

27 April 2023

REF: SHA/25839

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**APPEAL AGAINST NHS ENGLAND (NORTH EAST & YORKSHIRE AREA TEAM) DECISION TO GRANT AN APPLICATION BY HEALTHCARE TIME LTD FOR A RELOCATION THAT DOES NOT RESULT IN A SIGNIFICANT CHANGE TO PHARMACEUTICAL SERVICES PROVISION UNDER REGULATION 24 FROM 27 NEWMARKET STREET, SKIPTON, BD23 2JE TO UNIT 6 CROWN WORKS, BRADFORD ROAD, SANDBEDS, KEIGHLEY, BD20 5LN**

## 1 Outcome

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

A copy of this decision is being sent to:

Temple Bright LLP (on behalf of Healthcare Time Ltd),  
Crossflatts Pharmacy,  
NHS England,  
Community Pharmacy West Yorkshire

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### Advise / Resolve / Learn

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## 1 The Application

By application dated 27 July 2022, Healthcare Time Ltd (“the Applicant”) applied to NHS England for a relocation that does not result in a significant change to pharmaceutical services provision under Regulation 24 from 27 Newmarket Street, Skipton, BD23 2JE to Unit 6 Crown Works, Bradford Road, Sandbeds, Keighley, BD20 5LN. In support of the application it was stated:

In response to why the application should not be refused pursuant to Regulation 31 the applicant stated:

1.1 The Applicant left this section of the application form blank.

The Application confirmed that they were applying for a relocation in relation to distance selling premises by ticking “Yes” on the application form.

In response to why the application should not be refused pursuant to Regulation 25(2)(a) the Applicant stated:

1.2 The Applicant left this section of the application form blank.

1.3 The Applicant did not state that they were undertaking to provide appliances on the application form.

In response to the section headed “Information in support of all significant change applications” the Applicant stated:

1.4 The pharmacy which is the subject of this relocation application is a distance selling pharmacy. Currently the pharmacy provides essential services from the listed premises. The current pharmacy premises does not have adequate space for a consultation room and also carries out NMS services remotely via video/telephone facilities as per regulations and will continue to offer this service uninterrupted to all patients groups after the move to the new premises.

1.5 In accordance with regulation 64 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, patients who receive essential services from the listed premises do so otherwise than whilst present at the premises.

1.6 No patient visits the premises in order to access pharmaceutical services. Patients therefore receive pharmaceutical services from the listed premises remotely (for

example through the electronic transfer of prescriptions, delivery arrangements, the postal services, and electronically by email, telephone and website).

- 1.7 Since there are no patients who receive pharmaceutical services “at the existing premises” for the purposes of regulation 24(1)(a), there are no ‘patient groups’ who are ‘accustomed to accessing pharmaceutical services at the existing premises’. Regulation 24(1)(a) does not, therefore, apply to the determination of this application.
- 1.8 The pharmacy will continue to provide pharmaceutical services remotely and in accordance with regulation 64 following the proposed relocation, such that the pharmacy’s patients will be entirely unaffected by the proposed relocation.
- 1.9 As a distance selling pharmacy, the Applicant provides services to persons anywhere in England, rather than just within the area of the local HWB. The Applicant’s service provision will be unchanged by the proposed relocation and, consequently, will not result in a significant change in arrangements for the provision of pharmaceutical services within the HWB area.
- 1.10 The Applicant is not aware of any plans by the HWB to which any detriment would be caused by the granting of this application.
- 1.11 The services the Applicant undertakes to provide at the new premises are the same as the services the Applicant has been providing at the existing premises.
- 1.12 The provision of pharmaceutical services will not be interrupted.

In response to the why the application should not be refused pursuant to Regulation 25(2)(a):

- 1.13 The Applicant left this section of the application form blank.

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

- 1.14 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.
- 1.15 The answer to (a) and (b) above is as follows, and according to the regulatory requirements for distance selling pharmacies of NHS Regulations 25 and 64 as well as the guidance of the General Pharmaceutical Council:
- 1.16 The pharmacy is simply moving to a neighbouring HWB, in its entirety, this means that all of the current provision, policies and procedures including SOP’s will remain in place after the move and indefinitely. The current provisions, policies and procedures satisfy all the regulations in relation to this application and will continue to do so after the move has been completed. The Applicant is not aware of any concerns or complaints in relation to the way in which pharmaceutical services have been provided to date. This should satisfy NHS England that the pharmacy is operating safely and effectively and is providing services in accordance with the Terms of Service.
- 1.17 There will be no interruption to the services which this pharmacy provides. The superintendent reviews the SOP’s at least every two years and also continuously keeps policies and procedures of the pharmacy up to date in relation to any new legislation or guidance issued by the GPhC and NHS England.

- 1.18 The pharmacy also operates an up-to-date website which complies with all regulations, including GDPR. The pharmacy also complies with all of the relevant guidance for registered pharmacies by the GPhC issued in March 2022 in relation to providing pharmaceutical services at a distance.
- 1.19 The pharmacy will continue to provide essential services to any persons in England without face-to-face contact through the use of suppliers, couriers and services providers which are approved and operate in accordance to all regulations including cold chain and controlled drug requirements and also satisfy the SOP's and requirements of the pharmacy.
- 1.20 A Responsible Pharmacist is present and in charge during the core opening hours of the premises to ensure there is uninterrupted provision of essential services to patients who live anywhere in England who require and request the essential services.
- 1.21 2 supporting pharmacy staff are currently employed; if and when required, more staff will be hired to aid the Responsible Pharmacist in his/her role of uninterrupted provision.
- 1.22 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 are and will continue to be provided as follows:

#### Dispensing

- 1.23 Dispensing services are provided as per the NHS Terms of Services. All the steps carried out in accordance with the pharmacy Standard Operating Procedures (SOPs).
- 1.24 Prescriptions are received at the pharmacy by post via the use of pre-paid envelopes and via ETP/EPS through patient nominations which are requested by the patients via its website, Healthera app or telephone.
- 1.25 Prescription are checked for legal and clinical appropriateness and dispensed accordingly.
- 1.26 All dispensed items are delivered by a courier service or by a designated staff member to ensure delivery to patients anywhere in England. Deliveries comply with the GPhC guidelines of medicines delivery.
- 1.27 The SOP in regards to 'choice of delivery method' states, for local deliveries (up to 30-mile radius, but may be extended at the discretion of the RP) the delivery driver can deliver the medication. For local deliveries the delivery driver texts/emails the patients a definitive time period e.g. afternoon and date of delivery. The driver has access to the patient's delivery preferences as they are listed on the delivery label. If a patient has a safe place or request to leave with a neighbour set as a delivery preference, the Applicant tries its utmost to honour [sic] these preferences but make the patient fully aware that it may not be possible in certain circumstances such as delivery of controlled drugs.
- 1.28 Outside this area Royal Mail 24/48 is used, the medication is packaged into discreet high quality polythene bags/flat cardboard boxes in a large letter format for easy postage or into cardboard boxes for larger items like creams.
- 1.29 For Royal Mail deliveries the staff text/email the patients advising how their medication has been packaged and what exact Royal Mail service their package has been dispatched with. Large letters can fit through letter boxes, parcels can be left with neighbours/safe places (not applicable to CD's) if patients are not in or re-deliveries/collections from depot can be organised via Royal Mail website for a more appropriate date. Tracked Royal Mail services for Controlled drugs allow the patient to

have direct control over delivery day, offer a time range & delivery preferences while allowing the pharmacy team to ensure that GPS data, signature & image evidence is obtained upon delivery.

- 1.30 If the prescription is for a controlled drug, either the delivery driver is used (for “local deliveries”) or a fully tracked service from Royal Mail known as RM tracked 24/48 service is used. This tracked service offers the patients the ability to track their package via email or text, gives them a delivery time range & allows them to choose the day of delivery. GPS, image & signature data would be checked by the pharmacy team after delivery to ensure that the patient has received the CD delivery. (Extensively covered by SOP for Delivery of Controlled Drugs).
- 1.31 All cold chain deliveries are carried out in accordance with verified and approved cold chain procedures (Extensively covered under heading cold chain delivery by courier of SOP ‘Order Delivery’). Local cold chain deliveries involve the delivery driver adding the cold chain item to a polystyrene cool box which contains a calibrated thermometer. Ice packs are then added with cardboard blockers to ensure the temperature of the products remains between 2 and 8 degrees while delivering locally. As with all local deliveries the patient is informed via text/email of the date and time of day the delivery driver will be delivering. Particularly in regards to deliveries involving cold chain items the driver rings the patient to inform/confirm the estimated date and time of delivery before the medication is taken on the route to reduce the chance of delivery failure. In any case if the delivery fails the driver simply brings the medication back in the temperature controlled cool box and returns the items to the fridge & consequently re-organises delivery for a more convenient date/time with the patient.
- 1.32 This ensures the integrity of the cold chain and the maximum stability of thermo-labile drugs by packing, transporting and delivering in such a way that their integrity, quality and effectiveness are always preserved. This is a dedicated, fully monitored and temperature-controlled service.
- 1.33 For deliveries that are outside of the local delivery radius a combination of cold shipping packaging and RM tracked 24 is used. The Cold Shipping Package used currently is provided by ‘wool cool’ and is designed for customers that require a refrigerated environment of 2 – 8C for their shipments.
- 1.34 The packaging device maintain its exacting “cold ship” temperature requirements and has been extensively tested by both the pharmacy and manufacturer coupled with the appropriate delivery service (RM tracked 24) to ensure that timescales & temperatures are appropriate and any breach is detected by the pharmacy team who then promptly follow the failed delivery process.
- 1.35 RM tracked 24 service is a fully traceable transport is [sic] backed by the latest logistics technology which provides consignment tracking, ETA’s and electronic & image proof of delivery.
- 1.36 The patient is contacted once their prescription arrives to ascertain their availability to accept delivery of the cold chain medication. It is re-iterated to the patient that they must be available to accept the parcel due to its nature or make arrangements to have it left with a neighbour. They are offered the option to have it delivered to an alternative address such as their office or work place if appropriate. The patient is also informed that if they miss the delivery, they must collect or re-organise delivery of the parcel from the relevant depot within 24 hours to maintain the cold chain integrity of the medication, they are also told that they will be updated as to the tracking data of their parcel via the courier’s email/text notifications. Once the patient has agreed and is made fully aware of the date the package will be delivered, the Royal Mail tracked 24 service is initiated.
- 1.37 The cold chain item is kept in the fridge till [sic] 30 minutes before Royal Mail arrive to collect the delivery. At this point the item is packaged according to ‘Wool Cool’ instructions, tracked 24 service is selected and patients’ delivery preferences are

entered. The item is then collected, the patient receives all of the tracking data and updates. Staff then monitor the tracking & delivery status of the package the next day till [sic] positive confirmation by way of electronic and image proof of delivery is confirmed.

