. If any issues are identified, these will be queried with the hospital or the general practice. Pharmacy team members will check whether there are any existing dispensed prescriptions waiting for the patient or any electronic repeat dispensing prescriptions on the NHS spine. If there are, these need to be checked to see if they are still appropriate for the patient. The pharmacist will have a consultation with the patient and/or their carer to check their understanding of what medicines they should now be using and to provide further advice. If there are medicines the patient is no longer using, we will offer to dispose of them, to avoid potential confusion in the future. When the first prescription for the patient is received by the pharmacy following discharge, there will be a check to compare the medicines prescribed by the hospital and those prescribed by the GP. If there are discrepancies or other issues, the pharmacist will try to resolve them with the general practice. The pharmacist must use their clinical judgement when considering their actions and recommendations in respect of the service and consider the duty of confidentiality to the patient when involving a carer in discussions about the patient and their medication regimen.
- 3.49 Relevant information will be documented on the PMR/IT System for Stage 1, 2 and 3 to ensure continuity of the service.

Without face-to-face contact

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

Essential Service - Public Health (Promotion of Healthy Lifestyles) Prescription linked intervention/Uninterrupted service

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

Persons anywhere in England

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

Safe and effectively

- 3.53 This service will be delivered safe and effectively by pharmacists and appropriately trained staff. At risk patients will be targeted through prescription linked intervention. Opportunistic advice will be given by the pharmacist on specified healthy living/public health topics to patients who have their prescriptions fulfilled by the pharmacy. Staff

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

Without face-to-face contact

- 3.54 The service will be delivered without face-to-face contact via telephone, email, live chat or video link. Any educational material relating to certain conditions can also be sent in the post or inserted without face to face contact.

National Health Campaign

Uninterrupted Service

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

Persons anywhere in England

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

Safe and Effectively

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

Without face-to-face contact

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

Essential Service - Support for Self Care

Uninterrupted Service

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

Persons anywhere in England

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

Safe and Effectively

- 3.61 Support for self care will be delivered safe and effectively. Pharmacy staff will provide advice to patients including carers requesting help with the treatment of minor illness and long term conditions, including general information and advice on how to manage illness. Using website or telephone consultation, we can assess patients using a protocol based on the WWHAM model.

- 3.62 Visual symptoms can be accessed via a video link if necessary. The pharmacy staff will advise on the appropriate use of the wide range of non prescription medicines which can be used in the self-care of minor illness and long term conditions. When appropriate pharmacy staff will make healthy interventions in a similar manner to that provided in promotions of healthy lifestyle service. When appropriate and where necessary, pharmacy staff will signpost patients to other health and social care providers. Records of advice given, products purchased or referrals made will be put on to the patients PMR when the pharmacist deems it to be of clinical significance. Any medication sold online will be sent to the patient via City Sprint couriers.

Without face-to-face contact

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

Essential Service - Clinical Governance

- 3.64 There will be a named Clinical Governance Lead who will also be the Superintendent Pharmacist, Abu Taher.

Patient and public involvement

- 3.65 A practice leaflet will be easily accessible on the front page of the pharmacy website and we will also supply a paper copy to all patients when first delivering to them. Updated leaflets will sent to all registered patients should there be any significant changes. All services provided by the pharmacy will be listed on the leaflet and whether the service is funded by the NHS or privately. In addition, the pharmacy will produce an annual patient satisfaction survey presented to patients who use our service electronically and along with delivery of medication. Patients will have the option to return the satisfaction surveys electronically or through the post via a pre-paid envelope. The results of the patient satisfaction survey will be published on the pharmacy website and practice leaflet. The results will feed into the pharmacy's continuous quality improvement scheme.

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

Clinical audit

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

Risk management

- 3.68 GPhC near miss template and help identify trends or highlight weaknesses in pharmacy systems and procedures and would be rectified promptly. Any patient safety incidents will be reported to the National Patient Safety Agency (NPSA) online. We will analyse and learn from any patient safety incidents through a system of regular reviews. In addition, the pharmacist will be proactive in considering and preventing potential risks. This will include competence in risk management and the application of Root Cause Analysis. Health and Safety legislation will be complied with in order to reduce the risk of harm to pharmacy staff and the public.
- 3.69 All patient safety communications received at the pharmacy either by fax, email or post will be actioned by the Pharmacist and pharmacy staff promptly and records of this will be kept at the pharmacy for audit purposes. We will have adequate facilities in place to be able to dispose of any confidential waste. NHS Code of Practice on Confidentiality will also be met.
- 3.70 Kings Pharmacy Ltd have produced DRAFT- Standard Operating Procedures (SOPs) at this point in time to cover the Essential Services. These procedures will continue to be developed up until when we secure the contract and commence trading. The SOPs will be reviewed at a minimum annually or a result of changes in best practice, new regulations or as a corrective action following any adverse incidents. The Superintendent Pharmacist will be responsible for the maintenance of the SOPs and training all staff in the SOPs relevant to their role.
- 3.71 All pharmacy staff will be trained in and aware of child and vulnerable adult safeguarding procedures, and have access to safeguarding arrangements and reporting to all areas of United Kingdom via access to internet at the pharmacy. Any documentation will be kept for audit purposes.

Staffing and staff management

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

Education, training and continuing professional and personal development

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

Use of information to support clinical governance and health care delivery

- 3.74 Pharmacy staff will have full access to up to date reference sources such as the BNF and Drug Tariff and with appropriate IT links with electronic reference sources. Kings Pharmacy Ltd will ensure all employees will comply with data protection and confidentiality, including the Data Protection Act 2018, Human Rights Act 1998 and common law of confidentiality. Kings Pharmacy Ltd will ensure that all employees will conform to the NHS Code of Practice on confidentiality and will have systems and

policies in place to support this including ensuring all staff are appropriately trained. Employee contracts will include a duty of confidence as a specific requirement linked to disciplinary procedures.

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

Proof of exemption/prescription charges

- 3.76 If the patient is under 16 or over 60 years of age and the date of birth is printed on the front of the prescription then no check of exemption status is required. The pharmacy will make use of real time exemption checking (RTEC) via the PMR system if appropriate. For all other exemptions, the pharmacy will make contact with the patient and ask them for proof of their exemption. The pharmacy will ask patients to send proof of exemption to the pharmacy via post, fax or as an email attachment. The exemption details can also be updated on the secure pharmacy website. The pharmacy will keep records of exemption on the PMR, including when the exemption runs out or expires. On each dispensing occasion, we would verify exemption details and seek explicit permission from the patient if they would like the pharmacy to fill in the back of the prescription on their behalf. We would make a record each time the patient gave us permission to fill in the back of the prescription on their behalf so there is an audit trail. If the patient wishes to fill in the back of the prescriptions themselves we would send the prescription to the patient via courier for them to fill in and return to us. This could be done at the same time as the medication is being delivered or prior to delivery depending on patient preference. If patient is unable to provide proof of exemption, the pharmacy would mark the back of the prescription to indicate that the exemption has not been seen. Where prescription charge(s) need to be taken, the pharmacy will have facilities in place whereby card details can be taken over the telephone or via a secure internet site. The pharmacy will cover the cost of postage by arranging for an insured courier to collect prescription charges nationally via a tracked service.

