NHS Resolution

4 October 2024

REF: SHA/26260

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

Tel: 0203 928 2000
Email: nhsr.appeals@nhs.net

APPEAL AGAINST STAFFORDSHIRE AND STOKE ON TRENT ICB DECISION TO REFUSE AN APPLICATION BY DELIVERING HEALTHCARE LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT 74 HIGH STREET, BURTON ON TRENT, DE14 1LD UNDER REGULATION 25

1 Outcome

1.1 The Pharmacy Appeals Committee ("Committee"), appointed by NHS Resolution, quashes the decision of the Commissioner and redetermines the application.

1.2 The Committee determined that the application should be refused.

A copy of this decision is being sent to:

Delivering Healthcare Ltd
Pharmacy Sales & Consultancy on behalf of Dean & Smedley Ltd
Community Pharmacy Staffordshire & Stoke on Trent
PCSE on behalf of Staffordshire and Stoke on Trent ICB

NHS Resolution

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

Tel: 0203 928 2000
Email: nhsr.appeals@nhs.net

REF: SHA/26260

APPEAL AGAINST STAFFORDSHIRE AND STOKE ON TRENT ICB DECISION TO REFUSE AN APPLICATION BY DELIVERING HEALTHCARE LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT 74 HIGH STREET, BURTON ON TRENT, DE14 1LD UNDER REGULATION 25

1 The Application

In an undated application, received under cover of an email of 6 August 2023, Delivering Healthcare Ltd ("the Applicant") applied to Staffordshire and Stoke on Trent ICB ("the Commissioner") for inclusion in the pharmaceutical list at 74 High Street, Burton on Trent, Staffordshire, DE14 1LD under Regulation 25. In support of the application it was stated:

1.1 In response to "If you are undertaking to provide appliances, specify the appliances that you undertake to provide (or write 'none' if it is intended that the pharmacy will not provide appliances)" the Applicant left this blank.

1.2 In response to why the application should not be refused pursuant to Regulation 31 the Applicant left this blank.

1.3 In response to why the application should not be refused pursuant to Regulation 25(2)(a) the Applicant left this blank.

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

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

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

1.5 "The online pharmacy will have at least one Responsible Pharmacist (RP) at the premises at all times during the contracted hours. Patients will be able to order their medication online via the NHS app or via repeat requests to their GP and have it delivered to their doorstep same day/next day, ensuring that they can receive the essential services they need, without any disruption. Patients will be able to contact a qualified pharmacist directly through our online/email/video and phone service, and we will have measures in place to ensure that medication can be delivered quickly in the event of an urgent need. Urgent medications such as antibiotics or end-of-life will be stocked in advance and will be delivered same day unless there is a supply issue in which case the patient will be signposted to their nearest pharmacy. We will make sure adequate staffing levels meet the demand for Essential Services during the opening hours. Staff members will be trained in providing uninterrupted essential services, including how to handle unexpected events and emergencies. All staff members will have read and signed the comprehensive list of standard operating procedures (SOP).

1.6 All staff will be allocated time for training and courses from the 'centre for pharmacy postgraduate education (CPPE)'."

(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.

1.7 “Patient’s will not be provided face-to-face NHS essential services inside or within the vicinity of the premises. Patients attending for pharmacy services will be reminded by staff that medications can only be delivered to their house, as collection is not allowed at the pharmacy, and any unwanted medicines should be arranged to be collected from their house. There will also be a large sign at the entrance of the premises door to remind patients of “consultation by appointment only and no public access”. Alternatively the patient will be directed/signposted to their closest bricks and mortar pharmacy if patient prefers a face to face service.”

2 The Decision

The Commissioner considered and decided to refuse the application. The decision letter dated 10 June 2024 states:

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

2.1 “NHS England has considered the above application and I am writing to confirm that it has been refused. Please see the enclosed report for the full reasoning.”