- 1.38 In the event of an unsuccessful delivery, Royal Mail will leave a 'Missed Delivery' card, stating the date and time of the attempted delivery. The patient can then rearrange the delivery conveniently by telephone or Internet, as long as it is within 24 hours. The patient also has the option to collect from the relevant depot within 24 hours. The packaging will keep the cold chain intent [sic] until successful re-delivery or collection as it can maintain the correct temperature for up to 72 hours in total.
- 1.39 This method is designed to give the patient maximum convenience whilst maintaining cold chain for up to 72 hours. However, in the event of any breach in the integrity of this service the patient is contacted and informed immediately to not use any product that might have been affected. The pharmacy then arranges for immediate re-delivery of the items via the same service and the return of the items that have failed to be delivered to the pharmacy by the Royal Mail tracked return service. Items subject to a cold chain breach are not re-used and are to be segregated from the pharmacy stock upon arrival at the pharmacy.
- 1.40 In the Applicant's operational existence, it has never faced a failed delivery due to the preparation, ability to communicate with the patient prior to delivery & valuing the patient's delivery preferences however the Applicant is fully prepared if ever faced with this situation.
- 1.41 Procedures are in place to ensure the Responsible Pharmacist can consult and advise appropriately if the need arises, with the condition of non-face-to-face contact. This include, where necessary, advising the patient on how long it will take for the prescribed medication to be delivered, to enable the patient to utilise the medicines appropriately and to provide general information about the prescribed medication. Contact with the patient is made via email, telephone, live chat via WhatsApp, video calls, leaflets & notes.
- 1.42 Prescription charges are made via 3 secure methods which are invoice bank transfer or by phone using a credit/debit card or for local deliveries via handheld mobile card machine. Exemptions from payments are clarified by:
- 1.42.1 Phoning patients and asking about the type of exemption, the card exemption number and the date of expiry;
- 1.42.2 Collecting their exemption type on the online nomination form they fill out;
- 1.42.3 Additionally, seeking evidence of the exemption where appropriate to do so (such as a photocopy of the exemption card); and also
- 1.42.4 Recording the exemption information given on the PMR system.
- 1.43 Emergency supplies are carried out at the request of the prescriber. The RP has to be satisfied that there is a genuine reason why a prescription cannot be immediately sent to the pharmacy. The Prescriber has to furnish a prescription within 72 hours & the medication is supplied according to the prescriber's instructions. Schedule 1, 2 & 3 medications cannot be requested. After the supply is made an entry into the prescriptions book stored on CD smart is made.
- 1.44 Where a prescribed medication is subject to a Serious Shortage Protocol or a request for supply is made in accordance with a Pandemic Treatment Protocol or LPiV, supplies are made in accordance with the relevant SSP or PTP/LPiV.

- 1.45 Where Serious Shortage Protocols (SSP) has been issued, medicines not available or in short supply by the manufacturer, the SPP is followed to provide an alternative under the protocol. The patient is contacted via telephone to ensure they understand the change and ensure the patient knows how to use their medicine correctly. The patient is also be informed [sic] of what to do if they experience any problems with the alternative medicine. Finally, the patients GP is also informed of any adjustments made under the SSP.
- 1.46 Owings of medicines are dealt with in line with SOP's. Where manufacturers cannot supply medicines, the patient is contacted and the PMR (patient medication record) updated with information of any owings. An owing note is attached to the delivery to ensure the patient is informed about the owing items and of the expected date of delivery.
- 1.47 Where long term supply issues are apparent, after exhausting all possibilities of obtaining a certain medicine, either the patient is informed to enable them to contact their GP or the pharmacy contacts the patient's GP on their behalf with informed consent from the patient, for an alternative. The option of using another pharmacy, which has the medicine in stock is also presented to the patient, and the prescription is returned to the patient if needed, or in the case of EPS release 2 tokens, the prescription is returned to the spine and the patient is informed of any details they need to obtain their medicines from the pharmacy of choice.

#### Repeat Dispensing

- 1.48 Repeat dispensing is provided according to the NHS Terms of Service.
- 1.49 Appropriate patients are identified (with regard to the Terms of Service) and advice is given about the benefits of this service via telephone, email, website or via the appropriate leaflets. Patients are reminded that they should only request items which they actually need.
- 1.50 Any dosette dispensing as may be required under the Equality Act, is done via consultation of patients, prescribers and carers via telephone or other non-face-to-face contacts.

#### Disposal of Unwanted Medicines

- 1.51 The disposal of unwanted medicine service is advertised on the pharmacy website and on the practice leaflet. Patients or their representatives cannot return any medicines directly to the pharmacy and the team follows the procedures set out in the SOPs to avoid any face-to-face contact.
- 1.52 To arrange the return of unwanted medicines to the Pharmacy the patient telephones and speaks to a member of the dispensary team. For controlled drugs this is always the pharmacist on duty.
- 1.53 Unwanted medicines from patients and residential homes are collected by the designated driver if local or via a tracked return service from Royal Mail via pre-paid packaging. Returns are then stored accordingly in containers provided by the approved waste disposal contractor, contracted by the local NHS England Team. The waste contractor (PHS) collects the unwanted medicines as per their procedure.
- 1.54 Return and destruction of Controlled drugs are carried out in accordance to the GPhC guidelines. Where waste is a controlled drug, this requires a Royal Mail pre-paid tracked signed for return service. The controlled items returned by the patient are then segregated from the rest of the controlled drugs, labelled "patient returned" and stored in the controlled drug cabinet until destroyed by an authorised witness and the responsible pharmacist. All CD returns are recorded on the CD destruction register and signed for in accordance with relevant SOPs.

- 1.55 Where the patient needs to return any sharps or clinical/contaminated waste they are informed of the local procedures for disposing of them. The pharmacy staff signpost the patient to the relevant services.

#### Signposting

- 1.56 Further help or advice beyond the pharmacy input is provided on the pharmacy website. This includes details of local and national health and social care organisations and any NHS England recommended groups to provide support to patients. Information is also provided via email and telephone.
- 1.57 Patients are signposted to other health and social care professionals where this is appropriate via telephone, email, letter and written literature, and information on the pharmacy website. The pharmacy's website will contain links to other health care providers & also an A-to-Z healthcare section.
- 1.58 Staff are trained to use the WWHAM questions effectively and the RP takes a full medical history of the patient through the means of telephone, web chat and email consultation. Those patients, who require further support which cannot be provided by the pharmacy, are appropriately referred using reliable resources such as NHS Direct or NHS Choices.

#### Promotion of Healthy Lifestyles (Public Health)

- 1.59 The provision of opportunistic health lifestyle is provided via telephone, writing/email or via the pharmacy website. There is pro-active participation and contribution to agreed national and local health campaigns. Leaflets and/or information packs is [sic] sent via the dispensed medicine bags or delivered per patient request. Social media campaigns on the pharmacy social media channels are also shared. Records are made of participating in health campaigns as required.
- 1.60 The pharmacy also pro-actively targets relevant patient groups with healthcare advice through prescription linked interventions. Records of interventions are made as required. Identification of patients takes place through three forms, namely, passive, active, or as part of the repeat (or normal) dispensing process. This is through the use of lifestyle questionnaires available via email or sent to the patient and returned by post, during interactions e.g. medicine sales or the repeat dispensing process which will indicate what conditions a patient suffers from.
- 1.61 All lifestyle intervention are recorded on the patients PMR including the information provided by the patient and the information given to the patient, as well as any written materials that have been provided. All lifestyle interactions, advice (and requests for advice) operate without face-to-face interaction (e.g. telephone, email, Skype, WhatsApp and via the website). Advice and help is available to patients during opening hours of the pharmacy and patients can access information on the Applicant's website at all times. This ensures the uninterrupted provision of services to patients across England.
- 1.62 Furthermore, there is regular staff training to enable all staff to give advice on healthy lifestyle campaigns using remote communication methods.

#### Discharge Medicines Service

- 1.63 The DMS SOP's include all the stages & regulations in detail. Referrals are made to the pharmacy via secure electronic message via PharmOutcomes. A notification email is sent to the pharmacy email address which is accessible by staff and is checked at least 3 times a day. Referrals are actioned within 72 hours of receipt. Consent is taken by the referring trust & patients can withdraw consent in any stage.
- 1.64 Stage 1 – Receipt of discharge referral



- 1.64.1 Patient details are checked, medicines on discharge are compared with admission via PMR & SCR. Any concerns are raised with the NHS trust & patient GP, notes are added to the PMR. Alerts are set to conduct stage 2 & 3 when the first prescription or contact is received. Any previous prescriptions are returned to spine if not appropriate for supply.
- 1.65 Stage 2 – Receipt of first prescription following discharge
- 1.65.1 Pharmacist compared the discharge referral with the post discharge prescription to ensure no discrepancy. If one is found a referral is made to the GP to resolve any issue and records are made on the PMR. If consent is revoked in either stage 2/3/prescriptions are not received or no contact is made with the patient after a reasonable number of attempts, concerns are relayed to the GP.
- 1.66 Stage 3 – Shared decision making discussion with patient
- 1.66.1 Patient knowledge of what medication they are taking & how they are supposed to be taking is checked, any gaps in knowledge are filled with advice. The conversation is confidential & provided via phone/video consultation. The patients PMR is updated & with the patients consent any information of value is shared with the GP/PCN to support the patients on going care. Patient is also offered the return service for any unwanted medicines & also the NMS service if relevant.
- 1.67 The SOP also deals with issues such as patients moving community pharmacies after stage 1, temporary closures and record keeping & payment. At the end of each month, for each DMS provision a report of standard dataset is submitted via MYS for payment.

#### Support for Self-Care

- 1.68 Patients are provided with advice and support to help them look after their own health, especially on managing minor ailments, common conditions and long-term conditions. Appropriate advice on OTC medicine usage is provided via the website. Telephone, email & video call consultation is also available. Appropriate records are kept as required.

