

22 August 2025

REF: SHA/26616

8th Floor
10 South Colonnade
Canary Wharf
London
E14 4PU

Tel: 020 3928 2000
Email: nhsr.appeals@nhs.net

**APPEAL AGAINST SOMERSET ICB DECISION TO
GRANT AN APPLICATION BY IMPERIAL CHEMISTS
LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST
AT UNIT 4C, WESTPARK 26, WELLINGTON, TA21 9AD
UNDER REGULATION 25**

1 Outcome

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

A copy of this decision is being sent to:

Imperial Chemists Ltd
Jhoots Pharmacy
PCSE on behalf of Somerset ICB

REF: SHA/26616

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1 The Application

By application dated 27 October 2024, Imperial Chemists Ltd ("the Applicant") applied to Somerset ICB ("the Commissioner") for inclusion in the pharmaceutical list at Unit 4c, Westpark 26, Wellington, TA21 9AD 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 left this blank.
- 1.2 In response to why the application should not be refused pursuant to Regulation 31 the Applicant left this blank.
- 1.3 In response to why the application should not be refused pursuant to Regulation 25(2)(a) the Applicant left this blank.

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 "Please see the following attachments:
 - 1.5.1 Imperial Chemists Ltd Pharmacy Procedures
 - 1.5.2 Imperial Chemists Ltd DRAFT SOPs"Imperial Chemists Ltd Pharmacy Procedures
- 1.6 "Imperial Chemists 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.

- 1.7 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.
- 1.8 Imperial Chemists Ltd will have a website which facilitates the following:
 - 1.8.1 Patient accesses website via a secure log-in procedure;
 - 1.8.2 Patient provides details of prescription,
 - 1.8.3 Patient will be contacted by the pharmacy and medical history assessed.
 - 1.8.4 Patient posts prescription to pharmacy and/or prescription received via EPS.
 - 1.8.5 Item is dispensed and details added to PMR.
 - 1.8.6 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.
- 1.9 The website has been built by a colleague with a vast experience of web design. 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.
- 1.10 This will then enable us to deliver a service safely and effectively to anyone in England without face to face contact.
- 1.11 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.
- 1.12 Imperial Chemists Ltd has decided to use Titan (www.titanpmr.com) as the software provider which will be a key tool in providing a safe and effective provision of service.
- 1.13 Imperial Chemists 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.
- 1.14 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 without face-to-face contact, an example being how to elicit a comprehensive medical history by telephone or webcam.
- 1.15 Imperial Chemists Ltd is comprised of 2 directors, [D-A F] and [BC]. [D-A F] is the nominated superintendent and has suitable pharmacy experience. [D-A F] will act in overseeing the operations of the pharmacy and will maintain role of the Information Governance Lead, Clinical Governance Lead and Smartcard Sponsor. A full-time Responsible Pharmacist will be employed to be in attendance during the opening

hours. He will be supported by a staff team of one full-time and one part-time dispenser. This level of staff will be able to cover initial trade levels once the pharmacy is open and will ensure an uninterrupted provision of essential services during the opening hours. The team is expected to grow with the business and new members will be added as and when required.

- 1.16 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. 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

- 1.17 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

- 1.18 Patients anywhere in England can access these services via our pharmacy website a direct phone line to the pharmacy, fax, email as well as webcam. Internet connections at the pharmacy will be provided by the NHS HSCN network via BT.
- 1.19 All prescriptions dispensed will be delivered using a dedicated courier service provided by City Sprint (www.citysprinthealth.co.uk). This will include the delivery of prescriptions received via post, fax and EPS. City Sprint will also be delivering cold chain items and CDs. This is addressed in the SOPs which have been included.

Safe and effectively

- 1.20 The service will be delivered safe and effectively by using SOPs to manage the process. Please see the attached SOPs provided to show examples of how the pharmacy will be managed safely and efficiently at all times.
- 1.21 We will have a suitable number of staff who will be trained to a minimum of an NVQ level 2 standards. This training will be undertaken by National Pharmaceutical Association (NPA) (www.npa.co.uk)
- 1.22 Requests from patients to show the Pharmacist visual symptoms of conditions will be done via a secure video link. All conversations will be recorded on the PMR in detail.
- 1.23 If patient counselling is required for any dispensed medication, the pharmacy will have procedures so this can be done via the telephone, videoconferencing or email before

dispatch of medication. The pharmacy will require acknowledgment from the patient or another person that the counselling points have been understood. Patient interactions will be recorded on the PMR. A label will also be attached to the packaging asking the patient to contact the pharmacy for further details.

- 1.24 Prior to medication being delivered, staff will contact patient to confirm delivery address, date and time. Deliveries will be monitored with the online courier tracking service which will give real-time information and is also available as an app for smart phone and tablets.
- 1.25 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

- 1.26 This service will be delivered without face-to-face contact via the pharmacy website as a communication link as well as telephone post/email/fax/webcam. A courier service will provide a third-party delivery if this is required when it would not be practicable to use the in-house delivery service.
- 1.27 If needed, Controlled Drug (CD) deliveries will be undertaken by City Sprint who are accredited to handle and transport CDs. Their drivers will deliver to patients at a pre-determined time and the CD's must be signed for on receipt. Their drivers will only deliver the CD to the named recipient and they will ask for photographic proof of ID. In the instance of a failed delivery attempt, City Sprint will return any CDs to their overnight safe storage facility and the pharmacy will be contacted to arrange alternative delivery date to patient.
- 1.28 City Sprint is approved by the MHRA and has fully trained couriers to deal with all pharmacy deliveries including controlled drugs and fridge items. As well as collecting prescriptions from surgeries and collection of unwanted waste medication from patients. This will ensure there is no face to face contact.
- 1.29 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.
- 1.30 Cold chain products will be packed in such a way as to ensure that the required temperatures are maintained throughout the journey and the medicines are transported in accordance with their labelling requirements to maintain product integrity.
- 1.31 For delivery of medication with short journey times of less than 3 hours, validated medical cool boxes will be used as recommended by the MHRA. For extended journeys, gels/ ice packs will be added to the packaging to maintain appropriate temperatures throughout. Extra caution will be taken with regards to the positioning of these packs within the consignments as this would be deemed extremely important as they must not be allowed to come into direct contact with the medicines being delivered. Temperatures will be strictly controlled and monitored with calibrated temperature probes to provide temperature data for the entire journey. This will be done by the courier driver. Temperatures will be recorded at the beginning of the journey and again at the point of delivery to ensure it stays between 2-8°C. If the temperature is outside

of the required range, then the product will be deemed unsafe to deliver, marked as waste and returned to the pharmacy for destruction. Thermometer(s) will be calibrated annually against a certified standard to ensure safe and effective use. When used to deliver medication, the City Sprint delivery driver must only remove the item from cold storage once the patient has answered the door and verified their identity. In the event of failed delivery, the cold storage item must be returned to the pharmacy as soon as possible, with the maximum and minimum temperatures again being recorded at the point of return. Once again, if temperature monitoring suggests that the medication may have been transported outside of the required range, then the product will be destroyed by the pharmacy and then item will be re-dispensed by the pharmacy. Once again, a new delivery will be agreed with the patient prior to redelivery.

- 1.32 Acute or Urgent Dispensing Requests – Any acute, urgent medication received by ETP or directly via courier from a surgery for patients anywhere in England can be dispensed and dispatched the same day using City Sprint who offer a 24 hour, 365 day service for any type of delivery.
- 1.33 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

- 1.34 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

- 1.35 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

- 1.36 Patients, anywhere in England, can contact the pharmacy for collection of their unwanted medicines. We will take details of medication being returned by patients and assess if we are allowed to take them. We would provide patients with adequate packaging so medication can be returned securely via City Sprint couriers at no charge to the patient. All legal records will be kept and we would have procedures in place to comply with Hazardous Waste Regulations and we would keep any additional legal records such as those required for Controlled Drugs. Returned medication can be collected from patients' homes and residential homes but we will not be accepting from nursing homes. Returned medication will be stored in UN type containers provided by PHS.
- 1.37 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

- 1.38 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.