Extract from the Pharmacy Services Regulations Committee 23rd May 2024

2.2 “Application for a Distant Selling Pharmacy (Staffordshire and Stoke on Trent ICB) received from Delivering Healthcare Ltd, 74 High Street, Burton on Trent, Staffordshire, DE14 1LD

Pharmacy Services Regulations Committee Decision

2.3 The application was refused as [the] Committee could not be assured that regulation 25(2) b(i) and 25 (2) b(ii) would be met for the reasons provided below.

2.4 Regulation 25 – Distance Selling Premises Applications [quoted in full]

2.5 Regulation 25(2)(b)(i) This regulation is deemed to have NOT been met.

2.6 The pharmacy procedures do not meet the standard required to satisfy the regulatory requirements of the provision of essential services. The application, SOPs and additional information provided showed a lack of understanding of Essential Services and contained contradictory information, therefore, Committee were not assured that the pharmacy would provide Essential Services to persons anywhere in England who request them. The applicant stated that there will be at least one Responsible Pharmacist at the premises at all times during contracted hours.

2.7 The applicant stated that unwanted medicines will be collected from a patients home, however when the process was questioned by Staffordshire and Stoke on Trent LPC, the applicant then stated that “Medicines disposal units within the pharmacy are for internal medicines waste only. For patients to dispose of medicinal waste they are sign-posted to local services around them where medicines can be disposed of. If this is not an option, we notify patients of the possibility of collection, however this would be arranged via their local health authority”.

2.8 Regulation 25(2)(b)(ii) This regulation is deemed to have NOT been met.

2.9 The pharmacy procedures do not meet the standard required to satisfy the regulatory requirements of the provision of essential services without face to face contact. The application, SOPs and additional information provided showed a lack of understanding

of Essential Services and contained contradictory information, therefore, Committee were not assured that the pharmacy would provide Essential Services to persons anywhere in England who request them without face to face contact safely or effectively.

2.10 The Delivery SOP contains contradictory information compared to responses from the applicant, and appears to relate to a local delivery service provided by the Pharmacy. There is no mention of couriers or external delivery providers in any of the SOPs and therefore Committee cannot be assured that the delivery of prescriptions will be completed safely or effectively."

3 The Appeal

Through the NHS Resolution online appeal form dated 9 July 2024, the Applicant appealed against the Commissioner's decision. The grounds of appeal are:

3.1 "I am writing to formally appeal the decision regarding the rejection of our online pharmacy application. I appreciate the feedback provided and would like to address the specific discrepancies and concerns raised.

3.2 These we believe include

3.2.1 25 (2) (b) (ii): The application stated that only local delivery would be offered, whereas the distance selling service should be nationwide.

And,

3.2.2 25 (2) (b) (i): There is no provision for waste disposal in the SOP, and it is mentioned in the application that unwanted medicines are to be returned.

Key Discrepancies Addressed

3.3 Responsible Pharmacist (RP) Presence: We ensure that at least one Responsible Pharmacist (RP) will be on the premises during all contracted hours, guaranteeing the availability of essential services without disruption.

3.4 Medication Delivery and Urgent Needs: Patients can conveniently order medications online through the NHS app or submit repeat requests to their GP. For local prescriptions, we offer an in-house delivery service. For prescriptions outside our local area, we have partnered with third-party providers such as Royal Mail to ensure the timely delivery of essential medications. Urgent medications, such as antibiotics or end-of-life care drugs, are pre-stocked and will be delivered the same day/next day with providers such as City Sprint or Royal Mail next day delivery service, barring any supply issues.

3.5 Direct Contact with Pharmacists: Patients can contact a qualified pharmacist directly through various channels, including online, email, video, and phone services. We will have measures in place to handle urgent medication and advice needs efficiently.

3.6 Adequate Staffing and Training: We will ensure that staffing levels are adequate to meet the demand for essential services during operating hours. All staff will be trained to provide uninterrupted essential services and handle unexpected events and emergencies. Each staff member will read and sign the comprehensive list of Standard Operating Procedures (SOP) and will receive training from the Centre for Pharmacy Postgraduate Education (CPPE).