#### Clinical Governance

- 1.69 CG requirements cover a range of quality related issues, which are complied with.
- 1.70 This includes, clinical audits, compliance with Standard Operating Procedures, near miss records, patient safety incidents and drug recalls.
- 1.71 Patients are able to provide feedback for the services via an online or paper questionnaire survey (sent via the driver and post).
- 1.72 Practice leaflets are also available on the website which contain information approved by the Department of Health and provide information of the details required. Nothing in the pharmacy's practice leaflet or other material published by the pharmacy represents (either expressly or impliedly) that essential services are only available in particular areas of England or that the pharmacy is likely to refuse to provide prescribed medication by reference to particular categories of patients.

#### Information Governance

- 1.73 All patient data is kept private and confidential in accordance with the NHS obligations including GDPR.

#### Complaint Procedure

- 1.74 A complaints procedure is available in accordance with the GPhC and NHS requirements.
- 1.75 The procedure is available on the pharmacy website or can be emailed or delivered via the driver or post.

#### Compliance with GPhC guidance

- 1.76 In addition to the above the pharmacy complies with the March 2022 GPhC guidelines for distance selling pharmacies. This includes regular risk assessments and audits to ensure that the pharmacy continues to provide services safely and effectively and in accordance with current legislation, professional standards and guidance.
- 1.77 There is a robust accountability trail on all levels of pharmacy service provision.
- 1.78 A Responsible Pharmacist is onsite at all times and is accountable for the services provided. There are also clear lines of accountability for pharmacy staff members including the designated delivery driver, making sure the medicines are made up correctly and delivered to the correct patient.
- 1.79 Courier companies such as Royal Mail have been checked properly to make sure they are able to provide a safe and efficient service.
- 1.80 All this is already detailed in the Standard Operating Procedure.
- 1.81 For the pharmacy to provide a safe and efficient service, records are kept where appropriate using main stream safe, secure & approved service providers such as Pharm smart. The pharmacy IT equipment is used to keep record of issues such as selling of P medicines via delivery, risk assessments and reviews, staff accountability and training, patient consent, complaints and patient intervention. Records are kept as per NHS guidelines and legislations.
- 1.82 All staff are properly trained and competent to provide safe and efficient services. Apart from the relevant pharmacy training courses, training is provided about data protection, communication skills where non face to face contact is involved and on specialised equipment and technology. Staff are also trained on the Identity Verification and Authentication Standard for Digital Health and Care Services, to allow them to check that the patients receiving pharmacy services are who they claim to be.
- 1.83 The pharmacy premises are fit for the purpose of providing safe and efficient pharmacy services and meet the standards required by the GPhC.
- 1.84 The information provided about both the current premises and proposed premises and the services provided from them are honest and not misleading to the public. As with the Applicant's current premises the proposed premises are also closed to the public with controlled access via doors, locks & CCTV to prevent anyone unauthorised from entering.
- 1.85 Pharmacy medicines sold or supplied as well as dispensary services are provided via a website and application that is associated with the registered pharmacy. The information is clear, concise and provide all the relevant details required by the GPhC including the GPhC number, pharmacy details and registration status. All information is updated regularly as and when required.
- 1.86 Due to the risks associated with selling medicines over the internet, the pharmacy regularly assesses the suitability and timescale of the method of supply, dispatch and deliver of medicines, including controlled drugs and fridge items. Appropriate Courier services such as Royal mail tracked services, which can accommodate all requirements are used to deliver medication throughout England. Risk assessments are used to identify and manage all potential problems.

- 1.87 Due to the nature of non-face to face contact, all staff are provided training to make sure they can communicate any vital information clearly and effectively.
- 1.88 Patients are given clear and concise information regarding the choice available to them in using whichever pharmacy they want to provide a service for them. Informed consent is gained in order for this pharmacy to provide the services to them via the website and pharmacy leaflets. A record is kept of all consents received.
- 1.89 The equipment and facilities used are designed for the intended purpose of pharmacy service provision. Website and electronic communication are secure, maintained and serviced regularly. Maintenance logs are kept at all times. The pharmacy also complies with the necessary information provided by the NHS Data Security and Protection Toolkit.

## 2 The Decision

NHS England considered and decided to grant the application. The decision letter dated 20 December 2022 states:

[Any reference to 'Committee' is in relation to the Pharmaceutical Services Regulations Committee of NHS England and is not to be confused with the Committee of NHS Resolution.]

- 2.1 NHS England 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.

NHS England decision report

- 2.2 The Pharmaceutical Services Regulations Committee (PSRC) granted the application based on the following regulations and consideration.
- 2.3 This application was considered under Regulation 24(1) (a) (b) (c) (d) and (e), Regulation 24(2), Regulation 24(3a, b and c), Regulation 36, 37 and 65 for the No Significant Change Relocation and Regulation 25(2) (a) and (b), Regulation 31 and Regulation 64 – which sets out the specific conditions to be met by applications for Distance Selling Premises.
- 2.4 Regulation 31: The Committee noted that Regulation 31 does not apply as there are no other pharmacies at the same or adjacent premises.
- 2.5 Regulation 24(1)(a) is met as the Applicant identified that their patients fall into one patient group 'patients who access services other than at the premises' as none of the patients are accustomed to accessing pharmaceutical services by attending the premises, therefore, no patients would find the pharmacy significantly less accessible.
- 2.6 Regulation 24(1)(b) is satisfied. The Applicant has confirmed that they will provide the same opening hours and services at the proposed new premises as are provided at the existing premises and has confirmed that there will be no interruption to service provision.
- 2.7 Regulation 24(1)(c) is satisfied. Granting the application would not cause a significant detriment to the proper planning of services.
- 2.8 Regulations 24(1)(d) and (e) are met as the same services will be provided and there will be no interruption to services during the relocation.
- 2.9 Regulations 24(2) is not applicable. The pharmacy is not proposing to relocate outside the area of the HWB. [sic]

- 2.10 Regulations 24(3)(a) and (b) are not applicable. The individual criteria do not apply to this pharmacy as the Applicant does not intend to relocate outside a retail area or outside a primary care centre.
- 2.11 Regulations 24(3)(c) is not applicable to the application as the pharmacy has not relocated in the last 12 months.
- 2.12 Regulations 36 and 37 are not applicable as the premises are not within a controlled locality or within 1.6 km of one.
- 2.13 Regulation 65 is not applicable as NHS England will not be directing the pharmacy's opening hours.
- 2.14 Regulation 66 is not applicable as NHS England does not intend to direct further services to be provided.
- 2.15 This application was also considered under Regulation 25 (2)(a) & (b), Regulation 31 and Regulation 64 which sets out the specific conditions to be met by applications for Distance Selling Premises.
- 2.16 Regulation 31. The Committee noted that Regulation 31 does not apply, as there is no pharmacy at the same or adjacent premises to the proposed site, nor is there any suggestion that any of the nearby pharmacies are in any way connected with this application and the proposed premises are located in a business centre.
- 2.17 Regulation 25(2)(a) is met as no primary care provider with a patient list is present within the same premises as the proposed site.
- 2.18 Regulation 25(2)(b) is met as the applicant demonstrated how services will be provided remotely, and without interruption throughout the given opening hours.
- 2.19 Regulation 64 (detailed below) are met based on that fact that the applicant has provided assurance in the additional information that the specific conditions set out in Regulation 64 are met.

Distance selling premises: specific conditions of approval

- 2.20 As the application is in respect of distance selling premises, by virtue of regulation 64(3) of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended, if the Applicant is subsequently included in the pharmaceutical list for the area of Bradford Health and Wellbeing board in respect of the premise included in the application that inclusion will be subject to the following conditions:
  - 2.20.1 The Applicant must not offer to provide pharmaceutical services to persons who are present at (which includes in the vicinity of) the proposed premises;
  - 2.20.2 the means by which the applicant provides pharmaceutical services must be such that any person receiving those services does so otherwise than at the proposed premises;
  - 2.20.3 the proposed premises must not be on the same site or in the same building as the premises of a provider of primary medical services with a patient list;
  - 2.20.4 the pharmacy procedures for the premises must be such as to secure:
    - 2.20.4.1 the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services, and

- 2.20.4.2 the safe and effective provision of essential services without face to face contact between any person receiving the services, whether on their own or on someone else's behalf, and the applicant or the Applicant's staff; and
- 2.20.5 nothing in the applicant's practice leaflet, in the applicant's publicity material in respect of the proposed premises, in material published on behalf of the Applicant publicising services provided at or from the proposed premises or in any communication (written or oral) from the Applicant or the Applicant's staff to any person seeking the provision of essential services from the Applicant must represent, either expressly or impliedly, that:
- 2.20.5.1 the essential services provided at or from the premises are only available to persons in particular areas of England, or
- 2.20.5.2 the Applicant is likely to refuse, for reasons other than those provided for in the Applicant's terms of service, to provide drugs or appliances ordered on prescription forms or repeatable prescription forms which are presented by particular categories of patients (for example, because the availability of essential services from the Applicant is limited to other categories of patients)."
- 2.21 The Committee noted that regarding Regulation 24 (1)(b) granting the application would not result in a significant change to the arrangements that are in place for the provision of local pharmaceutical services. The Committee considered that there is no planned change to the services to be offered by the pharmacy, therefore, Regulation 24 (1)(c) is met. The Committee considered Regulations 24(1)(d & e) and confirmed these are met as the same services will be provided and there will be no interruption to services during the relocation. Regulation 24(2) is not applicable as the pharmacy will relocate within the area of the same HWB. [sic] Regulations 24(3)(a-c), 36 and 37 are not applicable.
- 2.22 In relation to DSP Regulations, the Committee noted Regulation 25 (2) (a) does not apply as no primary care provider with a patient list is present within the same premises as the proposed site. The Applicant has provided information in relation to the provision of Essential Services to persons anywhere in England who request those services. This provides assurances of how the applicant intends to meet their Terms of Service should the application be granted and meets Regulation 25(2)(b). The Committee was assured that the Applicant and Temple Bright LLP provided sufficient documentation to satisfy Regulation 64 and confirmed that Regulation 31 does not apply as there is no pharmacy at the same or adjacent premises to the proposed site nor is there any suggestion that any of the nearby pharmacies are in anyway connected with this application.
- 2.23 Decision: PSRC granted the application for a relocation to a neighbouring HWB area that does not result in a significant change on the grounds that the applicant has met the requirements set out in Regulation 25 and 64 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.
- 2.24 Appeal rights are granted to:
- Crossflatts Pharmacy.