Essential Service – Signposting

Uninterrupted Service

- 1.39 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

- 1.40 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

- 1.41 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

- 1.42 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

- 1.43 Provision of repeat dispensing throughout the opening hours of the pharmacy will be maintained by phone, fax, email, post or webcam. The Responsible Pharmacist will have undertaken the necessary training and is competent to provide the repeat

dispensing service. The CPPE certificate of the Responsible Pharmacist will be provided to the local NHS team for their records. During the opening hours the Responsible Pharmacist will be supported by a suitable trained team sufficient to deliver the repeat dispensing. The pharmacy IT system will be ETP compliant to allow for repeat prescriptions to be received electronically from surgeries anywhere in England that are ETP release 2 compliant. This will be promoted to patients as a quick way to receive prescriptions from participating surgeries for nominated patients repeat and acute prescriptions for quick despatch of medicines without any delay.

Persons anywhere in England

- 1.44 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

- 1.45 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.
- 1.46 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

- 1.47 All repeat dispensing patients will be communicated without face-to-face contact via phone, email, post, fax or webcam. All medications will be delivered using our in-house delivery service or the City Sprint courier service and will maintain service delivery without face-to-face contact. We have SOPs in place to manage these services without face-to-face contact.
- 1.48 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.
- 1.49 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

- 1.50 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.
- 1.51 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

- 1.52 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

- 1.53 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.
- 1.54 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

- 1.55 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

- 1.56 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

- 1.57 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

- 1.58 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

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

National Health Campaign

Uninterrupted Service

- 1.60 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

- 1.61 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

- 1.62 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

- 1.63 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

- 1.64 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

- 1.65 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

- 1.66 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.
- 1.67 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

- 1.68 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

- 1.69 There will be a named Clinical Governance Lead who will also be the Superintendent Pharmacist, [D-A F].

Patient and public involvement

- 1.70 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.
- 1.71 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

- 1.72 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

- 1.73 All incident reporting will be carried out in the pharmacy and this will involve near misses using the GPhC near miss template and help identify trends or highlight weaknesses in pharmacy systems and procedures and would be rectified promptly. Any patient safety incidents will be reported to the National Patient Safety Agency (NPSA) online. We will analyse and learn from any patient safety incidents through a system of regular reviews. In addition, the pharmacist will be proactive in considering and preventing potential risks. This will include competence in risk management and the application of Root Cause Analysis. Health and Safety legislation will be complied with in order to reduce the risk of harm to pharmacy staff and the public.
- 1.74 All patient safety communications received at the pharmacy either by fax, email or post will be actioned by the Pharmacist and pharmacy staff promptly and records of this will be kept at the pharmacy for audit purposes. We will have adequate facilities in place to be able to dispose of any confidential waste. NHS Code of Practice on Confidentiality will also be met.

- 1.75 Imperial Chemists 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 as a result of changes in best practice, new regulations or as a corrective action following any adverse incidents. The Superintendent Pharmacist will be responsible for the maintenance of the SOPs and training all staff in the SOPs relevant to their role.
- 1.76 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

- 1.77 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

- 1.78 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

- 1.79 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. Imperial Chemists 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 Imperial Chemists 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.
- 1.80 Pharmacists will be using their own professional judgement to make records of interventions they have made and any advice they may have given. Imperial Chemists 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

- 1.81 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

- 1.82 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.”

2 The Decision

The Commissioner considered and decided to grant the application. The decision letter dated 15 April 2025 states:

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

- 2.1 “Somerset ICB has considered the above application and I am writing to confirm that it has been granted. Please see the enclosed report for the full reasoning.
- 2.2 The report details the conditions that will be placed upon your inclusion in the relevant pharmaceutical list should a valid notice of commencement be received. Enclosed is a form confirming acceptance of these conditions. It should be completed by an authorised person and returned to me with your notice of commencement.
- 2.3 Also enclosed is a template of the notice of commencement which you are required to submit to us. Please note that if this is submitted before the end of the 30 day appeal period and a valid notice of appeal is then received by the Secretary of State, the notice of commencement will cease to have effect. This means that if you have opened your new premises then you will be required to close with immediate effect.
- 2.4 Please note that you must submit the notice of commencement no fewer than 30 days before the date you intend to start service provision. If it is received fewer than 30 days in advance it is not a valid notice of commencement and will not be accepted by Somerset ICB unless you successfully ask to give a shorter notice period. Should you wish to ask to give a shorter notice period please complete the enclosed application form.”

Extract from the South West Pharmaceutical Services Regulations Committee (PSRC) Decision report

- 2.5 “The SW Committee noted:

- 2.6 The applicant proposes opening a distance selling pharmacy in premises on a Business Park between Wellington and Taunton.
- 2.7 This is an application for a 'distance selling pharmacy' and is an excepted application and considered under regulation 25.
- 2.8 Regulation 31 (same or adjacent premises) [quoted in full]
- 2.9 There are no other pharmacies at the proposed premises, or adjacent. The nearest pharmacies are in Wellington 1 mile away from the proposed premises.
- 2.10 The SW Committee was satisfied it is not required to refuse the application by virtue of Regulation 31.

Representations received

- 2.11 Representations were received from:
- 2.12 Boots
 - 2.12.1 Boots UK Ltd would like to respectfully request that members of the deciding committee are satisfied that this application fully meets the criteria set out in Regulation 25 and the conditions set out in Regulation 64 when determining this application.
- 2.13 Somerset Healthwatch
 - 2.13.1 Please see our comment on behalf of Somerset Healthwatch below:
 - 2.13.2 We can see the benefit of online pharmacy services but the ability to have a face to face discussion is lost which often alleviates concerns and hence a visit to a GP surgery. However we were pleased to note that provision has been made to conduct remote consultations in a private space. We would also hope that should any patient arrive at the premises that they will be signposted to one of the nearby pharmacies.
 - 2.13.3 Part of our role as Healthwatch is to ensure that our local communities have a voice in health and social care, we therefore also reached out to Wellington Town Council for a comment from them. Please see the comments below:
 - 2.13.4 Our Policy and Finance Committee met last week and considered the plans that you sent through.
 - 2.13.5 The committee resolved to support the application in principle but want to emphasise the importance of taking into account the view of the local retail pharmacies in town. It recognises the value of online access to prescriptions but does not want this to be to the detriment of existing pharmacy provision.
- 2.14 Jhoots object to the application
 - 2.14.1 The application includes a copy of a floor plan of the premises. We note this includes a reception/ waiting area next to two consultation rooms. This would suggest that patients will and can access the premises. We would ask the NHS to satisfy themselves based on this that the consultation room and waiting area will be not and cannot be used for the provision of pharmaceutical services in the context of Regulation 25.

- 2.14.2 The applicant's supporting information states 'if patient counselling is required for any dispensed medication, the pharmacy will have procedures so this can be done via the telephone, videoconferencing or email before dispatch or medication'. There are not any details of such procedures in the application.
 - 2.14.3 The application states that 'All medication will be delivered in tamper-proof and seal-proof packaging. Several companies who produce packaging material have been researched view to order corrugated cardboard boxes and 5-panel wraps which are able to withstand a single trip. Limited information is provided with regards to this, in effect we are only advised that several companies have 'been researched'.
 - 2.14.4 For the Delivery of Refrigerated Medicinal Products the applicant states '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'. limited information is provided with regards to how these will be packed to ensure the temperatures will be maintained. It is also not clear how the local delivery driver will audit and monitor temperature whilst the medication is out for delivery.
- 2.15 The applicant responded to the representations:
- 2.15.1 The decision makers are reminded that the SOPs are Draft SOPs and so are under constant review and development.
 - 2.15.2 Turning now to the point raised about the consultation room, the consultation room can be used for various services which will include the provision of advanced and enhanced services and for private services outside the NHS contract. No essential services will be delivered in the consultation room unless it is by a method which ensures that the patient is OT present in the pharmacy i.e. videoconferencing telephone, email etc etc. This leads onto the 2nd point raised by Jhoots regarding patient counselling. Without fear of repetition the decision makers are reminded that the SOPs are Draft SOPs and so are under constant review and development.
 - 2.15.3 With reference to the 2nd point raised by Jhoots, the above comments in 1 and 2 are restated.
 - 2.15.4 With reference to the 3rd point raised by Jhoots, the committee need to be assured that the applicant has looked into this and does not, in our opinion, need detailed information regarding a commercial decision.
 - 2.15.5 With reference to the 4th point raised by Jhoots, this information can be provided, if needed, once the NHS contract is awarded and the cold chain delivery service is commenced. It is the committee who have to be satisfied that regulation 25 is met and not the writer of the Jhoots response.
- 2.16 REGULATION 25(2) – requirements for distance selling pharmacies
- 2.17 The SW Committee noted an application for distance selling premises is, by virtue of regulation 25(1), not subject to the market entry test.
- 2.18 Regulation 25(2) states: [quoted in full]
- Reg 25(2)(a) – same site as a provider of primary medical services

- 2.19 There is no provider of primary medical services at the proposed address, so the application does not have to be refused by virtue of Regulation 25(2)(a).