3.7 Patient Services and Waste Disposal: Patients will not be provided face-to-face NHS essential services within the premises. Patients will be reminded that medications can only be delivered to their home, and any unwanted medicines should be taken to their

nearest NHS commissioned pharmacy or GP surgery for disposal. We acknowledge the confusion caused by the previous wording and have clarified this in our SOP.

Clarifications and SOP Adjustments

3.8 Clarification on Waste Disposal: All patients will be advised to use their nearest NHS pharmacy or GP surgery for medicine returns. Our floor plans' waste section is intended for internal use only.

3.9 Consistency in Responses: We acknowledge the inconsistency between our application, response, and SOP. To rectify this, we have updated our SOP to explicitly state the process for medication delivery, including how staff produce labels for delivery and post medicines. This SOP will be designed specifically for internet pharmacy operations.

Conclusion

3.10 We sincerely apologise for any confusion caused and appreciate the opportunity to clarify and improve our processes. We believe that with these adjustments, our pharmacy will meet all necessary requirements and provide high-quality, efficient services to our patients.

3.11 We kindly request a reconsideration of our application based on the clarifications and updates provided. Please let us know if further information or documentation is required.

3.12 Thank you for your time and consideration."

4 Summary of Representations

This is a summary of representations received on the appeal.

4.1 PHARMACY SALES & CONSULTANCY ON BEHALF OF DEAN & SMEDLEY LTD

4.1.1 "We act for Dean & Smedley Limited and have provided a letter of authorisation from our client accordingly.

4.1.2 Our client has passed us a copy of your letter dated 17th July informing them of the above appeal. On behalf of Dean & Smedley Limited, I would like to object to this application and set out our client's ground for objection below.

Pharmaceutical Services Regulations Committee ("PSRC") report

4.1.3 Before considering the appellant's grounds of appeal, we wish to summarise the findings of the PSRC, set out in its decision report from the meeting on 25th May 2024.

4.1.4 The committee refused the application because it could not be satisfied that "regulation 25(2)(b)(i) and 25(2)(b)(ii) would be met". It found the following:

4.1.4.1 The information provided in respect of services showed a lack of understanding of Essential Services and contained contradictory information. As a result the committee could not be satisfied that the pharmacy would provide Essential Services to persons anywhere in England who requested them.

4.1.4.2 Information provided in respect of the disposal of unwanted medicines did not meet the requirements in respect of the proper provision of this Essential pharmacy service.

4.1.4.3 The committee was concerned that the procedures provided did not adequately explain how Essential pharmacy services would be provided without the risk of face to face provision.

4.1.4.4 The SOP provided in respect of deliveries appeared to relate to a local delivery service only and did not explain how other forms or delivery might be undertaken.

4.1.5 It was for these reasons the application was refused.

Appellant's grounds for appeal

4.1.6 We have considered the matters raised by the appellant in the document titled "Appeal 09 07 24". This sets out the appellant's responses to the specific reasons for refusal of the application.

4.1.7 As a preliminary matter, as far as we can see, the appellant has not provided any updated SOPs and those supplied with the appeal do not appear to specifically address the concerns identified by the PSRC. The three SOPs they have provided do not appear to been [sic] updated since 2022 according to the 'version control'.

4.1.8 The appellant then discusses five aspects of the services it proposes to offer. We address each of these using the same numbering:

Responsible Pharmacist (RP) Presence:

4.1.9 It is claimed that the applicant will ensure at least one RP will be on the premises during all contracted hours, yet no explanation is provided in respect of how this will be achieved in the case of unplanned absences e.g. due to illness.

Medication Delivery and Urgent Needs:

4.1.10 It is stated that "for prescriptions outside our local area, we have partnered with third-party providers such as Royal Mail…". This statement is somewhat equivocal. It is implied that partnership agreements have already been entered into, yet the appellant is not clear about exactly which providers would be providing this service. Use of the words "such as" suggests that no agreements are actually in place yet. If that is the case then the appellant cannot make claims in respect of how and when medication will be delivered, as it would appear no detailed discussions with providers have actually taken place.