### 3 The Appeal

In a letter dated 15 January 2023 addressed to NHS Resolution, Crossflatts Pharmacy appealed against NHS England's decision. The grounds of appeal are:

- 3.1 Crossflatts Pharmacy have been informed by NHS England that the above distance selling application has been approved and [I] wish to appeal this decision.

- 3.2 In the letter of objection to this application Crossflatts Pharmacy listed a number of reasons why the application should be refused. The NHS decision letter does not mention any of the objections raised. Instead, it simply says that they have received information from Temple Bright. Crossflatts Pharmacy have not seen any of this information and the NHS has not explained why the letter of objection was ignored.
- 3.3 Crossflatts Pharmacy has attached the original letter of objection as these points all remain valid.

Crossflatts Pharmacy letter to NHS England dated 29 September 2022

- 3.4 Crossflatts Pharmacy wish to object to this application and do not believe that the Applicant has provided enough information to show how they will provide safe and effective services to any person in England who requests them.
- 3.5 The Applicant has discussed some of their processes and procedures but have left out a lot of information.
- 3.6 The Applicant has provided little detail to enable NHS England to be satisfied that all essential service provision would be both safe and effective. Little information is provided about delivery of controlled drugs and instead they ask the NHS to look at a SOP about these deliveries but have not provided the SOP. It is the same for other areas where they say they have SOPs but have not provided them. How can NHS England consider SOPs that they do not have? It is the same for cold chain items where they say they have tested the packaging but have not provided any test results to review. Surely the pharmacy must send these test results to the NHS to review and not just say that they have them? Also the same for other area where they just say they will comply with the regulations but do not say how they will do this. [Emphasis provided by Crossflatts Pharmacy.]
- 3.7 The Applicant does not say what its procedure is when the pharmacist is absent or if they follow the GPhC guidance and limits for absence of the pharmacist.
- 3.8 Crossflatts Pharmacy also notes that the Applicant permits medicines to be left in what they describe as a “safe place”. This is not appropriate for medicines and NHS England should not approve an application that operates in this manner.
- 3.9 The information provided with this application appear to be copied from some other pharmacy as it does not seem to be related to this pharmacy in some places. For example the application says that the pharmacy sells medicines through the website and talks about the risks of doing this, but [timepharmacy.co.uk](http://timepharmacy.co.uk) does not sell medicines through its website.
- 3.10 Please keep [us] informed about this application.

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

This is a summary of representations received on the appeal.

- 4.1 HEALTHCARE TIME LIMITED (represented by TEMPLE BRIGHT LLP)
- 4.1.1 On behalf of the Applicant, the Applicant’s representative writes further to NHS Resolution’s letter of 6 February 2023 and in order to respond to an appeal by Crossflatts Pharmacy against a decision of NHS England to grant the above application.
- 4.1.2 By way of back [sic], the Applicant is currently included in the pharmaceutical list at the premises at 27 Newmarket Street, providing pharmaceutical services as a distance selling pharmacy (“the Pharmacy”).

- 4.1.3 The Pharmacy has been providing NHS pharmaceutical services in the distance selling context for several years. The Pharmacy originally opened in October 2016 when it was known as Olive Pharmacy Online. When the original pharmacy owner applied for inclusion in the pharmaceutical list, they provided sufficient information to satisfy NHS England that the regulatory test contained within regulation 25 was met and the application was, consequently, granted.
- 4.1.4 In November 2019, the Pharmacy was purchased by the Applicant and the trading name was changed to Time Pharmacy. Since that date, the Applicant has continued to provide NHS pharmaceutical services in the distance selling context.
- 4.1.5 It is of note that there has never been any complaint, whether from the NHS or from any patients, regarding the way in which pharmaceutical services are provided by the Applicant. In particular, there has never been any concern that the Pharmacy is failing to provide NHS services safely and effectively, without face-to-face contact, to patients anywhere in England throughout the Pharmacy's contractual opening hours.
- 4.1.6 It is submitted that this application should therefore be determined in the above context of a pharmacy which has been operating safely and effectively for many years and simply seeking to relocate the premises from which those services are provided.
- 4.1.7 In July 2022, the Applicant submitted an application to NHS England to relocate the Pharmacy to new premises in a neighbouring HWB's area. That application, which NHS Resolution will no doubt have obtained, included a 9-page document which details how the pharmacy provides each essential pharmaceutical service in the distance selling context.
- 4.1.8 The application was circulated to potentially interested parties and a response was received from only one pharmacy: Crossflatts Pharmacy. In its short letter of representations, Crossflatts Pharmacy stated that, in its opinion, the Applicant had "left out a lot of information". Crossflatts Pharmacy then stated that there was "little information" provided about the delivery of controlled drugs and the supply of medicines which are subject to cold chain measures.
- 4.1.9 On behalf of the Applicant, [I] responded to those representations by letter dated 8 November 2022. [I] attach a copy of that response for NHS Resolution's ease of reference.
- 4.1.10 In summary, [I] explained that the Applicant had detailed – sufficiently for the purposes of NHS England's determination of this relocation application and in the context of a pharmacy that had been providing services for many years – how the pharmacy currently provides (and would continue to provide) NHS essential pharmaceutical services safely and effectively in the distance selling context.
- 4.1.11 In relation to the supply of controlled drugs and cold chain products specifically, the Applicant comments as follows:
- 4.1.11.1 "In relation to the supply of controlled drugs, the information provided in the application form confirms that:
- 4.1.11.1.1 For deliveries within a 30-mile radius, controlled drugs are delivered by the pharmacy's delivery driver.
- 4.1.11.1.2 For deliveries outside the 30-mile radius, a Royal Mail tracked delivery service is used.

- 4.1.11.1.3 Medication is packed into discrete, high-quality polythene bags/flat cardboard boxes or cardboard boxes depending on the medication being supplied.
- 4.1.11.1.4 Controlled drug deliveries via Royal Mail allow for the patient to track the delivery and have direct control over delivery options, and this is also monitored and audited by the pharmacy to ensure that dispensed medication is successfully delivered.
- 4.1.11.1.5 Controlled drugs must be “signed for” on delivery.
- 4.1.11.1.6 Failed deliveries are held by Royal Mail and a re-delivery attempted.
- 4.1.11.2 This procedure is fully detailed in an SOP, but the information provided by the Applicant in its application form is sufficient to satisfy NHS England that controlled drugs will be supplied safely to a person present anywhere in England.”
- 4.1.12 For the avoidance of doubt, where controlled drugs are delivered by the local delivery driver (within a 30-mile radius of the Pharmacy), the delivery vehicle has a lockable safe in the boots [sic] of the car. The driver is instructed never to leave either the safe or the vehicle unlocked at any point during the delivery rounds.
- 4.1.13 In relation to cold chain deliveries, the Applicant’s response to NHS England provided as follows:
  - 4.1.13.1 “In relation to cold-chain products, the supporting information provided in the application form confirms that:
    - 4.1.13.1.1 For deliveries within a 30-mile radius, cold-chain products are delivered by the pharmacy’s delivery driver. Cold chain products are stored in the fridge until collection by the delivery driver and are then placed in a cool box within the delivery van which contains a calibrated thermometer. Local deliveries are pre-arranged with patients to ensure that someone will be present to receive the delivery and place it in their fridge, and cold chain deliveries are prioritised in the delivery schedule. Failed deliveries are returned to the pharmacy by the delivery driver.
    - 4.1.13.1.2 For deliveries outside the 30-mile radius, Royal Mail tracked 24 is used. Cold shipping packaging is used (WoolCool) which has been tested to ensure that the cold chain is maintained from the moment the product leaves the pharmacy fridge to delivery. Detailed product information for WoolCool, FAQs and accreditations/certifications can be viewed directly on the WoolCool website –<http://www.woolcool.com/pharmaceutical/>
    - 4.1.13.1.3 RM tracked 24 is fully trackable and traceable. Patients are contacted before the product is provided to Royal Mail to ensure that they will be available to receive the delivery and patients are reminded that the products must be placed within their own fridge immediately upon delivery.
    - 4.1.13.1.4 Cold chain deliveries via Royal Mail allow for the patient to track the delivery and have direct control over delivery options,



and this is also monitored and audited by the pharmacy to ensure that dispensed medication is successfully delivered.

4.1.13.1.5 If there is a failed delivery, patients can rearrange a further delivery within 24 hours as the wool cool packaging maintains the correct storage temperature for at least 72 hours (Pharmaceutical | Temperature Controlled Packaging for Pharma by Woolcool® Insulated Packaging). Failing that, the product will be returned to the pharmacy by Royal Mail.

4.1.13.2 As stated in my client's supporting information, it has never faced any failed delivery problems for either controlled drug or cold chain products as it communicates closely with patients who are kept fully informed about their delivery."

4.1.14 [I] also enclose, for NHS Resolution's information, further information from Woolcool in relation to its properties and use. [Appendix A provided for NHS Resolution's Committee]

4.1.15 In its representations to NHS England, Crossflatts Pharmacy also stated that the application form "does not say what their procedure is when the pharmacist is absent or if they follow the GPhC guidance and limits for absence of the pharmacist".

4.1.16 It should, of course, be assumed that any pharmacy complies with its legal obligations and any professional requirements unless there is evidence to the contrary (and there is no evidence to the contrary in this case). However, the Applicant in the response of 8 November 2022, confirmed that "there is a responsible pharmacist present and signed in during the pharmacy's contracted opening hours thus ensuring that pharmaceutical services are available throughout the pharmacy's opening hours".

4.1.17 For the avoidance of doubt, the superintendent pharmacist, Mr [NS], is also the regular responsible pharmacist and works in the Pharmacy on a full-time basis (i.e. for the whole of the pharmacy's contractual hours of opening). Where necessary locum cover is arranged through the Applicant's extensive network of trusted pharmacist colleagues and through locum agencies. This ensures that the Pharmacy always has a responsible pharmacist signed in and present during its contracted opening hours. Locums are given instruction and training via shared SOP access prior to their shift. There is also a locum folder in the pharmacy which details all of the pharmacy's procedures to ensure effective cover is in place. All staff involved in the delivery of NHS services (including the DMS) are therefore appropriately trained and qualified for their roles.

4.1.18 Finally, Crossflatts Pharmacy questioned whether medicines are permitted to be left in a "safe place" by the delivery driver/Royal Mail. As stated in the Applicant's response of 8 November, it is not accepted that medicines cannot be left in a "safe place" (for example, an enclosed porch) if this is done with the explicit consent of patients (except in relation to cold chain and controlled drugs medicines which require an adult to accept and sign for the delivery). The Applicant understands that this is common practice in the industry.