Additional Information

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

4 **Summary of Representations**

No representations received on the appeal.

5 **Consideration**

- 5.1 The Pharmacy Appeals Committee ("Committee") appointed by NHS Resolution, had before it the papers considered by the Commissioner.
- 5.2 It also had before it the responses to NHS Resolution's own statutory consultations.
- 5.3 On the basis of this information, the Committee considered it was not necessary to hold an Oral Hearing.
- 5.4 The Committee had regard to the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 ("the Regulations").

Regulation 31

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

5.6 The Committee noted the application form includes: "Not applicable as no other pharmacy in same or adjacent premises". The Committee further noted the Commissioner's decision letter states: "Regulation 31 does not apply as the proposed pharmacy will not be adjacent or in close proximity to an existing pharmacy premises." This had not been challenged on appeal. Based on the information provided, the Committee was not required to refuse the application under the provisions of Regulation 31.

Regulation 25

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

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

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

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

in respect of pharmacy premises that are distance selling premises.

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

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

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

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

(ii) the safe and effective provision of essential services without face to face contact between any person receiving

the services, whether on their own or on someone else's behalf, and the applicant or the applicant's staff."

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

Additional information to be included with excepted applications

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

Nature of details to be supplied

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

Regulation 25(1)

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

Regulation 25(2)(a)

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

Regulation 25(2)(b)

- 5.11 As far as Regulation 25(2)(b) is concerned, the Committee considered the information which had been provided by the Applicant in relation to its procedures for the provision of essential services, including its Standard Operating Procedures (SOPs) that it intends to use at the proposed pharmacy premises.
- 5.12 The Regulations require the Committee to be satisfied as to a number of matters, including that essential services will be provided on an uninterrupted basis, in a safe and effective way, across England, and without face to face contact.
- 5.13 Paragraph 8 of Schedule 2 requires an applicant to provide details in relation to an application, and paragraph 10 of Schedule 2 indicates that the obligation is only discharged if the information or documentation provided is sufficient to satisfy the

Commissioner in receipt of it, with good cause, that no relevant information or documentation is missing, having regard to the uses that the Commissioner may need to make of the information or documentation when carrying out its functions.

- 5.14 The Committee has asked itself whether it has sufficient information and documentation which would address the criteria in Regulation 25(2)(b). If the Committee is to be satisfied of the matters in that paragraph, the Committee must be provided with evidence to demonstrate these matters. In this case, that evidence put forward has taken the form of the original application and the SOPs which the Applicant has prepared or commissioned.
- 5.15 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 in order to satisfy itself that it is appropriate to grant the application, the absence of which would require it to reject it.
- 5.16 The Committee considered how the Applicant would provide essential services without interruption:
- 5.16.1 3.13 above - *“A full-time Responsible Pharmacist will be employed to be in attendance during the opening hours. He/she will be supported by a staff team of one full-time and one part-time dispenser. This level of staff will be able to cover initial trade levels once the pharmacy is open and will ensure an uninterrupted provision of essential services during the opening hours.”*
- 5.16.2 3.15 above - *“Provision of service through the opening hours of the pharmacy will be maintained by having a Responsible Pharmacist present at all times during the pharmacy opening hours and having sufficient support staff at all times. The pharmacy website will run throughout these hours together with a phone, fax, email and webcam service. If the responsible pharmacist is required to leave the premises, a further pharmacist will be on hand to ensure that there is no break in pharmacist cover during the opening hours.”*
- 5.17 The Committee considered how the Applicant would provide essential services without face to face contact:
- 5.17.1 3.12 above - *“The Superintendent Pharmacist will train all the staff members on the conditions of being a distance selling contractor. They will receive specific training on design [SIC] patients without face-to-face contact, an example being how to elicit a comprehensive medical history by telephone or webcam.”*
- 5.17.2 3.14 above - *“The premises have been carefully chosen to prevent face to face contact for any person seeking the provision of essential services, in, or within the vicinity of the premises. No person who is seeking essential services under the NHS contract will be allowed entry to the premises and this will be made clear by the positioning of posters on any outward facing window and door of the premises. The poster will inform any persons seeking to have essential services provided of the ways in which they can contact the pharmacy so that essential services can be provided to them. All entrances and exits will remain inaccessible to members of the public who are seeking the provision of essential services. An alarm system will cover the pharmacy premises which will notify the owner of unauthorised access when the premises are closed. All access routes will always be secured and kept locked when the premises not in use. Keys to the pharmacy premises will only be kept with authorised persons employed by the company.”*

- 5.17.3 3.24 above - *“This service will be delivered without face-to-face contact via the pharmacy website as a communication link as well as telephone post/email/fax/webcam. A courier service will provide a third-party delivery if this is required when it would not be practicable to use the in-house delivery service.”*
- 5.18 The Committee considered how the Applicant would provide essential services throughout England:
- 5.18.1 3.56 above - *“Patients anywhere in England can access these services via the pharmacy website, telephone, email, live chat, video link as well as sending out printed leaflets. The website will have a specific area for current health campaigns and allow outbound links to accredited organisations and clear routes to further resources.”*
- 5.18.2 3.17 above - *“All prescriptions dispensed will be delivered using a dedicated courier service provided by City Sprint (www.citysprinthealth.co.uk). This will include the delivery of prescriptions received via post, fax and EPS release 2. City Sprint will also be delivering cold chain items and CDs. This is addressed in the SOPs which have been included.”*
- 5.19 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.
- 5.20 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.
- 5.21 The Committee considered each essential service in paragraphs 3 to 22 of schedule 4 of the Regulations ("Terms of Service") in turn.
- 5.22 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

- 5.23 The Committee considered whether the Applicant had explained how non-electronic prescriptions will be presented by the patient and how products will be provided.
- 5.24 The Committee noted the Applicants comments:
- 5.24.1 *“Essential Service – Dispensing*
- 5.24.2 *Persons anywhere in England*
- 5.24.3 3.16 above - *Patients anywhere in England can access these services via our pharmacy website a direct phone line to the pharmacy, fax, email as well as webcam. Internet connections at the pharmacy will be provided by the NHS N3 network via BT.”*
- 5.24.4 3.56 above - *“Patients anywhere in England can access these services via the pharmacy website, telephone, email, live chat, video link as well as sending out printed leaflets. The website will have a specific area for current health campaigns and allow outbound links to accredited organisations and clear routes to further resources.”*