Direct Contact with Pharmacists:

4.1.11 The appellant describes in very broad terms what it intends to happen, by way of channels of communication but provides no details whatsoever on how these channels will actually work. Importantly, for example, no information is provided on what measures will be in place to ensure data security and therefore protect patient confidentiality. It is not clear, therefore, that Essential services will be delivered 'safely'.

4.1.12 Equally, simply stating that there will be "measures in place to handle urgent medication and advice needs efficiently" is not enough. The appellant needs to satisfy the decision maker that processes to achieve this objective will be in place. In the absence of any detailed SOPs or even outline procedures dealing

specifically with urgent requests, the Primary Care Appeals ("PCA") committee cannot be satisfied that the appellant will be able to deal with urgent requests adequately.

Adequate Staffing and Training:

4.1.13 Again the appellant states that "it will ensure staffing levels are adequate" and that "all staff will be trained to…….. handle unexpected events and emergencies" without explaining how it will do so. It appears that the appellant has not given any detailed thought to how it will actually operate the pharmacy safely and efficiently.

Patient Services and Waste Disposal:

4.1.14 It is stated that patients will not be provided face to face NHS essential services within the premises. However, there is negligible information provided on exactly how these Essential services will be provided. The provision of Essential services is a fundamental requirement, not an optional one. In order for the decision maker to be satisfied that the regulatory tests are met the appellant must provide information in respect of exactly how each and every one of the Essential services will be provided to enable the PCA committee to be satisfied that the regulatory requirements are met.

4.1.15 Specifically in respect of the disposal of unwanted medicines, the appellant cannot compel patients to take their unwanted medicines to a different pharmacy or to a GP surgery for disposal. Should the application be granted the appellant will be contractually obliged to provide this essential service for anyone in England who wishes to use it. The failure to offer this service would be a breach of the appellant's terms of service. That being the case it would not be providing "the safe and effective provision of essential services".

Clarifications and SOP adjustments

4.1.16 We have dealt with the matter of waste disposal already so I have nothing more to add on this matter.

4.1.17 The appellant acknowledges inconsistencies between responses it made and its SOPs. It goes on to say that these SOPs have been updated but does not appear to have provided these updated SOPs. Furthermore it states that "this SOP will be designed specifically for internet pharmacy operations". Use of the phrase "will be" contradicts the earlier comment that SOPs have already been updated.

4.1.18 The PCA committee cannot be satisfied that the appellant has a clear understanding of exactly how the proposed pharmacy will operate, and therefore whether the regulatory tests will be met.

SOPs provided

4.1.19 We note that three SOPs have been provided with this appeal and comment on two of these as follows:

Cold chain delivery

4.1.20 This SOP states "A regulated cold chain delivery firm should be used to deliver regular medicines. If this is not available, a cool pack/box must be used for transporting drugs requiring cold storage". No consideration is given to the time any refrigerated products might be in transit due to the distance they have to travel. In some circumstances it may be inappropriate to use a cool pack / box.

4.1.21 The SOP refers to “freezer malfunctions”. No explanation is given in respect of when it is appropriate for medication to be stored in a freezer. Mention of ‘samples’ suggests this wording has been taken from a document that relates to a different sector. This is further evidence that the appellant has not properly considered the documentation it has provided.

Delivering Controlled Drugs

4.1.22 The first paragraph of this SOP states: “For each patient, the pharmacist should clinically assess the prescription and using professional judgment consider whether it is necessary for face to face contact with the patient or their carer or if a direct conversation is required”.

4.1.23 There is no guidance provided on what to do if it is deemed necessary to have face to face contact, bearing in mind that this is not permitted at a distance selling pharmacy, given that dispensing of medication is an essential pharmacy service.

Other matters

4.1.24 The applicant has provided floor plans that show a consultation area and has listed services for provision, such as ‘flu vaccinations, that clearly require face to face contact.

4.1.25 The applicant makes the following comment: “There will also be a large sign at the entrance of the premises door to remind patients of “consultation by appointment only and no public access”. Whether services are provided ‘by appointment’ or on a walk-in basis, they are still face to face.