4.1.19 Prior to delivery, patients are asked to confirm that there are no pets or children who may access medicines posted through the letterbox. If the patient is concerned about this, alternative delivery arrangements can be made (for example, delivery to a neighbour or workplace). As NHS Resolution will be aware, medicines are commonly delivered through the patient's letter box without the patient being there to accept delivery.

- 4.1.20 The information provided by the Applicant in support of its application was carefully considered by NHS England. NHS England concluded that the Applicant had provided sufficient information to satisfy it that the requirements of the relevant regulatory test were met, including that the information “provides assurances of how the Applicant intends to meet their Terms of Service should the application be granted”.
- 4.1.21 In its letter of appeal, Crossflatts Pharmacy does not provide any information which was not available to NHS England when it determined – and granted – the Applicant’s application.
- 4.1.22 Crossflatts Pharmacy relies on submissions that it made to NHS England in response to the application but, for the reasons given above and those given in the application form and letter of 8 November 2022, it is submitted that the application does fully satisfy the regulatory test.
- 4.1.23 On behalf of the Applicant, [I] therefore invite NHS Resolution to dismiss this appeal and to uphold NHS England’s decision and to grant the Applicant’s application for relocation.

#### LETTER TO NHS ENGLAND DATED 8 NOVEMBER 2022

- 4.1.24 Temple Bright LLP act for the Applicant. On behalf of the Applicant, the Applicant’s representative writes further to your letter of 31 October 2022 and in order to respond to representations from interested parties.
- 4.1.25 Taking each letter in turn, the Applicant comments as follows:
- Crossflatts Pharmacy
- 4.1.26 As a starting point, NHS England will no doubt have regard to the fact that the Applicant’s pharmacy is already included in the HWB’s pharmaceutical list and has been providing pharmaceutical services safely and effectively and without complaint for many years. The supporting information provided by the Applicant in its application form is therefore given against the background of a distance selling pharmacy that is already providing services.
- 4.1.27 As NHS England will be aware, the regulations do not require an applicant to provide copies of the SOPs themselves (although these can be provided should NHS England wish to see them). The supporting information provided in the application is sufficient to satisfy NHS England that the regulatory test is met.
- 4.1.28 Crossflatts Pharmacy state that the information provided by the Applicant has “left out a lot of information”, but then only refers to the delivery of CDs and cold chain products.
- 4.1.29 In relation to the supply of controlled drugs, the information provided in the application form confirms that:
- 4.1.29.1 For deliveries within a 30-mile radius, controlled drugs are delivered by the pharmacy’s delivery driver.
- 4.1.29.2 For deliveries outside the 30-mile radius, a Royal Mail tracked delivery service is used.
- 4.1.29.3 Medication is packed into discrete, high-quality polythene bags/flat cardboard boxes or cardboard boxes depending on the medication being supplied.

- 4.1.29.4 Controlled drug deliveries via Royal Mail allow for the patient to track the delivery and have direct control over delivery options, and this is also monitored and audited by the pharmacy to ensure that dispensed medication is successfully delivered.
- 4.1.29.5 Controlled drugs must be “signed for” on delivery.
- 4.1.29.6 Failed deliveries are held by Royal Mail and a re-delivery attempted.
- 4.1.30 This procedure is fully detailed in an SOP, but the information provided by the Applicant in its application form is sufficient to satisfy NHS England that controlled drugs will be supplied safely to a person present anywhere in England.
- 4.1.31 In relation to cold-chain products, the supporting information provided in the application form confirms that:
- 4.1.31.1 For deliveries within a 30-mile radius, cold-chain products are delivered by the pharmacy’s delivery driver.
- 4.1.31.2 Cold chain products are stored in the fridge until collection by the delivery driver and are then placed in a cool box within the delivery van which contains a calibrated thermometer. Local deliveries are pre-arranged with patients to ensure that someone will be present to receive the delivery and place it in their fridge, and cold chain deliveries are prioritised in the delivery schedule. Failed deliveries are returned to the pharmacy by the delivery driver.
- 4.1.31.3 For deliveries outside the 30-mile radius, Royal Mail tracked 24 is used. Cold shipping packaging is used (WoolCool) which has been tested to ensure that the cold chain is maintained from the moment the product leaves the pharmacy fridge to delivery. Detailed product information for WoolCool, FAQs and accreditations/certifications can be viewed directly on the WoolCool website – [www.woolcool.com/pharmaceutical/](http://www.woolcool.com/pharmaceutical/)
- 4.1.31.4 RM tracked 24 is fully trackable and traceable. Patients are contacted before the product is provided to Royal Mail to ensure that they will be available to receive the delivery and patients are reminded that the products must be placed within their own fridge immediately upon delivery.
- 4.1.31.5 Cold chain deliveries via Royal Mail allow for the patient to track the delivery and have direct control over delivery options, and this is also monitored and audited by the pharmacy to ensure that dispensed medication is successfully delivered.
- 4.1.31.6 If there is a failed delivery, patients can rearrange a further delivery within 24 hours as the wool cool packaging maintains the correct storage temperature for at least 72 hours ([Pharmaceutical | Temperature Controlled Packaging for Pharma by Woolcool® Insulated Packaging](#)). Failing that, the product will be returned to the pharmacy by Royal Mail.
- 4.1.32 As stated in the Applicant’s supporting information, it has never faced any failed delivery problems for either controlled drug or cold chain products as it communicates closely with patients who are kept fully informed about their delivery.

- 4.1.33 In relation to the absence of a pharmacist, there is a responsible pharmacist present and signed in during the pharmacy's contracted opening hours thus ensuring that pharmaceutical services are available throughout the pharmacy's opening hours.
- 4.1.34 It is not accepted that medicines cannot be left in a "safe place" if this is done with the explicit consent of patients (except in relation to cold chain and controlled drugs medicines which require an adult to accept and sign for the delivery). As NHS England will be aware, medicines are commonly delivered through the patient's letter box without the patient being there to accept delivery.
- 4.1.35 It is denied that the information provided by the Applicant has been "copied from some other pharmacy". The information specifically relates to how the Applicant's pharmacy operates.
- 4.1.36 The sale of over the counter products by the Applicant (if any) is not an NHS service so is irrelevant to NHS England's determination of this application. The Applicant's website meets the requirements for the provision of NHS services via a distance selling pharmacy.

North Yorkshire LPC

- 4.1.37 It is noted that the LPC has no objection to the relocation application.

West Yorkshire LPC

- 4.1.38 In relation to the pharmacy's prescription data, as NHS England will be aware a distance selling pharmacy is only required to demonstrate how pharmacy services would be provided to patients throughout England. The Applicant has no control over where patients actually live and which patients choose to access its pharmacy.
- 4.1.39 Regarding the comments from the LPC in relation to the Applicant's website, the screenshots provided by the LPC are not taken from the Applicant's website. The Applicant operates the website "timepharmacy.co.uk" with the trading name "Time Pharmacy" whereas the website extracts contained within the LPC letter appear to relate to another pharmacy "Todmorden Pharmacy". It therefore appears that the LPC is mistaken in relation to the layout and presentation of information on my client's website which may have materially affected the submissions that the LPC makes.
- 4.1.40 For the avoidance of doubt, in relation to the return of unwanted medicines there is no terms of service requirement that this information must be displayed on a distance selling pharmacy's website. However, the pharmacy's website does contain information about how to organise the return of medicines ([Delivery and Returns - Time Pharmacy](#)). The website confirms that patients cannot return medicines to the pharmacy in-person but should contact the pharmacy via phone or email to arrange collection of unwanted medicines.
- 4.1.41 The pharmacy's website contains a range of resources and information in relation to public health ([Health Promotion Zone - Time Pharmacy](#)). NHS England may, of course, request records held by the pharmacy in relation to the provision of any essential service, including participation in public health campaigns, as part of its contract monitoring powers.
- 4.1.42 It is of note that the LPC supports the Applicant's application.

LMC

4.1.43 It is of note that the LMC has no comments to make on the Applicant's application.

4.1.44 [I] hope that the above assists NHS England in its determination of this application and look forward to hearing from you in due course.

## 4.2 NHS ENGLAND

[Any reference to Committee in this section refers to the NHS England Pharmaceutical Services Regulations Committee and should not be confused with the Committee of NHS Resolution.]

4.2.1 Thank you for allowing NHS England the opportunity to provide representation in relation to the above appeal, [we] would like to take this opportunity to make comment on the information provided by Crossflatts Pharmacy as part of the appeal.

4.2.2 NHS England approved the application for No Significant Change Relocation to a Neighbouring HWB area that does not result in a significant change from 27 Newmarket St, Skipton, BD23 2JE to Unit 6, Crown Works, Bradford Rd, Sandbeds, Keighley, BD20 5LN on the grounds that the Applicant had demonstrated that it would comply with Regulation 24, Regulation 31 and Regulation 64 – which set out the specific conditions to be met by application for Distance Selling Premises of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.

4.2.3 NHS England will respond to the points raised in Crossflatts Pharmacy's letter dated 15 January 2023.

4.2.4 Crossflatts Pharmacy states that they had provided representations in a letter dated 29 September 2022 which included several objection to the application and that the decision letter from NHS England does not mention any of [sic] objections made by them. NHS England recognises that the decision letter should have contained information about the consideration of all the objections raised through the representations carried out by the Pharmaceutical Services Regulation Committee (PSRC).

4.2.5 As per the minutes of the PSRC held 30 November 2022, the committee considered all the objection provided by Crossflatts Pharmacy in its original representations. The Committee noted that Crossflatts Pharmacy had made comments that were in relation to the Standard Operating Procedures (SOPs), the delivery of controlled drugs and cold chain items, the medicines left in a 'safe place' and the procedure when the pharmacist is absent.

4.2.6 The committee noted that, no SOPs had been submitted by the Applicant, but that assurance had been given in the supporting information to the application that all existing SOPs will remain in place and that there is no regulatory requirement for the contractor to provide the SOPs as part of this application.

4.2.7 In relation to the delivery of controlled drugs and cold chain items, the medicines left in a 'safe place' and the procedure when the pharmacist is absent, these concerned were considered and responded to be the Applicant's advisor during the 14 day additional representation and the committee felt that the response provided gave assurance on all the objection raised by Crossflatts Pharmacy.