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

- 2.20 Information about how the applicant would operate the proposed pharmacy is provided within the supporting information and draft SOPs attached to the application.

- 2.21 The SW Committee must be sure it has sufficient information to determine if it is satisfied that the procedures will secure uninterrupted provision of essential services during opening hours to persons anywhere in England, safely and effectively without face-to-face contact. If not, it must refuse the application.

Services available without interruption

- 2.22 The applicant has proposed core hours of 9.00am – 1.00pm and 2.00pm –6.00pm Monday to Friday. Closed Saturdays and Sundays and supplementary hours of 1.00pm – 2.00pm.

- 2.23 In the supporting information provided, the applicant lists the pharmacy systems and procedures which they state will ensure the safe, effective and uninterrupted provision of all essential services. In the supporting information the applicant describes the superintendent pharmacist, identifies a named operations manager and IG lead. They indicate that uninterrupted NHS Essential Services will be provided by the pharmacist being available at all times with qualified support staff on duty throughout the opening hours of the pharmacy premises. The applicant states that breaks taken by the Responsible Pharmacist will be covered by a second pharmacist who will then assume responsibility.

- 2.24 On the basis of the information provided, the SW Committee was satisfied that services will be provided without interruption.

Essential services will be provided without face-to-face contact.

- 2.25 In the supporting information the applicant states they will provide uninterrupted service provision to persons anywhere in England during the opening hours and without face-to-face contact. Patients will access services by telephone, live video call, website, email and postal services.

- 2.26 To establish if services will be provided without face-to-face contact it is useful to examine the Terms of Service (Schedule 4 Part 2 essential services) where compliance would ordinarily require face to face contact and assess if the applicant has explained how they will achieve it. [The National Health Service \(Pharmaceutical and Local Pharmaceutical Services\) Regulations 2013 \(legislation.gov.uk\)](https://www.legislation.gov.uk/ukdsi/2013/5136010000000001/pdfs/ukdsi20130513601000000001.pdf).

- 2.27 The applicant has provided confirmation of measures to ensure Essential Services are without face-to-face contact by providing:

2.27.1 Draft Standard Operating Procedures

2.27.2 Confirming there will be a secure internet connection, website, web cams and phones, post etc.

2.27.3 A courier will be used for deliveries beyond the range of their own delivery service

2.27.4 Confirms the premises will be inaccessible to patients seeking essential services by securing access routes.

Paragraph 5(2) & (3) – how will patients present prescriptions

2.28 In the pharmacy procedures document, it is stated that acute or urgent prescriptions will be received by EPS, or via courier from a surgery. The procedure document also states routine prescriptions will be received via post, fax and EPS.

2.29 The SW Committee was satisfied the pharmacy will receive prescriptions without face to face contact.

Paragraph 6 – Urgent request without a prescription

2.30 In the pharmacy procedures document, it is stated that acute or urgent prescriptions will be received by EPS, or via courier from a surgery and dispatched same day via 24 hour service available 365 days a year.

2.31 The SW Committee was satisfied the pharmacy has suitable arrangements in place for dealing with urgent requests without a prescription.

Paragraph 7 – Exemption Checking and payment

2.32 In the pharmacy procedures document under “proof of exemption/prescription charges”, the applicant states that evidence of exemption can confirmed by using the real time exemption checking service if appropriate. For other exemptions contact will be made with the patient and ask them to send proof via post, fax, email or on the secure pharmacy website.

2.33 In the same section the applicant states that facilities will be in place to collect charges via card over the phone or via a secure Internet site.

2.34 The SW Committee was satisfied the pharmacy has suitable arrangements in place for checking exemptions and collecting payments without face to face contact.

Paragraph 8 providing ordered drugs or appliances

2.35 In the pharmacy procedures document the applicant indicates that deliveries will be made with no charge to the patient. A dedicated courier will be used. Medications will be packaged in tamper proof packaging. The applicant indicates packaging will be obtained such as cardboard boxes and panels wraps designed to withstand a single trip. Double walled and/ or waterproof packaging will be used as required to protect the medicines and delivery person. A specialist courier will be used for the delivery of CDs and a process is detailed for failed deliveries. Delivery of temperature-controlled items will be pre-arranged, the courier will be provided contact information to warn the patient of their imminent arrival. Validated medical cool boxes will be used and for longer journeys gel/ice packs will be added to maintain an appropriate temperature.

2.36 The SW Committee was satisfied that suitable arrangements are in place for the delivery of items including temperature-controlled items and CDs.

Paragraph 8(4)

2.37 In the application form at part 4 it is left blank and in the pharmacy procedures document it states if prescriptions for appliances needing measuring and fitting are received the patient will be signposted to an alternative provider.

- 2.38 The SW Committee was satisfied that suitable arrangements are in place for the measuring and fitting of appliances.

Paragraph 9(4) – Repeat Dispensing

- 2.39 In the pharmacy procedures document under repeat dispensing, it states that the patient will be given advice relating to repeat dispensing using non face to face methods of communication. The service will be promoted to suitable patients. It also describes how requirements additional to those for dispensing will be managed – assessing need for a repeat supply and raising any clinical issues identified with the prescriber.

- 2.40 The SW Committee was satisfied that arrangements are in place for Repeat Dispensing including reminding patients of the importance of only requesting items they need, confirming the medication is being used appropriately, checking for side effects and the patient has not had any changes in health.

Paragraph 10(1) - Further activities to be carried out in connection with the provision of dispensing services

- 2.41 In the pharmacy procedures document various non face-to-face means of communication such as phone, fax, email, video calling and website are described. The applicant states that use will be made of telephones, email, video call facilities.

- 2.42 The SW Committee was satisfied that suitable arrangements are in place so the pharmacy can communicate with and provide essential services such as advice without face to face contact.

Paragraph 10(1)(da) – benefits of repeat dispensing

- 2.43 In the pharmacy procedures document under repeat dispensing, it states that the service will be promoted to suitable patients.

- 2.44 The SW Committee was satisfied that suitable arrangements are in place to advise suitable patients of the benefits of repeat dispensing without face to face contact.

Paragraph 13 – Disposal service in respect of unwanted drugs

- 2.45 In the pharmacy procedures document under “Disposal of Unwanted Medication” it states patients can request this via phone, fax, email or webcam. Sufficient packaging will be provided for the collection of unwanted medicines by a courier at no charge to the patient.

- 2.46 The SW Committee was satisfied that suitable arrangements are in place for the disposal of unwanted medicines without face to face contact.

Paragraph 17 – prescription linked interventions

- 2.47 In the pharmacy procedures document under “1. Prescription linked intervention” it states staff, using phone, email, live chat or video will provide opportunistic advice on appropriate healthy living topics by reference to the uses of prescribed medications. They also suggest suitable leaflets can be included into the packaging with dispensed medicines.

- 2.48 The SW Committee was satisfied that suitable arrangements are in place to provide prescription linked interventions and healthy lifestyle advice without face to face contact.

Paragraph 18 - Public health campaigns

- 2.49 In the pharmacy procedures document under "2. National Health Campaign" it is stated the pharmacy will participate in public health promotions by sending out leaflets and by providing information on the website.
- 2.50 The SW Committee was satisfied that suitable arrangements are in place to provide public health campaigns without face to face contact.