4.1.26 Whilst a distance selling pharmacy is permitted to provide NHS Advanced or Enhanced services face to face, particular care must be taken to ensure Essential services are not delivered inadvertently at the same time.

4.1.27 By way of example, the appellant proposes to offer ‘flu vaccinations’ yet these require the dispensing of the vaccination prior to administration.

4.1.28 The appellant also proposes to offer services such as the New Medicines Service and Hypertension Case Finding face to face at the pharmacy. There is a real risk that providing these services may also necessitate providing Essential pharmacy services such as Signposting or Public Health. However, doing so would breach Regulation 25(2)(b)(ii).

4.1.29 It is for the appellant to clearly explain how these face to face Advanced services will be provided without Essential services being provided at the same time. It has failed to do so.

4.1.30 It is our client’s opinion that the applicant has failed to provide sufficient information to enable the PCA committee to be confident that the application meets the requirements of Regulation 25. In fact, the information provided clearly demonstrates that those requirements will not be met. That being the case the application should be refused.

4.1.31 Should the committee decide to hold an oral hearing I can confirm that our client would wish to be represented.”

4.2 COMMUNITY PHARMACY STAFFORDSHIRE & STOKE ON TRENT

4.2.1 “Thank you for giving the Local Pharmaceutical Committee (LPC) the opportunity to respond to the above DSP application. This application was

discussed at a recent LPC meeting, where any members declaring an interest did not take part in discussions or decisions.

4.2.2 The Applicant is applying to provide pharmaceutical services as a distance selling pharmacy under Regulation 25 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations. The LPC would like to make comments regarding the disposal of unwanted medicines.

4.2.3 It is not clear that the applicant is aware that patients should have several options for disposal of unwanted medicines.

4.2.4 The pharmacy could use a specialist waste management company that could provide safe and secure disposal of unwanted medicines by collection of unwanted medicines from patients and residential home.

4.2.5 Patients wishing to return unwanted medicines to the pharmacy may do so by courier, which should be provided and paid for by the pharmacy.

4.2.6 Patients in locality could contact pharmacy by phone or email to arrange collection of unwanted medicines from their home or work.

4.2.7 Appropriate packaging should be sent to patients in advance and details of the service and how to book a collection should be available on the Pharmacy website.

4.2.8 Upon return to the pharmacy unwanted medicines should be sorted and placed in disposal units ready for waste management services to collect.

4.2.9 The disposal service should be advertised on the website/app and marketing leaflets.

4.2.10 We also note that;

4.2.10.1 The applicant has stated they will undertake same/next day delivery for all prescriptions. We need to further understand how this will take place when should be provided to the whole of the UK.

4.2.10.2 The applicant needs to provide more details on how they will deal with situations if the patient is not available to accept the medicine delivery.

4.2.10.3 The applicant needs to include more information on how they intend to handle and deliver fridge lines, maintaining the cold chain.

4.2.10.4 The applicant needs to provide more information on how Controlled Drugs will be handled and delivered.

4.2.11 The LPC look forward to being part of the appeals process for this application and will provide every support to the applicant and NHS to ensure all service standards are appropriately met."

5 Summary of Observations

This is summary of observations received.

5.1 THE APPLICANT

"Response to some of the relevant comments made by Dean & Smedley

5.1.1 Temperature-Controlled Packaging: We use insulated packaging with gel packs or phase change materials to maintain the required temperature (typically between 2°C and 8°C) for the 24-48 hours transport period. For any transport requiring longer than 48 hours a courier service experienced in handling temperature-sensitive deliveries will be used.

5.1.2 As we mentioned in our NHS appeal our SOPs have been updated hence we won't be needing a freezer as we won't be storing any medicines or vaccines that require a freezer.

5.1.3 For each patient the pharmacist will clinically assess the prescription and where it is necessary to have a conversation with the patient it would be done via phone call, text, email or video call.

5.1.4 Flu vaccinations are covered under national PGD and not prescription hence doesn't fit within the essential services.