4.2.8 NHS England have nothing further to add, the application was approved on the grounds that the Applicant had demonstrated in the application and additional information provided, that they would comply with Regulation 25(2)(a) and (b), Regulation 31 and Regulation 64 – which sets out the specific conditions to be

met by applications for Distance Selling Premises of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.

4.2.9 Based on the original application and information provided at the time NHS England is still satisfied that the correct decision was reached in relation to the this application and would therefore ask that the appeal be dismissed.

#### 4.3 COMMUNITY PHARMACY WEST YORKSHIRE

4.3.1 CPWY members still feel that the comments made in the letter to NHS England on 27 October 2022 are valid. These were as follows.

4.3.2 CPWY members would like to make the following observations:

4.3.2.1 Paragraph 1 of Schedule 2 has been met.

4.3.2.2 This application does not appear to breach regulation 31.

4.3.3 And the following comments:

4.3.4 With regards Regulation 24

4.3.4.1 Members did not believe that this relocation would significantly alter the accessibility of pharmaceutical services.

4.3.4.2 Members felt that it was unlikely that granting this application would cause significant changes to the arrangements that are in place for the provision of pharmaceutical services or significant detriment to the proper planning of the provision of pharmaceutical services.

4.3.4.3 The proposed services appear to be the same as those provided at the current premises.

4.3.5 Members noted that as a distance selling pharmacy patients would be accessing essential services remotely and therefore a change in location should not affect access to pharmaceutical services for current patient groups using the pharmacy and therefore the location of the new premises would not be significantly less accessible.

4.3.6 Members noted that the vast majority of pharmacy prescription data shows that prescription dispensed by the pharmacy are all geographically within the Skipton and Keithley [sic] vicinity. This brought into question if the pharmacy provides only local deliveries rather than a national service.

4.3.7 Members noted that the pharmacy website did not contain any information to waste medicines and how these could be returned to the pharmacy for safe disposal. The website section on health promotion only contained links. For current campaigns the website simply had a link to the PHE campaign resource centre, a website for health professionals not patients. Additionally, the lifestyle survey directs patients to a private clinic rather than NHS advice. CPWY were not assured that the pharmacy meets the requirements for a HLP (no healthy living information in the health action zone) or for the essential service: public health.

4.3.8 Members supported the granting of this application.

4.3.9 Members wish these comments to be taken into consideration by NHS Resolution and wish to be notified of the decision.

## 5 Observations on representations

### 5.1 HEALTHCARE TIME LIMITED (represented by TEMPLE BRIGHT LLP)

- 5.1.1 In relation to the letter received from Community Pharmacy West Yorkshire, the Applicant's representative knows that NHS Resolution will have obtained, from NHS England, a copy of the Applicant's response to the previous representations from CPWY. Those previous comments address the matters raised in the letter from CPWY dated 9 February 2023 but, for NHS Resolution's convenience, the Applicant's representative has copied the relevant response below:
- 5.1.2 In relation to the pharmacy's prescription data, as NHS England will be aware a distance selling pharmacy is only required to demonstrate how pharmacy services would be provided to patients throughout England. The Applicant has no control over where patients actually live and which patients choose to access its pharmacy.
- 5.1.3 Regarding the comments from the LPC in relation to the Applicant's website, the screenshots provided by the LPC are not taken from the Applicant's website. The Applicant operates the website "timepharmacy.co.uk" with the trading name "Time Pharmacy" whereas the website extracts contained within the LPC letter appear to relate to another pharmacy "Todmorden Pharmacy". It therefore appears that the LPC is mistaken in relation to the layout and presentation of information on the Applicant's website which may have materially affected the submissions that the LPC makes.
- 5.1.4 For the avoidance of doubt, in relation to the return of unwanted medicines there is no terms of service requirement that this information must be displayed on a distance selling pharmacy's website. However, the pharmacy's website does contain information about how to organise the return of medicines (Delivery and Returns - Time Pharmacy). The website confirms that patients cannot return medicines to the pharmacy in-person but should contact the pharmacy via phone or email to arrange collection of unwanted medicines.
- 5.1.5 The pharmacy's website contains a range of resources and information in relation to public health (Health Promotion Zone - Time Pharmacy). NHS England may, of course, request records held by the pharmacy in relation to the provision of any essential service, including participation in public health campaigns, as part of its contract monitoring powers.
- 5.1.6 It is of note that the LPC supports the Applicant's application.
- 5.1.7 The Applicant has no comments to make in respect of the letter from NHS England save to note that NHS England maintains that, in its view, the regulatory test was made out by the Applicant in its application.
- 5.1.8 The Applicant's representative looks forward to hearing from NHS Resolution.

### 5.2 CROSSFLATTS PHARMACY

- 5.2.1 Crossflatts Pharmacy wish to object to this application because it does not believe that the Applicant has provided enough information to show how they will provide safe and effective services to any person in England who requests them.
- 5.2.2 The Applicant's representative has provided some additional information about a small number of essential services but has still not provided any SOPs even though they refer to them.

- 5.2.3 The Applicant says that the application should be considered and determined in the context of a pharmacy which has been operating safely and effectively for many years and simply seeking to relocate the premises from which those services are provided. However, the advice Crossflatts Pharmacy have received is that the application must be properly reassessed to ensure it can provide safe and effective services to any patient in England who requests them and that it is the Applicant who has the responsibility for proving this.
- 5.2.4 The Applicant has discussed some of their processes and procedures but continues to leave out a lot of information. There is still no information about what packaging is to be used when the pharmacy's delivery driver delivers cold chain items and a thermometer in a "cool box" is not safe. In this initial information that the Applicant provided it referred to this box as a "polystyrene cool box". Adding ice packs does not make this safe as the medicine can freeze and then warm up again in transit without the driver ever knowing.
- 5.2.5 The information provided with this application appears to be copied from some other pharmacy as it does not seem to be related to this pharmacy in some places. For example, the application says that the pharmacy sells medicines through the website and talks about the risks of doing this, but [timepharmacy.co.uk](http://timepharmacy.co.uk) does not sell medicines through their website.
- 5.2.6 Crossflatts Pharmacy remain very concerned about the idea of leaving medicines in a "safe place" which could also be outside a property. It is the responsibility of the pharmacy to make sure the delivery process is safe, but with Royal Mail it is the patient who chooses what is "safe".
- 5.2.7 Please keep Crossflatts Pharmacy informed about this application.

## 6 Consideration

- 6.1 The Pharmacy Appeals Committee ("Committee") appointed by NHS Resolution had before it the papers considered by NHS England, together with a plan of the area showing existing pharmacies and doctors' surgeries and the location of the proposed pharmacy.
- 6.2 It also had before it the responses to NHS Resolution's own statutory consultations.
- 6.3 Since 1 April 2023 Integrated Care Boards have taken on delegated responsibility for the commissioning of pharmaceutical services. NHS Resolution will issue this decision to NHS England and it is for NHS England to inform the relevant Integrated Care Board.
- 6.4 On the basis of this information, the Committee considered it was not necessary to hold an Oral Hearing.
- 6.5 The Committee had regard to the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 ("the Regulations").
- 6.6 The Committee first considered Regulation 31 of the Regulations which states:
- (1) A routine or excepted application, other than a consolidation application, must be refused where paragraph (2) applies.*
- (2) This paragraph applies where -*
- (a) a person on the pharmaceutical list (which may or may not be the applicant) is providing or has undertaken to provide pharmaceutical services ("the existing services") from -*
- (i) the premises to which the application relates, or*



*(ii) adjacent premises; and*

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

- 6.7 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. In its decision letter, NHS England confirmed that the application did not need to be refused with regard to Regulation 31 and this has not been disputed by any party. The Committee therefore determined that it was not required to refuse the application under the provisions of Regulation 31.

#### **Regulation 24(2)**

- 6.8 The Committee noted that the application form states that the Applicant's current premises is located in the North Yorkshire HWB area. The Applicant is proposing to relocate to premises located within the neighbouring Bradford HWB area. Therefore the Committee considered the application in accordance with Regulation 24(2) which states:

*(2) Section 129(2A) of the 2006 Act does not apply to an application from a person already included in a pharmaceutical list for the area of a HWB (HWB2) for inclusion in the pharmaceutical list for the area of a neighbouring HWB (HWB3), or inclusion in the pharmaceutical list for the area of HWB3 also in respect of other premises than those already listed in relation to that person, if—*

*(a) the purpose of the application is to relocate to different premises;*

*(b) for the patient groups that are accustomed to accessing pharmaceutical services at the existing premises (P1), the location of the new premises (P2) is not significantly less accessible;*

*(c) in the opinion of the NHSCB, granting the application would not result in a significant change to the arrangements that are in place for the provision of local pharmaceutical services or of pharmaceutical services other than those provided by a person on a dispensing doctor list—*

*(i) in any part of HWB3's area, or*

*(ii) in a controlled locality in the area of a neighbouring HWB (including HWB2), where that controlled locality is within 1.6 kilometres of P2;*

*(d) the NHSCB is not of the opinion that granting the application would cause significant detriment to proper planning in respect of the provision of pharmaceutical services in the area of HWB3;*

*(e) the services the applicant undertakes to provide at P2 are the same as the services the applicant has been providing at P1 (whether or not, in the case of enhanced services, the NHSCB chooses to commission them);*

*(f) the provision of pharmaceutical services will not be interrupted (except for such period as the NHSCB may for good cause allow); and*

*(g) the applicant consents to—*

*(i) where the applicant has only one set of listed chemist premises in the pharmaceutical list for the area of HWB2, the removal of the applicant's name from that pharmaceutical list, or*

*(ii) where the applicant has more than one set of listed chemist premises in the pharmaceutical list for the area of HWB2, the removal of P1 from being listed in relation to the applicant in that pharmaceutical list,*

*with effect from the date on which the applicant undertakes to provide pharmaceutical services from P2.*

**Regulation 24(2)(a) & (b)**

- 6.9 The Committee noted that the Applicant is applying to relocate to different premises.
- 6.10 The Committee noted that, in its decision letter, NHS England state that the Applicant identified its patients as falling into “*one patient group ‘patients who access services other than at the premises’ as none of the patients are accustomed to accessing pharmaceutical services by attending the premises, therefore, no patients would find the pharmacy significantly less accessible.*” The Committee noted that this had not been disputed on appeal or in subsequent representations.
- 6.11 The Committee noted that the Applicant provides the NMS service remotely. In its application form, the Applicant states that the current premises does not have room for a consultation room and that the NMS service is provided remotely via non face-to-face contact, which the Committee noted had not been disputed. The Committee was therefore of the view that no issue arose as the NMS service is being accessed remotely rather than at the existing premises.
- 6.12 The Committee was therefore of the view that the conditions in Regulation 24(2)(a) & (b) are met.