Paragraph 19 and 20 – Signposting

- 2.51 In the pharmacy procedures document under "Signposting" it states patients will be signposted to other health and social care providers etc. whenever necessary. Any advice will be given using non face to face methods of communication.
- 2.52 The SW Committee was satisfied that suitable arrangements are in place to provide signposting services without face to face contact.

Paragraph 21 and 22 (self-care)

- 2.53 In the pharmacy procedures document under "Support for Self-Care" it states that advice to help a patient self-manage a condition will be given using non face to face methods.
- 2.54 The SW Committee was satisfied that suitable arrangements are in place to provide self-care services without face to face contact.

Paragraph 28C requirements in respect of websites and health promotion zones

- 2.55 In the pharmacy procedures document, it states in various places that information will be available on the website, including healthy living information.
- 2.56 However, it does not appear to specifically address the matter of 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". This will be raised with the pharmacy to ensure this is built into its webpage design.
- 2.57 The SW Committee was satisfied that the applicant has confirmed there will be a website to facilitate the following:
- 2.57.1 Patient accesses website via a secure log-in procedure;
- 2.57.2 Patient provides details of prescription,
- 2.57.3 Patient will be contacted by the pharmacy and medical history assessed.
- 2.57.4 Patient posts prescription to the pharmacy and/or prescription received via EPS.
- 2.57.5 Item is dispensed and details added to PMR.
- 2.57.6 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.

Other

- 2.58 In the pharmacy procedures document applicant states that the pharmacy will have an alarm system, with secured access routes. The applicant also states that should a patient attempt to obtain services face to face they will be informed that services cannot be provided on the premises.
- 2.59 In the pharmacy procedures document under "Discharge Medicine Service" it is stated that the service will be provided using phone, fax, email, post or webcam. It also describes a process for delivering the service.

Decision

- 2.60 The SW Committee was satisfied that the application should be GRANTED because:
- 2.60.1 The SW Committee is satisfied that the proposed premises were not adjacent to or in close proximity to other chemist premises.
- 2.60.2 The SW Committee is satisfied that the premises of the applicant are not on the same site or in the same building as the premises of a provider of primary medical services with a patient list.
- 2.60.3 The SW Committee is satisfied that all essential services were likely to be secured without interruption during the opening hours.
- 2.60.4 The SW Committee is satisfied that all essential services were likely to be secured for persons anywhere in England.
- 2.60.5 The SW Committee is satisfied that all essential services were likely to be secured without face to face contact.
- 2.60.6 The SW Committee is satisfied that all essential services were likely to be secured in a safe and effective manner because it had sufficient information to be satisfied that the procedures adopted by the applicant would be likely to secure the safe and effective provision essential services.
- 2.61 In approving the application, the SW Committee notes the applicant must ensure the website includes 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.

Appeal rights

- 2.62 The application is granted, so Jhoots are granted third-party appeal rights as they set out grounds for objecting to the application."

3 The Appeal

Using the online appeal form dated 14 May 2025, Jhoots Pharmacy Ltd ("the Appellant") appealed against the Commissioner's decision. The grounds of appeal are:

- 3.1 "As part of our representations to the NHS we stated the following points that we believed should lead to the application under Regulation 25 being refused. We do not believe NHS Commissioning Team (PSRC) fully considered these points. The additional information provided by the applicant as part of their 14 – day period for responses did not address these points either. I believe the matters listed below are

relevant and therefore ask Primary Care Appeals to reconsider the application in its entirety in accordance with Regulation 25 and the conditions set out in Regulation 64.

3.2 We submit that the application fails to meet the requirements set out in Regulation 25 and the conditions set out in Regulation 64.

3.2.1 The application includes a copy of a floor plan of the premises. We note this includes a reception/ waiting area next to two consultation rooms. This would suggest that patients will and can access the premises. We would ask the NHS to satisfy themselves based on this that the consultation room and waiting area will be not and cannot be used for the provision of pharmaceutical services in the context of Regulation 25.

3.2.2 The applicant's supporting information states 'if patient counselling is required for any dispensed medication, the pharmacy will have procedures so this can be done via the telephone, videoconferencing or email before dispatch of medication'. There are not any details of such procedures in the application.

3.2.3 The application states that '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. Limited information is provided with regards to this, in effect we are only advised that several companies have 'been researched'.

3.2.4 The applicant's response in section 6(3) of the decision report is that "*the Committee need to be assured the applicant has looked into this, and does not, in our opinion, need detailed information regarding a commercial decision*".

3.2.5 For the Delivery of Refrigerated Medicinal Products the applicant states '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'. Limited information is provided with regards to how these will be packed to ensure the temperatures will be maintained. It is also not clear how the local delivery driver will audit and monitor temperature whilst the medication is out for delivery.

3.2.6 (The decision report in paragraph 6(5) response from the applicant states: "*this information can be provided, if needed, once the NHS Contract is awarded and the cold chain delivery service is commenced*".

3.3 We do not see how the PSRC could be satisfied that this aspect of the application is met from the limited information provided and the evidence should be provided prior to an application being considered not afterwards."

4 **Comments to the Commissioner**

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

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

4.1 "I would like to make the following comments:

- 4.2 The decision makers are reminded that the SOPs are Draft SOPs and so are under constant review and development.
- 4.3 Turning now to the point raised about the consultation room, the consultation room can be used for various services which will include the provision of advanced and enhanced services and for private services outside the NHS contract. No essential services will be delivered in the consultation room unless it is by a method which ensures that the patient is NOT present in the pharmacy i.e. videoconferencing, telephone, email etc etc. This leads onto the 2nd point raised by Jhoots regarding patient counselling. Without fear of repetition, the decision makers are reminded that the SOPs are Draft SOPs and so are under constant review and development.
- 4.4 With reference to the 2nd point raised by Jhoots, the above comments in 1 and 2 are restated.
- 4.5 With reference to the 3rd point raised by Jhoots, the committee need to be assured that the applicant has looked into this and does not, in our opinion, need detailed information regarding a commercial decision.
- 4.6 With reference to the 4th point raised by Jhoots, this information can be provided, if needed, once the NHS contract is awarded and the cold chain delivery service is commenced. It is the committee who have to be satisfied that regulation 25 is met and not the writer of the Jhoots response.
- 4.7 It is also noted that the letter from Jhoots, dated 16 December 2024, is not signed and there is no indication that it has been sent from Sarbjit Jhooty's company email or personal email. The letter is addressed to Mr Hussain and not to the name set out in the reply address. This indicates that the writer of the response has paid little attention, if at all any attention, to the detail of the application.
- 4.8 Indeed, this point can be evidenced by the letter writer for Jhoots not ensuring that the text can be read as the body of the letter on the first page at the final paragraph is printed over a logo which makes the text hard to read. This may be an indication that the response has been rushed as the writer has not concerned themselves with how the letter looks.
- 4.9 We also ask the committee to consider whether there are other motives at play when the response from Boots and Jhoots have been received, for example, a financial motivation by either company to stop other contractors being awarded NHS contracts which could diminish NHS prescription and NHS services market share for these companies.
- 4.10 We request that the committee give little or no weight to the responses received from Boots or Jhoots."

5 **Summary of Representations**

This is a summary of representations received on the appeal.

5.1 THE COMMISSIONER

- 5.1.1 "Thank you for your letter, received 28th May 2025, addressed to Mr Speight at Primary Care Support England (PCSE) enclosing a copy of the above appeal. The South West Pharmaceutical Services Regulations Committee (SW Committee) wishes to make the following comments on the appeal.

- 5.1.2 The SW Committee noted this is an application for a 'distance selling pharmacy' and is an excepted application and therefore not subject to the market entry test.
- 5.1.3 The SW Committee noted the application must be approved unless the commissioner is not 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.*
- 5.1.4 Following consideration of the information provided by the applicant the SW Committee was satisfied that the application should be granted as:
- 5.1.4.1 the proposed premises were not adjacent to or in close proximity to other chemist premises.
 - 5.1.4.2 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.
 - 5.1.4.3 all essential services were likely to be secured without interruption during the opening hours.
 - 5.1.4.4 all essential services were likely to be secured for persons anywhere in England.
 - 5.1.4.5 all essential services were likely to be secured without face to face contact.
 - 5.1.4.6 all essential services were likely to be secured in a safe and effective manner because it had sufficient information to be satisfied that the procedures adopted by the applicant would be likely to secure the safe and effective provision essential services.
- 5.1.5 In approving the application, the SW Committee notes the applicant must ensure the website includes 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.
- 5.1.6 The SW Committee looks forward to receiving the Primary Care Appeals' decision in due course."