5.1.5 We will be providing New Medicines Service and Hypertension case finding service in our pharmacy without providing any face to face essential services. Essential services such as Public Health (promotion of healthy lifestyle) will be provided remotely via phone, video calls, or secure online platforms. We will have a dedicated page on our website that promotes Public Health. This ensures that the patient receives the necessary support without breaching regulations.

In Response to [Community Pharmacy] enquiries:

5.1.6 Medical waste disposal: Patients will be reminded that any unwanted medication should be taken to their nearest NHS commissioned pharmacy or GP surgery for disposal. We will have a dedicated page on our website to signpost patients to their nearest NHS commissioned pharmacy for safe disposal of medication. Patients have several options available as there are many places across the UK that provide this service. Just to give an example there are around 12 different pharmacies in Burton on Trent that provide safe disposal of medication hence this gives the patients lots of options.

5.1.7 Medication Delivery: For local prescriptions we offer an in-house delivery service and for prescriptions anywhere else in the UK we use Royal Mail Tracked delivery service to ensure timely delivery of essential medications. Only for urgent medication such as antibiotics or end of life drugs we will use Royal Mail Tracked 24, Royal Mail Special Delivery Guaranteed by 1pm or City Sprint for same day/next day delivery.

5.1.8 We want to clarify that only urgent medications will be delivered the same day/ next day due to their urgency.

5.1.9 Patient not available to accept the delivery:

5.1.10 Communication with the patient Pre-Delivery Communication: Notify the patient of the delivery time window through SMS, email, or a phone call to ensure they are aware and available.

5.1.11 Delivery Confirmation: Require the patient to confirm the delivery time, or give them an option to reschedule if they won't be available.

5.1.12 Alternative Contact Person: Ask the patient to nominate a trusted person (e.g., a family member or neighbour) who can accept the delivery on their behalf.

5.1.13 Reattempting Delivery: If the delivery is unsuccessful, we have a clear procedure for returning the medicines to the pharmacy, and informing the

patient about how they can rearrange delivery. All delivery attempts and communications are documented to comply with legal and professional obligations.

5.1.14 Delivering fridge lines to maintain cold chain:

5.1.15 Pre-Delivery Coordination, Advance Notification: Notify the patient in advance about the delivery time window, emphasizing the importance of being available due to the temperature-sensitive nature of the medicines. This will be done alongside patient confirmation where we would obtain confirmation from the patient that they will be available to receive the delivery, or allow them to reschedule if necessary.

5.1.16 Temperature-Controlled Packaging: We use insulated packaging with gel packs or phase change materials to maintain the required temperature (typically between 2°C and 8°C) for the 24-48 hours transport period. For any transport requiring longer than 48 hours a courier service experienced in handling temperature-sensitive deliveries will be used.

5.1.17 Temperature Monitoring: Consider using temperature-sensitive labels or data loggers that provide visual indicators or recorded data to confirm the medicine remained within the required temperature range during transit.

5.1.18 Delivery Options and Timing Timed Deliveries: Offer timed delivery slots (e.g., morning or afternoon) to increase the likelihood of the patient being available.

5.1.19 Handling Missed Deliveries: Safe Place or Neighbour Delivery: Due to the temperature-sensitive nature of fridge lines, leaving the package in a safe place or with a neighbour is not part of our protocol. However, if absolutely necessary and pre-arranged with the patient, ensure the designated person can store the medicine within the required temperature range.

5.1.20 Reattempting Delivery: If the patient is not available, arrange an immediate reattempt of the delivery. The urgency of fridge line deliveries means this should be prioritized.

5.1.21 Immediate Pharmacy Return Protocol: If delivery is unsuccessful and a reattempt is not possible, we have a protocol in place for the immediate return of the fridge lines to the pharmacy. The courier should ensure the medicines are kept within the correct temperature range during return transit. Once returned, the fridge lines should be immediately placed in a dedicated pharmacy refrigerator to maintain their integrity.

5.1.22 In regards to [sic] Controlled Drugs, here is an overview of our procedures:

5.1.23 Regulatory Compliance: Our pharmacy strictly adheres to all relevant regulations and guidelines outlined by the Medicines and Healthcare products Regulatory Agency (MHRA) and other regulatory bodies governing the handling, storage, and transportation of controlled drugs.