**Regulation 24(2)(c)**

- 6.13 In its decision letter, NHS England states that “granting the application would not result in a significant change to the arrangements that are in place for the provision of local pharmaceutical services... there is no planned change to the services to be offered by the pharmacy”. The Committee noted that this had not been disputed by any party either on appeal or in subsequent representations.
- 6.14 Therefore, on the information provided, the Committee was of the opinion that the granting of the application would not result in a significant change to the arrangements that are in place for the provision of local pharmaceutical services or of pharmaceutical services other than those provided by a person on a dispensing doctor list in any part of Bradford HWB's area or in a controlled locality of a neighbouring HWB (including the North Yorkshire HWB area), where that controlled locality is within 1.6 kilometres of the proposed premises. The Committee therefore concluded that the condition in Regulation 24(2)(c) is met.

**Regulation 24(2)(d)**

- 6.15 In its decision letter, NHS England states that “granting the application would not cause a significant detriment to the proper planning of services” which has not been disputed by any party.

- 6.16 On the information provided the Committee was not of the opinion that granting the application would cause significant detriment to proper planning in respect of the provision of pharmaceutical services in the Bradford HWB area and therefore concluded that Regulation 24(2)(d) is met.

**Regulation 24(2)(e)**

- 6.17 The Committee noted that the Applicant had given an undertaking in the application for that the same services would be provided at the proposed premises as it currently provides at its existing premises. On the information provided, the Committee therefore determined that the condition in Regulation 24(2)(e) is met.

**Regulation 24(2)(f)**

- 6.18 In relation to Regulation 24(2)(f), the Committee noted that the Applicant had confirmed in its application and subsequent representations that there will be no interruption to service provision by the relocation to the new premises. On the information provided the Committee therefore determined that the condition in Regulation 24(2)(f) is met.

**Regulation 24(2)(g)**

- 6.19 The Committee noted that NHS England, in its decision letter, did not produce any finding against the conditions set out in Regulation 24(2)(g).
- 6.20 The Committee did note, however, that the Applicant in its application form has ticked the relevant box to consent to the removal of its name from NHS England's pharmaceutical list in respect of the North Yorkshire HWB area should the application be approved and the pharmacy included in the pharmaceutical list for the Bradford HWB area. The Committee further noted that this had not been disputed by any party, therefore, based on the information provided it is determined that the condition set out in Regulation 24(2)(g) is met.

**Regulation 24(3)(d)**

- 6.21 The Committee noted that the application is for the relocation of a distance selling pharmacy.

- 6.22 The Committee therefore needed to have regard to Regulation 24(3)(d) which states:

*(3) An application pursuant to this regulation must be refused if the existing pharmacy premises from which the applicant is seeking to relocate (P3) –*

*(d) are distance selling premises, unless –*

*(i) the premises to which the applicant is seeking to relocate are also distance selling premises, and*

*(ii) if the application was one to which regulation 25(2) applied, it would not be refused pursuant to regulation 25(2).*

- 6.23 In relation to Regulation 24(3)(d)(i), the Committee noted that Applicant at paragraph 9.1 of the application form has ticked the box "Yes" in answer to the question "Are you applying for a relocation to distance selling premises?". The Committee was satisfied that the Applicant's current premises and the premises to which the Applicant is seeking to relocate are both distance selling premises.

- 6.24 In relation to Regulation 24(3)(d)(ii), the Committee had regard to Regulation 25, which states:

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

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

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

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

(a) if the premises in respect of which the application is made are on the same site or in the same building as the premises of a provider of primary medical services with a patient list; and 13 (b) unless the NHSCB is satisfied that the pharmacy procedures for the pharmacy premises are likely to secure—

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

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

6.25 The Committee also had regard to the provisions of Schedule 2 to the Regulations show below:

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

(a) A's belief that the application satisfies the criteria included in one of the regulations in Part 4 which need to be satisfied if section 129(2A) and (2B) of the 2006 Act (regulations as to pharmaceutical services) are not to apply in relation to that application; and

(b) if the regulation includes reasons for which the application must be refused, why the application should not be refused for those reasons.

*Nature of details to be supplied*

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

### **Regulation 25(1)**

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

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

- 6.27 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. NHS England, in its decision, determined that the application did not need to be refused on the basis on Regulation 25(2)(a) and this was not disputed by any party either on appeal or subsequent representations.
- 6.28 Based on the information available to it, the Committee therefore determined that the proposed premises were not on the same site as, or in the same building as the premises of a provider of primary medical services with a patient list.

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

- 6.29 The Committee noted the comments from the Applicant's representative with regard to the length of service which the pharmacy had operated at the current address and the lack of complaints received about the service currently offered. The Committee acknowledged the suggestion from the representative that it should therefore determine the application as a pharmacy that is looking to relocate a current service rather than a new application, however the Committee was of the view that to do so would not be in line with the Regulations. The Committee proceeded to determine the application in accordance with Regulation 25(2)(b).
- 6.30 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 current procedures for the provision of essential services.
- 6.31 The Regulations require the Committee to be satisfied as to a number of matters, including that essential services will be provided on an uninterrupted basis, in a safe and effective way, across England, and without face to face contact.
- 6.32 Paragraph 8 of Schedule 2 requires an applicant to provide details in relation to an application, and paragraph 10 of Schedule 2 indicate that the obligation is only discharged if the information or documentation provided is sufficient to satisfy NHS England in receipt of it, with good cause, that no relevant information or documentation is missing, having regard to the uses that NHS England may need to make of the information or documentation when carrying out its functions.
- 6.33 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, the evidence put forward has taken the form of the original application and the representations on the appeal which the Applicant has prepared.
- 6.34 The Committee noted in the application form it states:
- 6.34.1 *"A Responsible Pharmacist is present and in charge during the core opening hours of the premises to ensure there is uninterrupted provision of essential services to patients who live anywhere in England who require and request the essential services."*
- 6.35 The Committee noted the application form states "2 supporting pharmacy staff are currently employed; if and when required, more staff will be hired to aid the Responsible Pharmacist in his/her role of uninterrupted provision". The Committee further noted that the application form states:

- 6.35.1 *“Where necessary locum cover is arranged through the Applicant’s extensive network of pharmacist colleagues and through locum agencies. This ensures that the Pharmacy always has a responsible pharmacist signed in and present during its contracted opening hours. Locums are given instruction and training via shared SOP access prior to their shift. There is also a locum folder in the pharmacy which details all of the pharmacy’s procedures to ensure effective cover is in place.”*
- 6.36 Therefore the Committee was satisfied, that the provision of services would be without interruption.
- 6.37 The Committee noted in the application form it states:
- 6.37.1 *“The pharmacy will continue to provide essential services to any persons in England without face-to-face contact through the use of suppliers, couriers and service providers which are approved and operate in accordance to all regulations including cold chain and controlled drug requirements and also satisfy the SOP’s and requirements of the pharmacy.”*
- 6.38 The Committee also noted that the application form goes on to state:
- 6.38.1 *“All dispensed items are delivered by a courier service or by a designated staff member to ensure delivery to patients anywhere in England.”*
- 6.39 The Applicant refers throughout the information provided to the provision of services to all of England, using Royal Mail tracked 24/48 or a local delivery driver for deliveries within a 30 mile radius to the proposed premises.
- 6.40 The Committee was therefore satisfied that the provision of services would be available to persons anywhere in England.
- 6.41 The Committee noted that in the application form, it states:
- 6.41.1 *“Procedures are in place to ensure the Responsible Pharmacist can consult and advise appropriately if the need arises, with the condition of non-face-to-face contact. This will include, where necessary, advising the patient on how long it will take for the prescribed medication to be delivered, to enable the patient to utilise the medicines appropriately and to provide general information about the prescribed medication. Contact with the patient is made via email, telephone, live chat via WhatsApp, video calls, leaflets & notes.”*
- 6.42 The Committee was aware that when the pharmacy opens, it will be the responsibility of NHS England, in keeping with Regulation 64, to ensure that services are provided other than with face to face contact.
- 6.43 Based on the information provided, the Committee was satisfied that the provision of services would be without face-to-face contact.
- 6.44 The Committee went on to consider whether safe and effective provision of essential services was likely to be secured.
- 6.45 The Committee considered each essential service in paragraphs 3 to 22 of schedule 4 of the Regulations (“Terms of Service”) in turn.
- 6.46 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:
- 6.46.1 Dispensing of drugs and appliances;

- 6.46.2 Urgent supply without a prescription;
- 6.46.3 Preliminary matters before providing ordered drugs or appliances;
- 6.46.4 Providing ordered drugs or appliances;
- 6.46.5 Refusal to provide drugs or appliances ordered;
- 6.46.6 Further activities to be carried out in connection with the provision of dispensing services;
- 6.46.7 Disposal service in respect of unwanted drug;
- 6.46.8 Promotion of healthy lifestyles;
- 6.46.9 Prescription linked intervention;
- 6.46.10 Health campaigns;
- 6.46.11 Signposting;
- 6.46.12 Support for self-care;
- 6.46.13 Discharge medicines service; and
- 6.46.14 Websites and health promotion zones.

#### **Providing ordered drugs or appliances**

6.47 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).