5.2 THE APPLICANT

- 5.2.1 "Re: Response from Imperial Chemists Ltd to the appeal against awarding a DSP contract

5.2.2 After reading the appeal letter and original responses to the application from the parties who did respond to the circulation of the application, we respond as follows:

5.2.3 The appeal committee will be aware that the application must be heard afresh. However, this does not prevent the appeal committee considering the original decision in the which the DSP contract was successfully awarded. We respectfully ask the committee to consider this document carefully and to take into account the matters which the original committee commented upon.

5.2.4 The original committee stated the following:

The SW Committee was satisfied that the application should be GRANTED because:

a. The SW Committee is satisfied that the proposed premises were not adjacent to or in close proximity to other chemist premises.

b. The SW Committee is 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.

c. The SW Committee is satisfied that all essential services were likely to be secured without interruption during the opening hours.

d. The SW Committee is satisfied that all essential services were likely to be secured for persons anywhere in England.

e. The SW Committee is satisfied that all essential services were likely to be secured without face to face contact.

f. The SW Committee is satisfied that all essential services were likely to be secured in a safe and effective manner because it had sufficient information to be satisfied that the procedures adopted by the applicant would be likely to secure the safe and effective provision essential services.

5.2.5 We urge the appeal committee to pay particular attention to these comments as the original application has already been scrutinised by a competent committee who are well versed in making these decisions.

5.2.6 We note that the original response to the application, from Jhoots, dated 16 December 2024, is not signed and there is no indication that it has been sent from Sarbjit Jhooty's company email or personal email. The letter is addressed to Mr Hussain and not to the name set out in the reply address. This indicates that the writer of the response has paid little attention, if at all any attention, to the detail of the application. Indeed, this point can be evidenced by the letter writer for Jhoots not ensuring that the text can be read as the body of the letter on the first page at the final paragraph is printed over a logo which makes the text hard to read. This may be an indication that the response has been rushed as the writer has not concerned themselves with how the letter looks.

5.2.7 We note that the appeal lodged by Jhoots is very similar to the original letter which they submitted. This begs the question as to whether Jhoots have considered their appeal in full or whether there are other factors at play which have caused them to lodge the appeal i.e. to cause doubt and disruption to the

application in a futile attempt to dissuade Imperial Chemists Ltd from their contract application.

- 5.2.8 Further to paragraph 4 above, the appeal brings no new points to the original objection as ledged by Jhoots. [sic]
- 5.2.9 Imperial Chemists Ltd reiterate the points made in their response to objections raised when the application was first heard.
- 5.2.10 In the appeal Jhoots make numerous comments on the Draft SOP bundle provided with the original application. This SOP bundle was submitted in its entirety and included the Draft SOPs for the running of the pharmacy and other matters out with the provision of Essential Services.
- 5.2.11 The provision of enhanced and advanced services is out with the provision of Essential Services. The committee will only be dealing with, and have consideration of, the delivery of essential services for this application. Providing that those seeking enhanced and advanced services are informed that any service provided which is consequential to, and flows from, the enhanced and advanced service provided is a private service, then no essential service will have been provided face to face. It is also noted that there are upcoming changes to the provision of enhanced and advanced services from a DSP so that no enhanced or advanced NHS service can be provided from a DSP. The appeal committee should be satisfied, based on the information before it, that no NHS service will be delivered face to face.
- 5.2.12 Imperial Chemists Ltd has provided all documentation which we say satisfies the test under regulation 25.
- 5.2.13 The appeal committee must also ask itself the real reason why the objections have been placed. Is it out of genuine need to prevent an unnecessary provision of services or is it out of the other parties' fear of financial detriment and reduced market share of the NHS prescription business. We also make the same comment about the appeal letter.
- 5.2.14 The appeal committee will note that the substance of the appeal from Jhoots is very similar in construction to the original representations that were made in the first instance. We ask the appeal committee to consider the real underpinning reasons for this appeal. We say that the appeal was lodged not out of a genuine need to prevent unnecessary provision but as a further attempt to undermine and block the DSP application through fear of financial detriment to Jhoots. We say they have attempted to muddy the waters and that the appeal from Jhoots, is a last ditch attempt to be able to retain Jhoots market share of NHS business.
- 5.2.15 Taking all of this into account, we urge the appeal committee to dismiss the appeal in its entirety and to allow the contract to Imperial Chemists Ltd to proceed by granting the application."

5.3 THE APPELLANT

- 5.3.1 "Thank you for your letter dated 27th May 2025 providing an opportunity to comment on the '14-day comments' dated 13th January 2025, that had not been circulated prior to the application being considered by the Commissioner. As requested, I have limited this response to the content of the '14-day comments'. I have, however, for point of reference, attached a copy of our letter

to the Commissioner that contained our response within the 45-day period. I would be grateful if you would consider this alongside the appeal.

- 5.3.2 Jhoots submit that the application fails to meet the requirements set out in Regulation 25 and the conditions set out in Regulation 64.
- 5.3.3 The applicant reminds the Committee the SOPs are draft and therefore under constant review and development. I submit that for the purpose of the application the Committee must base its decision on the evidence presented and not on the basis it may change in the future
- 5.3.4 The Committee will be aware of the imminent change to the Regulations that mean that the pharmacy will be unable to provide advanced and enhanced services from the premises and therefore must be delivered remotely. The applicant has not set out a process for this. The applicant also states, *"This leads onto the 2nd point raised by Jhoots regarding patient counselling. Without fear of repetition, the decision makers are reminded that the SOPs are Draft SOPs and so are under constant review and development"*. We submit this response by the applicant does not set out what process and procedures are in place to facilitate this effectively, and without face-to-face contact.
- 5.3.5 The applicant states in point 4 *"with reference to the 3rd point raised by Jhoots, the committee need to be reassured that the applicant has looked into this, and does not, in our opinion, need detailed information regarding a commercial decision"*. This may well be a commercial decision, but we submit the information, and detail is required to fulfil the requirements of Regulation 25 and the conditions set out in Regulation 64. We are only advised regarding delivery packaging that several companies have 'been researched'.
- 5.3.6 In point 5 of the applicant email response, (relating to delivery of refrigerated medicinal products) the applicant states *"this information can be provided, if needed, once the NHS contract is awarded, and the cold chain delivery service is commenced"*. The Committee should be satisfied all conditions are met before any contract is awarded.
- 5.3.7 The applicant also suggests our letter of response Date 9th December (attached) was not signed. It was signed but this appears to have been redacted by PCSE upon circulation to the applicant."

In a letter to PCSE of 16 December 2024, the Appellant stated:

- 5.3.8 "Thank you for your letter dated 26th November 2024 enclosing a copy of the application listed, to provide pharmaceutical services under Regulation 25 as a Distant Selling Pharmacy. As an interested party Jhoots pharmacy would like to submit the following response to be taken into consideration.
- 5.3.9 We submit that the application fails to meet the requirements set out in Regulation 25 and the conditions set out in Regulation 64.
 - 5.3.9.1 The application includes a copy of a floor plan of the premises. We note this includes a reception/ waiting area next to two consultation rooms. This would suggest that patients will and can access the premises. We would ask the NHS to satisfy themselves based on this that the consultation room and waiting area will be not and cannot be used for the provision of pharmaceutical services in the context of Regulation 25.

5.3.9.2 The applicant's supporting information states 'if patient counselling is required for any dispensed medication, the pharmacy will have procedures so this can be done via the telephone, videoconferencing or email before dispatch of medication'. There are not any details of such procedures in the application.

5.3.9.3 The application states that '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. Limited information is provided with regards to this, in effect we are only advised that several companies have 'been researched'.