- 5.24.5 3.17 above - *“All prescriptions dispensed will be delivered using a dedicated courier service provided by City Sprint (www.citysprinthealth.co.uk). This will include the delivery of prescriptions received via post, fax and EPS release 2. City Sprint will also be delivering cold chain items and CDs. This is addressed in the SOPs which have been included.”*
- 5.25 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
- 5.26 The Committee considered whether the Applicant had explained how it proposes safely and effectively to receive requests from prescribers for urgent supplies of drugs and appliances.
- 5.27 The Committee noted the Applicant’s information on appeal:
- 5.27.1 3.31 above - *“Acute or Urgent Dispensing Requests – Any acute, urgent medication received by ETP or directly via courier from a surgery for patients anywhere in England can be dispensed and dispatched the same day using City Sprint who offer a 24 hour, 365 day service for any type of delivery.”*
- 5.27.2 SOP 184 for Urgent Medicine Supply and noted that the Applicant had described how it would process such a request. The Committee noted the SOPs state that *“All communication must be via email, phone, fax, webcam service or post”*. The Committee considered that it was reasonable to infer that these methods would be used to receive requests from prescribers for the urgent supply of drugs.
- 5.28 The Committee was therefore satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 6 of Schedule 4.
- Preliminary matters before providing ordered drugs or appliances
- 5.29 The Committee considered whether the Applicant had explained how evidence will be sought and provided about the patients’ entitlement to exemption or remissions from NHS Charges.
- 5.30 The Committee noted the Applicant’s information on appeal includes:
- 3.76 above - *“Proof of exemption/prescription charges*
- 5.30.1 *If the patient is under 16 or over 60 years of age and the date of birth is printed on the front of the prescription then no check of exemption status is required. The pharmacy will make use of real time exemption checking (RTEC) via the PMR system if appropriate. For all other exemptions, the pharmacy will make contact with the patient and ask them for proof of their exemption. The pharmacy will ask patients to send proof of exemption to the pharmacy via post, fax or as an email attachment. The exemption details can also be updated on the secure pharmacy website. The pharmacy will keep records of exemption on the PMR, including when the exemption runs out or expires. On each dispensing occasion, we would verify exemption details and seek explicit permission from the patient if they would like the pharmacy to fill in the back of the prescription on their behalf. We would make a record each time the patient gave us permission to fill in the back of the prescription on their behalf so there is an audit trail. If the patient wishes to fill in the back of the prescriptions themselves we would send the prescription to the patient via courier for them to fill in and return to us. This could be done at the same time as the medication is being delivered or prior to delivery depending on patient preference. If patient is unable to provide proof of*

exemption, the pharmacy would mark the back of the prescription to indicate that the exemption has not been seen.”

5.31 The Committee further noted SOP 1 for Prescription Reception:

5.31.1 *“Take any charge or document the [sic] reason for exemption*

5.31.2 *Check the back of the prescription to see if it is filled in if the prescription is not an EPS prescription. If using the Real Time Exemption Check facility, the PMR will show whether the patient is exempt.*

5.31.2.1 *If the patient is claiming exemption, make sure a box is ticked and they have signed in the correct place. Attach a note to the prescription as a prompt to enquire with the patient to ask to see a scan of their proof of exemption.*

5.31.2.2 *If they have none put a cross in the top left hand circle.*

5.31.2.3 *If the patient pays, collect the appropriate money per item via credit card or ensure the driver knows to collect the money when he delivers, make sure the back is filled incorrectly, and do a sale’s transaction in the usual way.*

5.31.2.4 *Record the amount of money you have taken for the Rx on the front of the Rx form. This may well be different from what the patient / representative will have written on the back of the form*

5.31.2.5 *If you are unsure how many fees to take for, ask a member of the dispensary staff or check the list on the wall of prescription items and their charges.*

5.31.2.6 *If it is a private Rx ring the patient to let them know how much it will cost before the dispensary staff prepare the item*

5.31.2.7 *Fill out a docket with the patient’s name and how many prescriptions they have*

5.31.2.8 *Tell the patient the expected time for delivery of the script, either using your judgement or checking with the pharmacist/driver when the next delivery will be made”*

5.32 The Committee further noted SOP 4 for Prescription Labelling:

5.32.1 *“If, or once, you have a patient match check the following details are present any middle names, DOB, postcode, NHS identification number, prescriber’s name, any medical conditions, allergy status, reason for exemption, and then write the labels”*

5.33 The Committee further noted SOP 184 for Urgent Medicine Supply:

5.33.1 *“We will need to ask the patient or their representative the reason for the exemption and this will need to be recorded on the back of the token. We will also need to complete the back of the token on the patient’s behalf. This will include asking for evidence of their exemption, if they have one, to be shown to us over a webchat service or sent to us on email.*

5.33.2 *If the patient can’t provide evidence of exemption we must record this on the dispensing token. NHS England may check a patient’s entitlement and if necessary recover any charges that should have been paid”.*

5.34 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.

- 5.35 The Committee considered whether the Applicant had explained how charges will be paid.
- 5.36 The Committee noted the Applicant's information on appeal [see point 3.76 above] includes: *"Where prescription charge(s) need to be taken, the pharmacy will have facilities in place whereby card details can be taken over the telephone or via a secure internet site. The pharmacy will cover the cost of postage by arranging for an insured courier to collect prescription charges nationally via a tracked service."*
- 5.37 The Committee further noted SOP 1 for Prescription Reception:
- 5.37.1 *"If the patient pays, collect the appropriate money per item via credit card or ensure the driver knows to collect the money when he delivers, make sure the back is filled incorrectly, and do a sale's transaction in the usual way."*
- 5.37.2 *Record the amount of money you have taken for the Rx on the front of the Rx form. This may well be different from what the patient / representative will have written on the back of the form*
- 5.37.3 *If you are unsure how many fees to take for, ask a member of the dispensary staff or check the list on the wall of prescription items and their charges.*
- 5.37.4 *If it is a private Rx ring the patient to let them know how much it will cost before the dispensary staff prepare the item"*
- 5.38 The Committee further noted SOP 9b for The Receipt and Endorsement of Repeat Prescriptions:
- 5.38.1 *"Contact the patient to ascertain the details so that the back of the first batch issue can be completed in the usual manner before sending it or when the driver delivers the medication and take the necessary charge via credit/debit card if the patient pays".*
- 5.39 The Committee further noted SOP 142 the supply of OTC medicines online:
- 5.39.1 *"This company has a shop on the web that advertises for sale various types of OTC medicines, including P medicines that can only be sold under the supervision of a pharmacist."*
- 5.39.2 *Details of an order taken on the web is emailed to the pharmacy.*
- 5.39.3 *Payment will be made by the clients leaving their credit / debit card details."*
- And*
- 5.39.4 *"If they are now happy with the sale, put the payment details through the terminal to check the details are valid and payment is accepted."*
- 5.39.5 *Pack the item up in a secure parcel with the sales receipt and credit card slip."*
- 5.40 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 7(5)(b) of Schedule 4.
- Providing ordered drugs or appliances
- 5.41 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).