6.48 The Committee noted that the application form states:

6.48.1 *"All dispensed items are delivered by a courier service or by a designated staff member to ensure delivery to patients anywhere in England. Deliveries comply with the GPhC guidelines of medicines delivery.*

*The SOP in regards to 'choice of delivery method' states, for local deliveries (up to 30-mile radius, but may be extended at the discretion of the RP) the delivery driver can deliver the medication. For local deliveries the delivery driver texts/emails the patients a definitive time period e.g. afternoon and date of delivery. The driver has access to the patient's delivery preferences as they are listed on the delivery label. If a patient has a safe place or request to leave with a neighbour set as a delivery preference, the Applicant tries its utmost to hour [sic] these preferences but make the patient fully aware that it may not be possible in certain circumstances such as delivery of controlled drugs.*

*Outside this area Royal Mail 24/48 is used, the medication is packaged into discreet high quality polythene bags/flat cardboard boxes in a large letter format for easy postage or into cardboard boxes for larger items like creams.*

*For Royal mail deliveries the staff text/email the patients advising how their medication has been packaged and what exact Royal Mail service their package has been dispatched with. Large letters can fit through letter boxes, parcels can be left with neighbours/safe places (not applicable to CD's) if patients are not in or re-deliveries/collections from depot can be organised via*

*Royal Mail website for a more appropriate date. Tracked Royal Mail services for Controlled drugs allow the patient to have direct control over delivery day, offer a time range & delivery preferences while allowing the pharmacy team to ensure that GPS data, signature & image evidence is obtained upon delivery.”*

6.49 The Committee noted that, in relation to deliveries for a controlled drug, the application form states:

6.49.1 *“If the prescription is for a controlled drug, either the delivery driver is used (for “local deliveries”) or a fully tracked service from Royal Mail known as RM tracked 24/48 service is used. This tracked service offers the patients the ability to track their package via email or text, gives them a delivery time range & allows them to choose the day of delivery. GPS, image & signature data would be checked by the pharmacy team after delivery to ensure that the patient has received the CD delivery. (Extensively covered by SOP for Delivery of Controlled Drugs).”*

6.50 The Committee noted that the Applicant confirmed in its representations that:

6.50.1 *“For avoidance of doubt, where controlled drugs are delivered by the local delivery driver (within a 30-mile radius of the Pharmacy), the delivery driver has a lockable safe in the boots [sic] of the car. The driver is instructed never to leave either the safe or the vehicle unlocked at any point during the delivery rounds.”*

6.51 The Committee noted that, in relation to cold chain deliveries, the application form states:

6.51.1 *“All cold chain deliveries are carried out in accordance with verified and approved cold chain procedures (Extensively covered under heading cold chain delivery by courier of SOP ‘Order Delivery’). Local cold chain deliveries involve the delivery driver adding the cold chain item to a polystyrene cool box which contains a calibrated thermometer. Ice packs are then added with cardboard blockers to ensure the temperature of the products remains between 2 and 8 degrees while delivering locally. As with all local deliveries the patient is informed via text/email of the date and time of day the delivery driver will be delivering. Particularly in regards to deliveries involving cold chain items the driver rings the patient to inform/confirm the estimated date and time of delivery before the medication is taken on the route to reduce the chance of delivery failure. In any case if the delivery fails the driver simply brings the medication back in the temperature controlled cool box and returns the items to the fridge & consequently re-organises delivery for a more convenient date/time with the patient.*

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

*For deliveries that are outside of the local delivery radius a combination of cold shipping packaging and RM tracked 24 is used. The Cold Shipping Package used currently is provided by ‘wool cool’ and is designed for customers that require a refrigerated environment of 2 – 8C for their shipments.*

*The packaging device maintain its exacting “cold ship” temperature requirements and has been extensively tested by both the pharmacy and manufacturer coupled with the appropriate delivery service (RM tracked 24) to ensure that timescales & temperatures are appropriate and any breach is detected by the pharmacy team who then promptly follow the failed delivery process.”*



6.52 The Committee noted that, in relation to unsuccessful deliveries, the application form states:

6.52.1 *"In the event of an unsuccessful delivery, Royal Mail will leave a 'Missed Delivery' card, stating the date and time of the attempted delivery. The patient can then rearrange the delivery conveniently by telephone or Internet, as long as it is within 24 hours. The patient also has the option to collect from the relevant depot within 24 hours. The packaging will keep the cold chain intent [sic] until successful re-delivery or collection as it can maintain the correct temperature for up to 72 hours in total.*

*This method is designed to give the patient maximum convenience whilst maintaining cold chain for up to 72 hours. However, in the event of any breach in the integrity of this service the patient is contacted and informed immediately to not use any product that might have been affected. The pharmacy then arranges for immediate re-delivery of the items via the same service and the return of the items that have failed to be delivered to the pharmacy by the Royal Mail tracked return service. Items subject to a cold chain breach are not re-used and are to be segregated from the pharmacy stock upon arrival at the pharmacy.*

*In the Applicant's operational existence, it has never faced a failed delivery due to the preparation, ability to communicate with the patient prior to delivery & valuing the patient's delivery preferences however the Applicant is fully prepared if ever faced with this situation.*

*Procedures are in place to ensure the Responsible Pharmacist can consult and advise appropriately if the need arises, with the condition of non-face-to-face contact. This include, where necessary, advising the patient on how long it will take for the prescribed medication to be delivered, to enable the patient to utilise the medicines appropriately and to provide general information about the prescribed medication. Contact with the patient is made via email, telephone, live chat via WhatsApp, video calls, leaflets & notes."*

6.53 The Committee noted concerns by Crossflatts Pharmacy that by having the patient select a 'safe place' for deliveries that they are unable to physically accept, places the onus on the patient to ensure that any deliveries are obtained in a safe and effective manner. The Committee considered the information provided by the Applicant stating that any Royal Mail 'Safe Place' has to be confirmed and consented to by the patient prior to any delivery leaving the premises, and further that the Applicant has confirmed 'Safe Places' would not be used for deliveries of Controlled Drugs..

6.54 The Committee was of the view that the use of a thermometer without any description of how the temperature will be monitored and recorded does not provide assurance that the integrity of local cold chain deliveries will be maintained. In addition, the Committee noted the use of cold shipping packaging and Royal Mail tracking but there was no mention of how the temperature would be monitored throughout transit up to the point of delivery.

6.55 The Committee concluded that it could not be satisfied as it is required to be, that there would be compliance with paragraph 8(1) of Schedule 4.

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

6.57 The Committee noted that in its application form that in leaving the relevant section blank, the Applicant had not stated that it intends to provide appliances. In the event that the application is granted, the Applicant would not therefore be able to provide appliances.

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

6.59 The Committee noted that the application form states:

6.59.1 *“Outside this area Royal Mail 24/48 is used, the medication is packaged into discreet high quality polythene bags/flat cardboard boxes in a large letter format for easy postage or into cardboard boxes for larger items like creams,”*

and

*“Local cold chain deliveries involve the delivery driver adding the cold chain item to a polystyrene cool box which contains a calibrated thermometer. Ice packs are then added with cardboard blockers to ensure the temperature of the products remains between 2 and 8 degrees while delivering locally.”*

6.60 The Committee noted the Applicant had provided information with regard to the Woolcool technology that it proposed to use when sending items that require a consistent temperature:

6.60.1 *“Woolcool Thermal Systems are available in three stock sizes and are most suitable for those smaller payloads or direct to patient deliveries. Woolcool Flexible solutions offer two types of outer pouch, an LDPE or a Paper version, both with an extra secure self-adhesive strip. Bespoke sizing, colour and branding options are available.*

*All Woolcool Systems are available in two Woolcool Grades:-*

*Woolcool StandardGrade*

*Woolcool StandardGrade Thermal Solutions have been specifically developed for shorter deliveries or those within milder climates.*

*2-8C – Performance for the delivery of temperature sensitive pharmaceutical for up to 48 hours.*

*CRT – Woolcool Controlled Room Temperature (CRT) or ‘ambient’ Range maintain 15-25C for up to 72 hours.*

*Woolcool PharmaGrade*

*Woolcool PharmaGrade Thermal Solutions have been specifically developed for longer deliveries, more extreme climates or particularly sensitive products.*

*2-8C – Performance for the delivery of temperature sensitive pharmaceutical for up to 120 hours.*

*CRT (Ambient) – Delivery within CRT range up to 120 hours.”*

6.61 The Committee considered that although the Applicant had provided information regarding types of outer packaging this was limited to temperature controlled products and limited information was provided to demonstrate how other deliveries would be packaged and transported to patients in a safe and effective manner.

6.62 The Committee was therefore unable to be satisfied that there would be compliance with paragraph 8(15) of Schedule 4.

#### **Refusal to provide drugs or appliances ordered**

- 6.63 The Committee asked itself how the Applicant will be satisfied that when dispensing a repeatable prescription other than on the first occasion, that the patient is still using the medication, is not suffering from any side effects, the medicine regime has not changed in any way and there has been no changes to the patient's health, which may indicate the desirability of review the patients treatment.
- 6.64 The Committee noted that no information had been provided by the Applicant in this regard and therefore it could not be satisfied that there would be compliance with paragraph 9(4) of Schedule 4.

#### **Websites and health promotion zones**

- 6.65 The Committee considered whether the Applicant had explained how it will ensure that it has a website for use by the public for the purposes of accessing pharmaceutical services from those premises, on which there is an interactive page, clearly promoted to any user of the website when they first access it, which provides public access to a reasonable range of up to date materials that promote healthy lifestyles by addressing a reasonable range of health issues.
- 6.66 The Committee noted that whilst reference had been made to the Applicant's website in the application and subsequent representations, no information had been provided by the Applicant with regard to this service and therefore it could not be satisfied that there would be compliance with paragraph 28C of Schedule 4.

#### *Summary*

- 6.67 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.
- 6.68 The Committee therefore determined that it was required to refuse the application under Regulation 24(3)(d).

#### *Overall*

- 6.69 Pursuant to paragraph 9(1)(a) of Schedule 3 to the Regulations, the Committee may:
- 6.69.1 confirm NHS England's decision;
  - 6.69.2 quash NHS England's decision and redetermine the application; or
  - 6.69.3 quash NHS England's decision and, if it considers that there should be a further notification to the parties to make representations, remit the matter to NHS England for it to redetermine the application.
- 6.70 As NHS England did not consider the provisions of Regulation 24(2) in its decision, the Committee determined that the decision of NHS England must be quashed.
- 6.71 The Committee went on to consider 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 remit the matter to NHS England) or whether it was preferable for the Committee to redetermine the application.
- 6.72 The Committee noted that representations on Regulation 24 had already been made by parties to NHS England, and these had been circulated and seen by all parties who made representations on the application, as part of the processing of the application by NHS England. The Committee further noted that when the appeal was circulated representations had been sought from parties on Regulation 24.

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

**7 Decision**

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

7.2 The Committee quashes the decision of NHS England and redetermines the application.

7.3 The Committee has determined that the conditions set out in Regulation 24(2) (a), (b), (c), (d), (e), (f) and (g) are satisfied.

7.4 The Committee has determined that it was required to refuse the application under Regulation 24(3)(d) after considering the grounds set out in Regulation 25.

7.5 The application is refused.

**Case Manager  
Primary Care Appeals**