5.3.9.4 For the Delivery of Refrigerated Medicinal Products the applicant states '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'. Limited information is provided with regards to how these will be packed to ensure the temperatures will be maintained. It is also not clear how the local delivery driver will audit and monitor temperature whilst the medication is out for delivery.

5.3.10 We submit this application should not be granted as Regulation 25 is not met."

6 Amendments to Regulation 25

On 23 June 2025, amendments to Regulation 25 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 came into force which affect this application. Given the amendments represent a new test the Applicant was given the opportunity to make comments in support of its application and parties given the opportunity to provide comments in response.

6.1 THE APPLICANT

6.1.1 "Thank you for your letter dated 1 July 2025, concerning the recent amendments to Regulation 25 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, which came into force on 23 June 2025. We have carefully reviewed the updated wording and understand the implications for our ongoing application and appeal, reference SHA/ 26616.

6.1.2 As the regulatory framework has now changed so that no advanced or enhanced services can be delivered to a patient who is physically present at the premises, any SOPs that will be written for advanced and enhanced service delivery will ensure that any service MUST not be delivered face to face within the pharmacy. Any patient who requests any NHS service to be delivered face to face will be informed that this is not possible, under any circumstance. All staff employed by the pharmacy will be informed of this change in the rules.

6.1.3 In response to your correspondence, and to provide comprehensive detail regarding our proposed operations and our commitment to compliance with all relevant regulations, please find attached:

6.1.3.1 Our Standard Operating Procedures (SOP) [Appendix A]

6.1.3.2 Detailed Pharmacy Procedures.[see below].

6.2 Imperial Chemists Ltd Pharmacy Procedures

- 6.2.1 Imperial Chemists 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.
- 6.2.2 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.
- 6.2.3 Imperial Chemists Ltd will have a website which facilitates the following:
 - 6.2.3.1 Patient accesses website via a secure log-in procedure;
 - 6.2.3.2 Patient provides details of prescription,
 - 6.2.3.3 Patient will be contacted by the pharmacy and medical history assessed.
 - 6.2.3.4 Patient posts prescription to pharmacy and/or prescription received via EPS.
 - 6.2.3.5 Item is dispensed and details added to PMR.
 - 6.2.3.6 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.
- 6.2.4 The website has been built by a colleague with a vast experience of web design. 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.
- 6.2.5 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. Imperial Chemists Ltd has decided to use Titan (www.titanpmr.com) as the software provider which will be a key tool in providing a safe and effective provision of service.
- 6.2.6 Imperial Chemists 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.

- 6.2.7 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 without face-to-face contact, an example being how to elicit a comprehensive medical history by telephone or webcam.
- 6.2.8 Imperial Chemists Ltd is comprised of 2 directors, [D-A F] and [BC]. [D-A F] is the nominated superintendent and has suitable pharmacy experience. [D-A F] will act in overseeing the operations of the pharmacy and will maintain role of the Information Governance Lead, Clinical Governance Lead and Smartcard Sponsor. A full-time Responsible Pharmacist will be employed to be in attendance during the opening hours. He will be supported by a staff team of one full-time and one part-time dispenser. This level of staff will be able to cover initial trade levels once the pharmacy is open and will ensure an uninterrupted provision of essential services during the opening hours. The team is expected to grow with the business and new members will be added as and when required [sic]
- 6.2.9 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. 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

- 6.2.10 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

- 6.2.11 Patients anywhere in England can access these services via our pharmacy website a direct phone line to the pharmacy, fax, email as well as webcam. Internet connections at the pharmacy will be provided by the NHS HSCN network via BT.
- 6.2.12 All prescriptions dispensed will be delivered using a dedicated courier service provided by City Sprint (www.citysprinthealth.co.uk). This will include the delivery of prescriptions received via post, fax and EPS. City Sprint will also be delivering cold chain items and CDs. This is addressed in the SOPs which have been included.

Safe and effectively

- 6.2.13 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.
- 6.2.14 We will have a suitable number of staff who will be trained to a minimum of an NVQ level 2 standards. This training will be undertaken by National Pharmaceutical Association (NPA) (www.npa.co.uk)
- 6.2.15 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.
- 6.2.16 If patient counselling is required for any dispensed medication, the pharmacy will have procedures so this can be done via the telephone, videoconferencing or email before dispatch of medication. The pharmacy will require acknowledgment from the patient or another person that the counselling points have been understood. Patient interactions will be recorded on the PMR. A label will also be attached to the packaging asking the patient to contact the pharmacy for further details.
- 6.2.17 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.
- 6.2.18 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

- 6.2.19 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.
- 6.2.20 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.
- 6.2.21 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.
- 6.2.22 Delivery of Refrigerated Medicinal Products - For cold chain products, delivery times will always be pre-arranged with the patient to minimise the risk of failed

delivery. The patient's contact number will be given to the City Sprint delivery driver so they can again call the patient approximately 15-30 minutes prior to so they can check that somebody will be at the address to receive the medication. Cold chain products will be packed in such a way as to ensure that the required temperatures are maintained throughout the journey and the medicines are transported in accordance with their labelling requirements to maintain product integrity.

- 6.2.23 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.
- 6.2.24 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.
- 6.2.25 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

- 6.2.26 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

- 6.2.27 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

- 6.2.28 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.
- 6.2.29 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

- 6.2.30 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.

Essential Service – Signposting

Uninterrupted Service

- 6.2.31 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

- 6.2.32 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

- 6.2.33 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

- 6.2.34 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

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

Persons anywhere in England

- 6.2.36 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

- 6.2.37 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.

- 6.2.38 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

- 6.2.39 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.
- 6.2.40 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.
- 6.2.41 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

- 6.2.42 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.
- 6.2.43 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

- 6.2.44 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

- 6.2.45 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.
- 6.2.46 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

- 6.2.47 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

- 6.2.48 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

- 6.2.49 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.
- 6.2.50 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

- 6.2.51 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

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

National Health Campaign

Uninterrupted Service

- 6.2.53 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

- 6.2.54 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

- 6.2.55 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

- 6.2.56 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

- 6.2.57 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

- 6.2.58 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

- 6.2.59 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.
- 6.2.60 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

- 6.2.61 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

- 6.2.62 There will be a named Clinical Governance Lead who will also be the Superintendent Pharmacist, [D-A F]

Patient and public involvement

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

- 6.2.64 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

- 6.2.65 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

- 6.2.66 All incident reporting will be carried out in the pharmacy and this will involve near misses using the GPhC near miss template and help identify trends or highlight weaknesses in pharmacy systems and procedures and would be rectified promptly. Any patient safety incidents will be reported to the National Patient Safety Agency (NPSA) online. We will analyse and learn from any patient safety incidents through a system of regular reviews. In addition, the pharmacist will be proactive in considering and preventing potential risks. This will include competence in risk management and the application of Root Cause Analysis. Health and Safety legislation will be complied with in order to reduce the risk of harm to pharmacy staff and the public.
- 6.2.67 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.
- 6.2.68 Imperial Chemists 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.

- 6.2.69 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

- 6.2.70 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

- 6.2.71 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.
- 6.2.72 Use of information to support clinical governance and health care delivery 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. Imperial Chemists 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 Imperial Chemists 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.
- 6.2.73 Pharmacists will be using their own professional judgement to make records of interventions they have made and any advice they may have given. Imperial Chemists 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

- 6.2.74 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

- 6.2.75 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.
- 6.2.76 As the regulatory framework has now changed so that no advanced or enhanced services can be delivered to a patient who is physically present at the premises, any SOPs that will be written for advanced and enhanced service delivery will ensure that any service MUST not be delivered face to face within the pharmacy. Any patient who requests any NHS service to be delivered face to face will be informed that this is not possible, under any circumstance. All staff employed by the pharmacy will be informed of this change in the rules."

7 Observations and Parties comments in response

Comments were provided in response to the Applicant's comments regarding the amendments to Regulation 25. This is a summary of observations received.

7.1 THE APPELLANT

- 7.1.1 "Thank you for your letter dated 15th July 2025 advising of the representations on the appeal. I would like to make the following observations.
- 7.1.2 The applicant states in their email Date 7th July 2025 that "As the regulatory framework has now changed so that no advanced or enhanced services can be delivered to a patient who is physically present at the premises, any SOPs that will be written for advanced and enhanced service delivery will ensure that any service MUST not be delivered face to face within the pharmacy".
- 7.1.3 As part of the determination of this application the Committee must be satisfied that the applicant has procedures in place to provide these services safely and effectively without face-to-face contact. We submit these procedures have not been set out in the application process.