- 5.42 The Committee noted the Applicant's information on appeal includes the following [see point 3.27 to 3.30 above]:

“Essential Service Dispensing

Without face to face contact

- 5.42.1 *“Delivery of Refrigerated Medicinal Products - For cold chain products, delivery times will always be pre-arranged with the patient to minimise the risk of failed delivery. The patient's contact number will be given to the City Sprint delivery driver so they can again call the patient approximately 15-30 minutes prior to so they can check that somebody will be at the address to receive the medication.*
- 5.42.2 *Cold chain products will be packed in such a way as to ensure that the required temperatures are maintained throughout the journey and the medicines are transported in accordance with their labelling requirements to maintain product integrity.*
- 5.42.3 *For delivery of medication with short journey times of less than 3 hours, validated medical cool boxes will be used as recommended by the MHRA. For extended journeys, gels/ ice packs will be added to the packaging to maintain appropriate temperatures throughout. Extra caution will be taken with regards to the positioning of these packs within the consignments as this would be deemed extremely important as they must not be allowed to come into direct contact with the medicines being delivered. Temperatures will be strictly controlled and monitored with calibrated temperature probes to provide temperature data for the entire journey. This will be done by the courier driver. Temperatures will be recorded at the beginning of the journey and again at the point of delivery to ensure it stays between 2-8°C. If the temperature is outside of the required range, then the product will be deemed unsafe to deliver, marked as waste and returned to the pharmacy for destruction. Thermometer(s) will be calibrated annually against a certified standard to ensure safe and effective use. When used to deliver medication, the City Sprint delivery driver must only remove the item from cold storage once the patient has answered the door and verified their identity. In the event of failed delivery, the cold storage item must be returned to the pharmacy as soon as possible, with the maximum and minimum temperatures again being recorded at the point of return. Once again, if temperature monitoring suggests that the medication may have been transported outside of the required range, then the product will be destroyed by the pharmacy and then item will be re-dispensed by the pharmacy. Once again, a new delivery will be agreed with the patient prior to redelivery.”*
- 5.43 The Committee noted from the Applicant's information on appeal [see point 3.17 above]:
- 5.43.1 *“All prescriptions dispensed will be delivered using a dedicated courier service provided by City Sprint (www.citysprinthealth.co.uk). This will include the delivery of prescriptions received via post, fax and EPS release 2. City Sprint will also be delivering cold chain items and CDs. This is addressed in the SOPs which have been included.”*
- 5.44 The Committee noted the information on appeal [see 3.25 to 3.26 above]:
- 5.44.1 *“If needed, Controlled Drug (CD) deliveries will be undertaken by City Sprint who are accredited to handle and transport CDs. Their drivers will deliver to patients at a pre-determined time and the CD's must be signed for on receipt. Their drivers will only deliver the CD to the named recipient and they will ask for photographic proof of ID. In the instance of a failed delivery attempt, City*

Sprint will return any CDs to their overnight safe storage facility and the pharmacy will be contacted to arrange alternative delivery date to patient.

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

5.45 The Committee further noted SOP 70 for Running a Prescription Delivery Service:

5.45.1 *“Firstly an audit trail book of some description needs to be started that has the date at the top, spaces for the names and addresses for the delivery service, room for any additional information e.g. if something is owed and will be delivered later etc, space for the delivery driver to make comments i.e. that the patient was not at home, couldn’t find the address etc. and a column for successful completion of the delivery.*

5.45.2 *Secondly a clearly designated area should be set aside for storage of the scripts requiring delivery, so the driver knows where he will find his deliveries.*

On Receipt of a Request

5.45.3 *If a patient sends in a script for delivery or a patient rings to ask for a repeat script to be delivered, discuss with them when would be most convenient for both your pharmacy and the patient.*

5.45.4 *If possible, make sure you have the patient’s telephone number (including mobile number) or email and record it on their PMR, so that if there are any problems with the delivery system at any time, you can contact them. Patients like to know at every stage what has happened to their medicines.*

5.45.5 *Mark the script clearly for delivery either at the time or as soon as it arrives in the dispensary.*

5.45.6 *This mark should include the date, and possibly a rough time of day, that the delivery has been requested. It should also indicate if it is an item that must be handed only to the named patient. Mark it "Return to pharmacy if this named patient is not present to receive these goods" This should include any items where important advice must be passed to a patient.*

5.45.7 *At the same time, enter the details of the delivery onto the drop sheet.*

5.45.8 *Once it has been dispensed, the bag should be clearly marked with the delivery address and date and stored in the appropriate area.*

5.45.9 *Any comments about missing items etc should be added to the drop sheet for the driver to pass on.*

5.45.10 *Delivery dates for missing items should be taken from the audit trail and marked on the appropriate drop sheets so they do not get lost in the system.*

The driver collects his/her deliveries

5.45.11 *When the driver arrives, check the drop sheet against the items in the designated area.*

5.45.12 *If there are items marked for delivery that are not in the designated area, find them.*

- 5.45.13 *If you cannot find them or there is some other reason the delivery is not going to be made that trip, mark the drop sheet with the reason and when the delivery will be made.*
- 5.45.14 *Ring the patient to tell them why the delivery will be delayed and agree a new delivery date. Record this information in the audit trail book*
- 5.45.15 *Ensure the new delivery information is transferred to the appropriate drop sheet.*
- 5.45.16 *Go over with the driver any special information that he must pass onto the patient or their carers. Make sure the driver is not being asked to pass on advice that exceeds his or her training level.*
- 5.45.17 *The driver should have a supply of "missed" delivery cards that he can put through patient's doors, if they are not in when he tries to deliver.*
- 5.45.18 *Make a copy of the drop sheet and hand it to the driver.*
- On arrival at the patient's address*
- 5.45.19 *The items should ideally be handed to the person who ordered them*
- 5.45.20 *Previously agreed ID should be shown unless the patient is known to the driver.*
- 5.45.21 *Give the complete order to the patient and get them to sign for each parcel.*
- 5.45.22 *The driver should verbally pass on any information recorded on the bag, in order to ensure the message is received and understood by the patient. The patient should also sign to confirm that.*
- 5.45.23 *Any items marked "Return to pharmacy if this named patient is not present to receive these goods" should clearly be returned to the pharmacy if the patient is not at home.*
- 5.45.24 *If any special arrangements have been made to drop goods at a neighbour the driver MUST be sure of the identity and address of the neighbour. That neighbour should sign for the parcels and any message.*
- 5.45.25 *Under NO circumstances must any items be left unsecured.*
- The driver returns to the pharmacy*
- 5.45.26 *When the driver returns, put any items not delivered, back into the designated delivery area and ensure the reason why is recorded in your delivery audit trail book.*
- 5.45.27 *Mark the next available drop sheet, with the delivery information from that returned item.*
- 5.45.28 *Make sure each delivery has either been signed for or been returned to the pharmacy.*
- 5.45.29 *Keep this completed drop sheet in a book for a couple of weeks so any queries at a later stage can be answered".*
- 5.45.30 *The Committee further noted SOP 74 for delivery of CDs by a driver:*