7.1.4 Jhoots submit that the application fails to meet the requirements set out in Regulation 25 and the conditions set out in Regulation 64.”

8 Consideration

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

8.2 It also had before it the responses to NHS Resolution’s own statutory consultations.

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

8.4 The Committee had regard to the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (“the Regulations”).

Regulation 31

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

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

(2) This paragraph applies where -

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

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

(ii) adjacent premises; and

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

8.6 The Committee noted that the Applicant had not provided any information in the application form on this point but the Committee noted that the wording of the application form only required the Applicant to include information in the relevant section if the proposed premises were adjacent to, or in close proximity to, another pharmacy or dispensing appliance contractor premises. The Committee considered it reasonable to determine that the lack of information in the application form on this point when read with the wording of the application form allowed it to be reasonably satisfied that the Applicant considered that the proposed premises were not adjacent to, or in close proximity to, another pharmacy or dispensing appliance contractor premises.

8.7 The Committee noted the Commissioner had determined that “*There are no other pharmacies at the proposed premises or adjacent. The nearest pharmacies are in Wellington 1 mile away from the proposed premises. The SW Committee was satisfied it is not required to refuse the application by virtue of Regulation 31.*” The Committee noted that this had not been disputed by any party either on appeal or in subsequent representations.

8.8 The Committee therefore determined, based on the information provided, that it was not required to refuse the application under the provisions of Regulation 31.

Regulation 25

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

- "(1) Section 129(2A) and (2B) of the 2006 Act (regulations as to pharmaceutical services) does not apply to an application—
- (a) for inclusion in a pharmaceutical list by a person not already included; or
 - (b) by a person already included in a pharmaceutical list for inclusion in that list in respect of premises other than those already listed in relation to that person,
- in respect of pharmacy premises that are distance selling premises.*
- (2) NHS England must refuse an application to which paragraph (1) applies—
- (a) if the premises in respect of which the application is made are on the same site or in the same building as the premises of a provider of primary medical services with a patient list; and
 - (b) unless NHS England is satisfied that the pharmacy procedures for the pharmacy premises are likely to secure—
 - (i) the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services, and
 - (ii) the safe and effective provision of pharmaceutical services without face to face contact at the pharmacy premises between any person receiving the services, whether on their own or on someone else's behalf, and the applicant or the applicant's staff."

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

Additional information to be included with excepted applications

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

Nature of details to be supplied

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

that NHS England may need to make of the information or documentation when carrying out its functions.

Regulation 25(1)

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

Regulation 25(2)(a)

- 8.12 The Committee noted that the Applicant had not included any information in the relevant section of the application form that deals with this point. The Committee noted that the application form states that the relevant section should only be completed if the proposed premises are on the same site or in the same building as the premises of a provider of primary medical services with a patient list. The Committee considered that, where the Applicant did not include any information in this section, it was reasonable to consider that the Applicant was indicating that the proposed premises were not on the same site or in the same building as the premises of a provider of primary medical services with a patient list. The Commissioner, in its decision report, stated that *"There is no provider of primary medical services at the proposed address, so the application does not have to be refused by virtue of Regulation 25(2)(a)"* which had not been disputed. Based on the information available to it, the Committee therefore determined that the proposed premises were not on the same site as, or in the same building as the premises of a provider of primary medical services with a patient list.

Regulation 25(2)(b)

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

- 8.17 It is not for the Committee to 'approve' or 'disapprove' of these SOPs (as they may contain matters not relevant to the Committee's consideration, and there are many ways an applicant can choose to organise itself in order to comply with the various requirements of the Regulations) and the Committee has not sought to do so. The Committee has sought evidence within the SOPs and application in order to satisfy itself that it is appropriate to grant the application, the absence of which would require it to reject it.
- 8.18 The Committee noted in the information provided, the Applicant refers to prescriptions being received via post or via EPS and that *"medication is delivered nationwide"* and that this would *"enable us to deliver a service safely and effectively to anyone in England without face to face contact"*.
- 8.19 The Committee noted the Applicant had repeatedly stated, throughout the Pharmacy Procedures that *"Patients anywhere in England can access these services ...from our pharmacy via phone, fax, email, post or webcam."* The Committee further noted the comments from the Applicant that as well as their own delivery drivers they would be using Royal Mail as well as couriers.
- 8.20 Based on the information before it, the Committee was satisfied that the provision of essential services would be available to persons anywhere in England.
- 8.21 With regard to uninterrupted provision of essential services, the Committee noted the Applicant's Pharmacy Procedures state:
- 8.21.1 *"A full-time Responsible Pharmacist will be employed to be in attendance during the opening hours. He will be supported by a staff team of one full-time and one part-time dispenser. This level of staff will be able to cover initial trade levels once the pharmacy is open and will ensure an uninterrupted provision of essential services during the opening hours."*
- 8.22 And further under "Dispensing" state:
- 8.22.1 *"Uninterrupted service"*
- 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."*
- 8.23 The Committee also noted SOP i105 "For assuming Responsibilities as RP" however it noted that this SOP dealt with assuming duties *"when taking on a booking as a locum pharmacist"* and whilst the absence of the RP was referred to it stated:
- 8.23.1 *"The SOPs must cover"*
- ...*
- E Arrangements during the responsible pharmacists absence*
- ..."*

- 8.24 The Committee noted the information regarding the absence of the Responsible Pharmacist and that the Applicant had confirmed that *"... a further pharmacist will be on hand to ensure that there is no break in pharmacist cover during the opening hours."*
- 8.25 Based on the information before it, the Committee was satisfied that the provision of services would be without interruption.
- 8.26 With regard to the safe and effective provision of pharmaceutical services without face to face contact, the Committee noted the Applicant had referred to communication with patients by phone, fax, email and webcam and further that *"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. All entrances and exits will remain inaccessible to members of the public who are seeking the provision of essential services."*
- 8.27 The Committee noted the comments from the Appellant that *"the application includes a copy of the floor plan of the premises. We note this includes a reception/waiting area next to two consultation rooms"* which the Appellant states *"this would suggest that patients will and can access the premises .."*
- 8.28 The Committee was of the view that the presence of consultation rooms and a reception/waiting area did not necessarily mean that the pharmacy was going to be providing pharmaceutical services face to face. The Committee noted that there are various reasons why a consultation room might be required, in particular for conversations which the pharmacist may be having with patients using the permissible means of communication i.e. telephone or video chat. Further there are various reasons why the pharmacy might have a reception/waiting area including for the receipt of deliveries.
- 8.29 The Committee noted the Applicant's updated SOPs contain the statement *"All communication must be via email, phone or post for essential services..."* which is repeated numerous times. The Committee noted the further representations from the Applicant state:
- 8.29.1 *"As the regulatory framework has now changed so that no advanced or enhanced services can be delivered to a patient who is physically present at the premises, any SOPs that will be written for advanced and enhanced service delivery will ensure that any service MUST not be delivered face to face within the pharmacy. Any patient who requests any NHS service to be delivered face to face will be informed that this is not possible, under any circumstance. All staff employed by the pharmacy will be informed of this change in the rules."*
- 8.30 The Committee also had regard to the front page of the "Pharmacy Procedures" which states:
- 8.30.1 *"Imperial Chemists 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."*

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."

- 8.31 The Committee further noted the SOP i184 for "Urgent Medicine Supply" which included the heading *"All communication must be via email, phone or post for essential services, advanced services and enhanced services"* but goes on to state:

8.31.1 *"Governance*

l) no payment will be made for patients who have not been referred by NHS 111 e.g. walk in patients."

- 8.32 Whilst the Committee appreciated that SOPs are subject to being updated, it must have regard to the information before it in order to satisfy itself regarding the distance selling conditions. In this instance, the Committee considered the Applicant's repetition of the statement at 8.29 and 8.30 together with the statement in SOP i184 as noted above, created sufficient doubt that it could not be satisfied that pharmaceutical services would be consistently provided other than on a face to face basis at the pharmacy premises.