- 5.45.31 *"If there are controlled drugs to be delivered extra care and record keeping is required"*
- 5.45.32 *Once the CD has been dispensed, following the SOP for CD dispensing, the item should be sealed in a bag with the address label of the patient and the prescription attached.*
- 5.45.33 *This should then be put in the patient section of the CD cabinet, clearly marked as awaiting delivery.*
- 5.45.34 *When preparing the drivers drop sheet, the fact that a CD is to be delivered should be marked on the rest of the delivery, if any, so it easily seen by the drive.*
- 5.45.35 *On the drop sheet, there should be space for the patient or their carer to sign to confirm that they have received the drug.*
- 5.45.36 *When the driver is ready to leave he asks the pharmacist for the CD that needs delivering and the original prescription so they can get the recipient's signature on it.*
- 5.45.37 *The pharmacist should then get the bag out of the cupboard, checking that it is the correct bag with the correct address on it.*
- 5.45.38 *The driver must then store the CD bag in the secure transit system.*
- 5.45.39 *Once they arrive at the correct address, they take the medication out of the bag and to the front door.*
- 5.45.40 *They must ensure that they supply the medication to the correct patient or their carer and gets them to sign the drop sheet and the original prescription as proof that they have received the CD.*
- 5.45.41 *It may be necessary for the patient/carer to confirm that the medication and the quantity is what they ordered.*
- 5.45.42 *If neither the patient nor their designated carer is there, they should check with the pharmacist as to whether they can leave the medication with another member of the household or a qualified professional e.g. a Macmillan nurse.*
- 5.45.43 *If there is nobody in the house the CD must be returned to the pharmacy and other arrangements made either for collection, or a later delivery.*
- 5.45.44 *Under these circumstances, the pharmacist should sign the CD back in to his possession, possibly from the drop sheet.*
- 5.45.45 *The above procedure must be repeated when the delivery is next attempted."*
- 5.46 The Committee further noted SOP 167 for delivery via cold chain:
 - 5.46.1 *"Every pharmacy must have at least one well maintained pharmacy fridge, and preferably two, one for dispensary stock and one for dispensed items,*
 - 5.46.2 *These must be kept at between 2-8 degrees C at all times -see fridge maintenance SOP*

- 5.46.3 *You must check all orders for any fridge item carefully before you transmit as no wholesaler will accept returned fridge items unless the error is on their part*
- 5.46.4 *As soon as a delivery is made in to our pharmacy, you must check it immediately for any fridge items*
- 5.46.5 *If there are any, check them against the delivery note to confirm they are correct and put into the fridge at once*
- 5.46.6 *When dispensing a fridge item, you should label the item as soon as it is taken out of the fridge and return it immediately to the dispensed-item fridge*
- 5.46.7 *You need to mark the script clearly to indicate there is an item in the fridge so when the script is sent for delivery this is not missed.*
- 5.46.8 *You should not take a fridge item out of the fridge until the last minute and it should be put into a cool bag before delivery*
- 5.46.9 *You should store cool bags in a fridge so they are already cold when the dispensed item is put in them for delivery*
- 5.46.10 *The delivery containing the fridge item should be the first drop off on the delivery round, and the patient advised to put the item in the 'fridge right away.*
- 5.46.11 *If the patient is not there it must be returned to the pharmacy before the rest of the delivery round is done.*
- 5.46.12 *You need to keep an audit trail of the length of time the items are out of the fridge*
- 5.46.13 *Check with the manufacturers how long is acceptable for the item to be out of the fridge for each item you stock*
- 5.46.14 *If at any time there is an incident involving fridge items e.g. fridge temperature out of range, stock kept out of fridge too long, wrong fridge item ordered, disruption to electricity supply you need to make an incident report similar to CD incident investigation.*
- 5.46.15 *You then run a root cause analysis to find out what caused the problem and how it can be resolved.”*
- 5.47 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.
- 5.48 The Committee considered whether the Applicant had explained the arrangements which ensure that, for appliances which require fitting / measuring, a registered pharmacist measures / fits them.
- 5.49 The Committee noted that the Applicant did not intend to provide appliances which require measuring or fitting. In the event that the application is granted, the Applicant would not, therefore, be able to provide those appliances as listed in the application form to patients.
- 5.50 The Committee considered whether the Applicant had explained what containers will be “suitable” for posted/delivered items.

5.51 The Committee noted the following from the Applicant's information on appeal [point 3.23 above]:

5.51.1 *"All medication will be delivered in tamper-proof and seal-proof packaging. Several companies who produce packaging material have been researched with a view to order corrugated cardboard boxes and 5-panel wraps which are able to withstand a single trip. It will be packed so it is protected from the environment which may include using a double walled package design or using waterproofing on the packaging material. This will also ensure that the delivery person is protected from cytotoxics and sharps."*

5.52 The Committee further noted SOP 74 for delivery of CDs by a driver:

5.52.1 *"Once the CD has been dispensed, following the SOP for CD dispensing, the item should be sealed in a bag with the address label of the patient and the prescription attached"*.

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

Refusal to provide drugs or appliances ordered

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

5.55 The Committee noted the Applicant's information on appeal [see points 3.43]:

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

5.56 The Committee further noted SOP 9b for The Receipt and Endorsement of Repeat Prescriptions:

5.56.1 *"Check with the patient whether they wish to have all the items on the prescription, that they are not suffering from any side effects and they understand how to use their medicines/appliances"*

5.57 The Committee further noted SOP 9a for Repeat Dispensing under the heading "Self Selection REPEAT DISPENSING":

- 5.57.1 *If it is the patient requesting and they are a regular with this pharmacy, check their PMR to ensure that:*
- 5.57.1.1 *they have not had a medication change in the last six months*
 - 5.57.1.2 *their medical condition is stable*
 - 5.57.1.3 *there have been no recent hospitalisations.*
 - 5.57.1.4 *If this is not the case, explain the situation to them and suggest they try again when their condition is better controlled.*
 - 5.57.1.5 *If the patient fits the criteria, then fill in the relevant referral document, email or post it and ask them to visit their prescriber.”*
- 5.58 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
- 5.59 The Committee considered whether the Applicant had explained how appropriate advice about the benefits of repeat dispensing is given to any patient who (i) has long term, stable medical condition (that is, a medical condition that is unlikely to change in the short to medium term), and (ii) requires regular medicine in respect of that medical condition.
- 5.60 The Committee noted the Applicant’s information on appeal [points 3.45]:
- 5.60.1 *“Essential Service - Repeat Dispensing*
 - 5.60.2 *Without face-to-face contact*
 - 5.60.3 *For patients who request our service and who are NOT signed up to the repeat dispensing service, we will request that they contact the pharmacy so that we can discuss their suitability for the service but also provide further information on the benefits of the service. The initial contact with the patient will be via a leaflet which will be included within their dispensed medication. Benefits will include saving time for the patient and the prescriber due to a decreased workload on both parties. A further benefit will include an improvement of medication safety as the pharmacy will check each and every request to ensure that the medication is still suitable before dispensing. During these checks, if a medication is flagged as being unsuitable or there are side effects, then the patient will be referred to the prescriber for discussion.”*
- 5.61 The Committee further noted SOP 9a for Repeat Dispensing under the heading “Selecting suitable patients REPEAT DISPENSING from their PMR”:
- 5.61.1 *“Look through their medication and see if there have been any changes to either the drugs or the doses in the last six months. Either of these would indicate that the patient’s condition is not stable and therefore they will not be able to join the scheme.*
 - 5.61.2 *If there are months when they have not collected, check the quantities dispensed to see if they are on 56 day scripts.*
 - 5.61.3 *If there is any doubt you will definitely have to discuss it with the patient next time you contact them.*