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

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

- 8.35 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:

8.35.1 Dispensing of drugs and appliances

8.35.2 Urgent supply without a prescription

8.35.3 Preliminary matters before providing ordered drugs or appliances

8.35.4 Providing ordered drugs or appliances

8.35.5 Refusal to provide drugs or appliances ordered

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

8.35.7 Disposal service in respect of unwanted drugs

8.35.8 Promotion of healthy lifestyles

8.35.9 Prescription linked intervention

8.35.10 Health campaigns

8.35.11 Signposting

8.35.12 Support for self-care

8.35.13 Discharge medicines service

8.35.14 Websites and health promotion zones

- 8.36 The Committee noted that the Applicant had left the application form blank in response to the question as to whether or not they were undertaking to provide appliances. The Committee noted however that contained within the "Pharmacy Procedures" it states:

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

- 8.37 The Committee noted that, although the application form had not been completed, the Applicant was not proposing to provide appliances which require measuring and/or fitting. In the event that the application was granted, the Applicant would not therefore be able to provide appliances to patients.

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

Providing ordered drugs or appliances

- 8.39 The Committee considered whether the Applicant had explained how drugs/appliances will be provided to the patient (including to ensure that (i) the 'cold chain' is maintained, where relevant, and (ii) that the requirements of the Misuse of Drugs Regulations 2001 and, in particular, Regulations 14 and 16, are met).

- 8.40 The Committee noted the comments from the Appellant with regard to the limited information provided with regard to how temperatures will be maintained as well as being unclear as to how local delivery drivers would audit and monitor temperature whilst the medication was out for delivery.

- 8.41 The Committee noted, in the "Pharmacy Procedures" that the Applicant states

8.41.1 *"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."*

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."

- 8.42 And further

8.42.1 *"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."

8.43 The Committee noted in SOP i167 "For delivery via cold chain" it states:

8.43.1 "For delivery via cold chain

Objective: to ensure that all refrigerated items are maintained between 2-8 degrees C from delivery into the pharmacy, through storage and then delivery to the patient and that there are procedures in place to confirm and correct any situations that may occur.

Scope: To cover all items that requires storage between 2-8 degrees C

Responsibility

Names:

Job Titles: Responsible Pharmacist, Pharmacists, Pharmacy Technicians, Accuracy Checking Technicians, Dispensers, Dispensing Assistants, Delivery Drivers

...

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.

You should store cool bags in a fridge so they are already cold when the dispensed item is put in them for delivery.

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.

If the patient is not there it must be returned to the pharmacy before the rest of the delivery round is done.

You need to keep an audit trail of the length of time the items are out of the fridge.

Check with the manufacturers how long is acceptable for the item to be out of the fridge for each item you stock."

- 8.44 The Committee was of the view that the process contained within the SOP i167 was for the local pharmacy delivery driver as the information contained within the SOP differed from that contained within the "Pharmacy Procedures" under the heading "Delivery of Refrigerated Medicinal Products" which referred to deliveries being made by City Sprint.
- 8.45 With the exception of a reference to use of a cool box, the Committee noted that the Applicant had not provided information within the SOP as to how the local delivery driver would ensure that the cold chain was maintained or, if there was a breach in the cold chain, how they would become aware of this and what the process was for the return of any medication where the integrity of the cold chain had been breached.
- 8.46 Taking all of the information before it into account, the Committee was of the view that the Applicant had not provided sufficient information for it to be satisfied that there would be compliance with paragraph 8(1) of Schedule 4.
- 8.47 In relation to all other essential services, the Committee was, on balance, satisfied that procedures adopted by the pharmacy (and general adherence to the Terms of Service) would be "likely to secure" safe and effective provision.

Other considerations

Providing ordered drugs or appliances

- 8.48 The Committee considered if the Applicant had explained what containers will be "suitable" for posted/delivered items.
- 8.49 The Committee noted the comments from the Appellant on appeal with regard to the packaging that the Applicant was proposing to use and that limited information had been provided on this point.
- 8.50 The Committee noted that within the "Pharmacy Procedures" the Applicant had stated:
- 8.50.1 *"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."*
- 8.51 The Committee noted the comments from the Appellant with regard to companies being "researched" which can supply this type of packaging but no further information had been provided as to which companies the Applicant would be using. The Committee was of the view that the Applicant did not have to provide information as to where they would be getting appropriate packaging from, but that the Applicant did have to explain what containers would be "suitable" for posted or delivered items. 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.
- 8.52 The Committee noted that on appeal the Appellant had made reference to the comment from the Applicant that *"if patient counselling is required for any dispensed medication, the pharmacy will have procedures so this can be done via the telephone, videoconferencing or email before dispatch of the medication"* and the Appellant had

gone on to state, in the letter of appeal, that “*there are not any details of such procedures in the application*”.

- 8.53 The Committee was of the view that it did not have to be provided with all SOPs to cover all processes that the Applicant would be carrying out as part of the normal business of a pharmacy, but that it should be provided with information sufficient to demonstrate that where there was the possibility of face to face contact, the Applicant had demonstrated that it had processes in place to demonstrate that this would not occur. The Committee noted that the Applicant was proposing to offer counselling via non face to face methods including, telephone, videoconferencing.
- 8.54 The Committee was of the view that the Applicant had provided sufficient information for it to be satisfied that there would be general adherence to the Terms of Service in respect of patient counselling.
- 8.55 In relation to all other essential services, the Committee was, on balance, satisfied that procedures adopted by the pharmacy (and general adherence to the Terms of Service) would be “likely to secure” safe and effective provision.

Summary

- 8.56 On the information before it, the Committee could not be satisfied that there are procedures likely to secure safe and effective provision of pharmaceutical services as required by Regulation 25(2)(b). Also, for the reasons set out at above the Committee concluded that pharmaceutical services would not be delivered by non-face to face means.
- 8.57 Pursuant to paragraph 9(1)(a) of Schedule 3 to the Regulations, the Committee may:
- 8.57.1 confirm the Commissioner’s decision;
 - 8.57.2 quash the Commissioner’s decision and redetermine the application;
 - 8.57.3 quash the Commissioner’s decision and, if it considers that there should be a further notification to the parties to make representations, remit the matter to the Commissioner.
- 8.58 In view of the change to the wording of the Regulations since the Commissioner made its decision as well as coming to a different conclusion to that of the Commissioner, the Committee determined that the decision of the Commissioner must be quashed.
- 8.59 The Committee considered whether there should be a further notification to the parties detailed at paragraph 19 of Schedule 2 of the Regulations to allow them to make representations if they so wished (in which case it would be appropriate to quash the original decision and remit the matter to the Commissioner) or whether it was preferable for the Committee to reconsider the application.
- 8.60 The Committee noted that representations on Regulation 25 had already been made by parties to the Commissioner, and these had been circulated and seen by all parties as part of the processing of the application by the Commissioner. The Committee further noted that when the appeal was circulated representations had been sought from parties on Regulation 25.
- 8.61 The Committee concluded that further notification under paragraph 19 of Schedule 2 would not be helpful in this case.

9 Decision

- 9.1 The Committee concluded that it was not required to refuse the application under the provisions of Regulation 31.
- 9.2 The Committee:
 - 9.2.1 quashes the decision of the Commissioner; and
 - 9.2.2 redetermines the application as follows -
 - 9.2.2.1 the Committee was satisfied that the proposed premises were not adjacent to or in close proximity to other chemist premises;
 - 9.2.2.2 the Committee was satisfied that the premises of the Applicant are not on the same site or in the same building as the premises of a provider of primary medical services with a patient list;
 - 9.2.2.3 the Committee was satisfied that all essential services were likely to be secured without interruption during the opening hours;
 - 9.2.2.4 the Committee was satisfied that all essential services were likely to be secured for persons anywhere in England;
 - 9.2.2.5 the Committee was not satisfied that pharmaceutical services were likely to be secured in a safe and effective manner; and
 - 9.2.2.6 the Committee was not satisfied that pharmaceutical services were likely to be secured without face to face contact.
 - 9.2.3 The application is refused.

Case Manager
Primary Care Appeals