- 5.61.4 *If you are happy that their condition is stable and they are suitable for repeat dispensing, chat to the patient explaining the system.”*
- 5.62 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
- 5.63 The Committee considered whether the Applicant had explained how it will safely and effectively accept and dispose of unwanted drugs presented to it for disposal.
- 5.64 The Committee noted the Applicant’s information on appeal [see points 3.33 to 3.36]:
- 5.64.1 *“Essential Service - Disposal of Unwanted Medication*
- 5.64.2 *Uninterrupted Service*
- 5.64.3 *Provision for disposal of unwanted medications can be requested by any patients during the core opening hours of the pharmacy. This can be requested via telephone, fax, email or webcam. All staff will be trained to deal with such enquiries.*
- 5.64.4 *Persons anywhere in England*
- 5.64.5 *Patients anywhere in England can request for safe disposal of their unwanted medication from our pharmacy via phone, fax, email, post or webcam.*
- 5.64.6 *Safe and Effectively*
- 5.64.7 *Patients, anywhere in England, can contact the pharmacy for collection of their unwanted medicines. We will take details of medication being returned by patients and assess if we are allowed to take them. We would provide patients with adequate packaging so medication can be returned securely via City Sprint couriers at no charge to the patient. All legal records will be kept and we would have procedures in place to comply with Hazardous Waste Regulations and we would keep any additional legal records such as those required for Controlled Drugs. Returned medication can be collected from patients homes and residential homes but we will not be accepting from nursing homes. Returned medication will be stored in UN type containers provided by PHS.*
- 5.64.8 *Returned medication will be stored in UN type containers provided by PHS. Returned solid medicines/ ampoules, liquids and aerosols will be separated. Schedule 2 and 3 Controlled Drugs that are subject to safe custody regulations which are returned by patients will be segregated from other returned medicines and stored in compliance with the Safe Custody Regulations until they have been rendered irretrievable. As the Environment Agency has suggested that the denaturing of CDs is likely to constitute a waste treatment, the pharmacy will hold a waste management license. We will ensure that the courier collecting returned medication is registered as a waste carrier with each local environmental agency office that it operates in. We will keep full records of any waste collected and disposed of for at least three years.*
- 5.64.9 *Without face-to-face contact*
- 5.64.10 *Disposal of unwanted medication will be delivered without face-to-face contact via City Sprint couriers or, for local requests, out [sic] in-house delivery service. This courier service will provide a third party delivery. Patients would communicate with the pharmacy via phone, fax, email*

website, post or webcam. We have SOPs in place to ensure this service is offered without having them to be present the pharmacy.”

- 5.65 The Committee further noted SOP 11 for The disposal of unwanted medicines:
- 5.65.1 *“Waste from nursing homes and GP surgeries are subject to stringent controls. Hazardous waste and mixed medicines of unknown origin must be sent to your pharmacy with a hazardous waste consignment note, your pharmacy must keep a register, a site inventory and send returns to the producer and Environmental Agency. You will be charged for each consignment received. Non-hazardous waste must be transferred to your pharmacy, under Duty of Care controls with a consignment note.*
 - 5.65.2 *These unwanted medicines must be brought to the pharmacy by the organisation and not collected by you.*
 - 5.65.3 *If a patient contacts the pharmacy wishing to return unwanted medication, check what type of drugs are to be returned. State that you will arrange collection of these drugs from the patients address and that some medications cannot to be sent via the post or courier. If the patient does want to return any prohibited drugs, explain that they would have to return these to a pharmacy where they can go into.*
 - 5.65.4 *When the unwanted medicines are delivered into the pharmacy, again check with the person via email or phone, if there are any cytotoxic or controlled drugs in the returns so they can be separated out. If there are controlled drugs you cannot accept the returns unless your Responsible Pharmacist is present.*
 - 5.65.5 *Having received the waste, you must be sort it into various bins if your local area team requests it.*
 - 5.65.6 *One for solids, one for liquids and one for aerosols.*
 - 5.65.7 *Otherwise you need to make a list of the types of waste in each container and you must give this to the waste collector when he calls.*
 - 5.65.8 *If there is outer packaging you may remove it, but you cannot take tablets out of blisters or bottles etc. as this is defined as "waste processing" and requires a separate licence.*
 - 5.65.9 *Ensure when handling the waste that you protect your hands and face from cuts on broken glass etc.*
 - 5.65.10 *If you need to destroy controlled drugs, you should keep a record of the number and description of what was collected from patients and hence what is being destroyed, in the appropriate CD register.*
 - 5.65.11 *You destroy these drugs using the specific CD denaturing kit, and you can then add this mixture to the customer returned waste medicine bin.*
 - 5.65.12 *You must register with the Environment Agency if you denature Controlled Drugs using the T28 exemption. You can complete this on line on the Environment Agency's website.*
 - 5.65.13 *There should be a witness to the whole procedure to prevent any suspicion of misbehaviour. The witness should countersign the record kept in the CD register.*

- 5.65.14 *If the waste comes from out of date stock in the dispensary, this too must be split into solid, liquid and aerosols but can be mixed in with the patient-returned waste. However you must use the different EWC codes to describe the waste. The six digit code for pharmacy stock would begin with 18 and for patient returns starts with 20.*
- 5.65.15 *An official person e.g. the GPhC inspector or the CD police inspector, must still destroy any CD out of date stock that has never been dispensed. Check with your local area team if they have authorised persons who can destroy CDs for you.*
- 5.65.16 *The bins that all this waste is stored in should be collected at regular intervals, of no more than three months.*
- 5.65.17 *There should be no more than 50 cubic metres of waste at any one time in the pharmacy*
- 5.65.18 *When waste is transferred your pharmacy should ensure a transfer note (containing the required information) is provided to the carrier. If you have a series of transfers of the same waste between the same two parties they can agree a "season ticket" i.e.. one transfer note to cover a number of transfers. On collection the paperwork that is provided should be stored in a folder, drawer, file for a minimum of 3 years.*
- 5.65.19 *If you find that your collections are not frequent enough and you have overflowing bins, you must contact the relevant local area team department and ask for an emergency collection or a more regular one”.*
- 5.66 Based on all of the information before it, the Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 13 - 15 of Schedule 4.
- 5.67 The Committee considered whether the Applicant had explained how it will safely and effectively promote healthy lifestyles.
- 5.68 The Committee noted the Applicant’s information on appeal [see points 3.53 to 3.54 above] includes;
- 5.68.1 *“Essential Service - Public Health (Promotion of Healthy Lifestyles)*
- 5.68.2 *Safe and effectively*
- 5.68.3 *This service will be delivered safe and effectively by pharmacists and appropriately trained staff. At risk patients will be targeted through prescription linked intervention. Opportunistic advice will be given by the pharmacist on specified healthy living/public health topics to patients who have their prescriptions fulfilled by the pharmacy.*
- 5.68.4 *Without face-to-face contact*
- 5.68.5 *The service will be delivered without face-to-face contact via telephone, email, live chat or video link. Any educational material relating to certain conditions can also be sent in the post or inserted without face to face contact.”*
- 5.69 The Committee further noted SOP 72 for Giving Advice on Healthy Lifestyles:
- 5.69.1 *“When you are generally chatting to your customers over the phone, note any habits that will affect their future well being and try to encourage them to make small changes that could make a big difference.*

- 5.69.2 *Ways to eat 5 portions of fruit or vegetables. You may even be able to sell portions of fresh fruit and vegetables in season, which your driver could deliver.*
- 5.69.3 *Ways to increase their exercise without the expense of joining a gym- like parking their car further away from the place they want to get to, always taking the stairs instead of the escalator or lift, having a short walk at lunchtime instead of sending somebody else for their sandwich. Sell pedometers so people can see how many extra steps they have taken, and encourage them to increase their steps daily.*
- 5.69.4 *Ways to reduce the amount of alcohol they drink- like alternating an alcoholic drink with a soft one, making one drink last longer or having smaller drinks each time.*
- 5.69.5 *Ways to reduce the amount they smoke- like only smoking half a cigarette at a time (most of the dangerous chemicals build up in the bottom end of the cigarette so they will inhale less of them if you only smoke the first half), pacing themselves during the day to limit the number.*
- 5.69.6 *Ways to reduce stress in their lives like- planning their work load, learning the 5 minute relaxation technique and others, ensuring they have a day away from their usual routine and time for themselves.*
- 5.69.7 *Have leaflets on these subjects that can be delivered or emailed to customers including diet sheets etc.*
- 5.69.8 *Run campaigns, either as part of a LAT one, local initiative or national drive.*
- 5.69.9 *Have displays on your website, run competitions, involve the local community.*
- 5.69.10 *Keep books on healthy living, stress reduction, diets, etc so you can direct people for further advice.*
- 5.69.11 *Encourage people on regular medication to make sure they take their tablets.*
- 5.69.12 *The more you explain to customers the benefits of changing their lifestyles the more likely they are to attempt to.*
- 5.69.13 *Tell them that it takes about 60 days to change a habit and the more you follow the new routine the more likely it is to become the new habit."*
- 5.70 The Committee further noted SOP 135 for giving advice about a healthy diet:
 - 5.70.1 *"Run campaigns on a regular basis, on your website/Facebook page to promote healthy lifestyles, maybe concentrating on one topic at a time".*
- 5.71 The Committee further noted SOP 136 for advising on physical exercise:
 - 5.71.1 *"Try to run regular promotions on the internet to encourage your customers to take up more exercise".*
- 5.72 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

- 5.73 The Committee considered whether the Applicant had explained how it will assess whether persons require prescription linked intervention advice because they have diabetes, are at risk of coronary heart disease, smoke or are overweight.
- 5.74 The Committee noted the Applicant's information [see points 3.51 to 3.54 above]:
- 5.74.1 *“Essential Service - Public Health (Promotion of Healthy Lifestyles)*
- 5.74.2 *Prescription linked intervention*
- 5.74.3 *Uninterrupted service*
- 5.74.4 *Provision of service through the core opening hours of the pharmacy will be maintained by having a Responsible Pharmacist rostered on for all opening hours and having sufficient support staff at all times. Provision of service through the core opening hours of the pharmacy will be maintained by the pharmacy website email and telephone.*
- 5.74.5 *Persons anywhere in England*
- 5.74.6 *Patients anywhere in England can access these services via the pharmacy website, phone, email, chat, video link or distribution of leaflets within the prescription that is delivered to the patient. When the pharmacist identifies an intervention on a prescription he/she will communicate with the patient and other healthcare professionals. All interventions will be documented on their PMR record.*
- 5.74.7 *Safe and effectively*
- 5.74.8 *This service will be delivered safe and effectively by pharmacists and appropriately trained staff. At risk patients will be targeted through prescription linked intervention. Opportunistic advice will be given by the pharmacist on specified healthy living/public health topics to patients who have their prescriptions fulfilled by the pharmacy. Staff will be trained to assess for prescription linked interventions and if any doubt will refer the matter to the pharmacist. In particular, patients with diabetes, coronary heart disease, high blood pressure, smokers and obesity. These patients will be identified through the type of medication being requested the patients PMR, or the online questionnaire completed by new patients. Once a prescription linked intervention has been made, a note will be made on the patient's PMR. This note will ensure continuity of advice and as a reference for future interactions with the patients.*
- 5.74.9 *Without face-to-face contact*
- 5.74.10 *The service will be delivered without face-to-face contact via telephone, email, live chat or video link. Any educational material relating to certain conditions can also be sent in the post or inserted without face to face contact.”*
- 5.75 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
- 5.76 The Committee considered whether the Applicant had explained how it will safely and effectively participate in public health campaigns, if and to the extent required by the Commissioner.

- 5.77 The Committee noted the Applicant's information on appeal [see points 3.55 to 3.58 above]:

"National Health Campaign

Uninterrupted Service

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

Persons anywhere in England

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

Safe and Effectively

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

Without face-to-face contact

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

- 5.78 The Committee further noted SOP 53 for Staff Training:

- 5.78.1 *"Also ensure they cover a certain number of hours each year improving their pharmacy knowledge e.g. attending local health events about public health campaigns, reading the pharmacy magazines to learn about new products that the patients may ask them about, gaining another level of qualification within the pharmacy structure.*

- 5.79 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

- 5.80 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. The Committee noted the Applicant's information on appeal [see points 3.37 to 3.40 above]:

- 5.80.1 *"Essential Service – Signposting*

- 5.80.2 *Uninterrupted Service*

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

Persons anywhere in England

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

Safe and Effectively

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

Without face-to-face contact

- 5.80.6 *Signposting will be delivered without face-to-face contact via the website email phone, post fax or webcam. All patients will communicate with the pharmacy via these methods and as such there will be no face-to-face patient interaction. The SOPs in place ensure we can deliver the service without face to face contact in a distance selling model."*

- 5.81 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

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

- 5.83 The Committee noted the Applicant's information on appeal includes [see points 3.59 to 3.63 above]:

5.83.1 *"Essential Service - Support for Self Care*

5.83.2 *Uninterrupted Service*

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

5.83.4 *Persons anywhere in England*

- 5.83.5 *Patients anywhere in England can access these services via the pharmacy website, telephone, email, live chat or video link. The majority of interactions will come whilst giving advice to the patient using these methods.*
- 5.83.6 *Safe and Effectively*
- 5.83.7 *Support for self care will be delivered safe and effectively. Pharmacy staff will provide advice to patients including carers requesting help with the treatment of minor illness and long term conditions, including general information and advice on how to manage illness. Using website or telephone consultation, we can assess patients using a protocol based on the WWHAM model.*
- 5.83.8 *Visual symptoms can be accessed via a video link if necessary. The pharmacy staff will advise on the appropriate use of the wide range of non prescription medicines which can be used in the self-care of minor illness and long term conditions. When appropriate pharmacy staff will make healthy interventions in a similar manner to that provided in promotions of healthy lifestyle service. When appropriate and where necessary, pharmacy staff will signpost patients to other health and social care providers. Records of advice given, products purchased or referrals made will be put on to the patients PMR when the pharmacist deems it to be of clinical significance. Any medication sold online will be sent to the patient via City Sprint couriers*
- 5.83.9 *Without face-to-face contact*
- 5.83.10 *This service will be delivered without face-to-face contact via telephone, email, live chat or video link. Support for Self-Care will be prevalent in all patient interactions which will be maintained using these methods.”*
- 5.84 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 21 – 22 of Schedule 4.

Discharge medicines service

- 5.85 The Committee considered whether the Applicant had explained how it will provide advice, assistance and support to and in respect of a health service patient – (a) recently discharged from hospital who is referred to P for advice, assistance and support in respect of the patient’s medication regimen by the staff of the hospital in which the patient stayed; or (b) who is otherwise referred to P for advice, assistance and support in respect of the patient’s medication regimen by the staff of an NHS trust and NHS foundation trust as part of arrangements linked to the transfer of care between different providers of NHS services.
- 5.86 Further the Committee considered whether the Applicant had explained what procedures it has in place for checking referrals for the discharge medicines service.
- 5.87 The Committee noted the Applicant’s information on appeal [see points 3.46 to 3.50 above]:

Essential Service – Discharge Medicine Service

Uninterrupted service

- 5.87.1 *“Provision of discharge medicine service throughout the opening hours of the pharmacy will be maintained by phone, fax, email, post or webcam. The Responsible Pharmacist will have undertaken the necessary training and is competent to provide the discharge medicine service. The CPPE certificate for the Responsible Pharmacist will be provided to the local NHS team for their records. During the opening hours the Responsible Pharmacist will be supported by a suitable trained team sufficient to deliver the discharge*

medicine service. The pharmacy IT system will be compliant to allow for discharge medicine service to be undertaken via Pharmoutcomes website or the pharmacy dedicated NHS mailbox.

Persons anywhere in England

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

Safe and Effectively

- 5.87.3 *Discharge Medicine service will be delivered safe and effectively via the staff completing sufficient clinical and legal training to provide the service. Hospitals will identify patients who will benefit from discharge medicine service and will send a referral to the patient's pharmacy via secure electronic system. When a referral is received, the pharmacist will review the information in the referral, including comparing the revised medicines prescribed to those the patient used before being admitted to hospital. If any issues are identified, these will be queried with the hospital or the general practice. Pharmacy team members will check whether there are any existing dispensed prescriptions waiting for the patient or any electronic repeat dispensing prescriptions on the NHS spine. If there are, these need to be checked to see if they are still appropriate for the patient. The pharmacist will have a consultation with the patient and/or their carer to check their understanding of what medicines they should now be using and to provide further advice. If there are medicines the patient is no longer using, we will offer to dispose of them, to avoid potential confusion in the future. When the first prescription for the patient is received by the pharmacy following discharge, there will be a check to compare the medicines prescribed by the hospital and those prescribed by the GP. If there are discrepancies or other issues, the pharmacist will try to resolve them with the general practice. The pharmacist must use their clinical judgement when considering their actions and recommendations in respect of the service and consider the duty of confidentiality to the patient when involving a carer in discussions about the patient and their medication regimen.*
- 5.87.4 *Relevant information will be documented on the PMR/IT System for Stage 1, 2 and 3 to ensure continuity of the service.*

Without face-to-face contact

- 5.87.5 *All discharge medicine service patients will be communicated without face-to-face contact via phone, email, post, fax or webcam. All medications will be delivered using our in-house delivery service or the City Sprint courier service and will maintain service delivery without face-to-face contact. If medicines need to be returned, this will be done in accordance to disposal of unwanted medication. We have SOPs in place to manage these services without face-to-face contact. This discharge medicine service will ensure better communication of changes to a patient's medication when they leave hospital and to reduce incidences of avoidable harm caused by medicines."*
- 5.88 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 22B and 22C of Schedule 4.

Websites and health promotion zones

- 5.89 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.
- 5.90 The Committee noted point 3.9 above *“The website will be built by a company called the ‘Dash Media’ (<https://dashmedia.co.uk>) who are web developers that have experience within the pharmacy web development market. Each patient will have their own personal login account once registered which will include their own personalised password for added security. Upon patient consent the pharmacy will then nominate them for EPS. This will then enable us to deliver a service safely and effectively to anyone in England without face to face contact”*.
- 5.91 The Committee noted SOP 208 for Ensuring Premises and Website meet Standards required in PAAD (Pharmacy At A Distance):
- 5.91.1 *“Our website must be clear, accurate and updated regularly. It must not be misleading in any way”*.
- 5.91.2 *“We must consider the design and layout of our website and make sure that it works effectively and looks professional”*
- 5.92 The Committee noted point 3.15 of the Applicant’s above information includes *“Provision of service through the opening hours of the pharmacy will be maintained by having a Responsible Pharmacist present at all times during the pharmacy opening hours and having sufficient support staff at all times. The pharmacy website will run throughout these hours together with a phone, fax, email and webcam service. If the responsible pharmacist is required to leave the premises, a further pharmacist will be on hand to ensure that there is no break in pharmacist cover during the opening hours.”*
- 5.93 The Committee noted that in several instances throughout its information on appeal the Applicant had said: *“The service will be delivered without face to face contact via telephone, email, live chat or video link.”*
- 5.94 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

- 5.95 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).
- 5.96 Pursuant to paragraph 9(1)(a) of Schedule 3 to the Regulations, the Committee may:
- 5.96.1 confirm the Commissioner’s decision;
- 5.96.2 quash the Commissioner’s decision and redetermine the application;
- 5.96.3 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.
- 5.97 In those circumstances and given the Committee has reached a different decision, the Committee determined that the decision of the Commissioner must be quashed.
- 5.98 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.

- 5.99 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.
- 5.100 The Committee concluded that further notification under paragraph 19 of Schedule 2 would not be helpful in this case.

6 Decision

- 6.1 The Committee concluded that it was not required to refuse the application under the provisions of Regulation 31.
- 6.2 Accordingly, the Committee:
- 6.2.1 quashes the decision of the Commissioner; and
 - 6.2.2 redetermines the application as follows -
 - 6.2.2.1 the Committee was satisfied that the proposed premises were not adjacent to or in close proximity to other chemist premises;
 - 6.2.2.2 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;
 - 6.2.2.3 the Committee was satisfied that all essential services were likely to be secured without interruption during the opening hours;
 - 6.2.2.4 the Committee was satisfied that all essential services were likely to be secured for persons anywhere in England;
 - 6.2.2.5 the Committee was satisfied that all essential services were likely to be secured in a safe and effective manner; and
 - 6.2.2.6 the Committee was satisfied that all essential services were likely to be secured without face to face contact.
- 6.3 The application is granted.

**Case Manager
Primary Care Appeals**