5.1.24 Authorized Personnel: Only authorized and trained personnel are involved in the handling and delivery of controlled drugs. This includes pharmacists and pharmacy staff who have undergone specialized training in compliance with regulatory requirements. All the controlled drugs medicines are sent by tracked and signed for delivery service.

5.1.25 Secure Storage Facilities: Controlled drugs are stored in secure, access-restricted areas within our pharmacy. These areas are equipped with additional security measures to prevent unauthorized access.

5.1.26 Real-Time Monitoring and Surveillance: Our storage facilities and in-house delivery vehicles are equipped with advanced security and surveillance systems to monitor and record activities in real time, ensuring the integrity and security of controlled drugs. The courier used for CD deliveries provides real time tracking service.

5.1.27 Chain of Custody Protocols: We have established rigorous chain of custody protocols to track the movement of controlled drugs from the point of receipt to the final delivery. This includes detailed documentation at each stage of the process.

5.1.28 Regular Audits and Compliance Checks: We conduct regular internal audits and compliance checks to ensure that our procedures align with regulatory standards. This includes assessments of storage conditions, documentation practices, and security measures.

5.1.29 Emergency Response Plan: We have an established emergency response plan in place to address unforeseen circumstances, ensuring a swift and appropriate response to any incidents that may impact the delivery of controlled drugs."

6 Consideration

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

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

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

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

Regulation 31

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

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

(2) This paragraph applies where -

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

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

(ii) adjacent premises; and

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

6.6 The Committee noted that the Applicant had not provided any information in the application form on this point 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.

6.7 The Committee noted that the Commissioner had not considered Regulation 31 in its decision report however the Committee further noted that no party had sought to argue that Regulation 31 applied in respect of this application.

6.8 Based on the information before it, the Committee determined that it was not required to refuse the application under the provisions of Regulation 31.

Regulation 25

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

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

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

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

in respect of pharmacy premises that are distance selling premises.

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

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

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

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

(ii) the safe and effective provision of 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."

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

Additional information to be included with excepted applications

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

(a) A's belief that the application satisfies the criteria included in one of the regulations in Part 4 which need to be satisfied if section 129(2A) and

(2B) of the 2006 Act (regulations as to pharmaceutical services) are not to apply in relation to that application; and

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

Nature of details to be supplied

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

Regulation 25(1)

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

Regulation 25(2)(a)

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

6.13 Whilst the Commissioner, in it is decision report had quoted regulation 25(2)(a) it had not considered whether the proposed premises are on the same site or in the same building of a provider of primary medical services with a patient list. The Committee noted that no party has sought to argue the application of Regulation 25(2)(a) in representations.

6.14 Based on the information available to it, the Committee 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)

6.15 As far as Regulation 25(2)(b) is concerned, the Committee considered the information which had been provided by the Applicant in relation to its procedures for the provision of essential services, including its Standard Operating Procedures (SOPs) that it intends to use at the proposed pharmacy premises.

6.16 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.

6.17 Paragraph 8 of Schedule 2 requires an applicant to provide details in relation to an application, and paragraph 10 of Schedule 2 indicates that the obligation is only discharged if the information or documentation provided is sufficient to satisfy the Commissioner in receipt of it, with good cause, that no relevant information or

documentation is missing, having regard to the uses that the Commissioner may need to make of the information or documentation when carrying out its functions.

6.18 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 SOPs which the Applicant has prepared or commissioned.

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

6.20 The Committee noted the comment from the Applicant in the application from that "*Patient's will not be provided face-to-face NHS essential services inside or within the vicinity of the premises."* The Applicant had gone on to state "*Patients attending for pharmacy services will be reminded by staff that medications can only be delivered to their house, as collection is not allowed at the pharmacy, and any unwanted medicines should be arranged to be collected from their house."*

6.21 The Committee noted the comments from the Applicant that the premises will have a large sign at the entrance to remind patients that "*consultation by appointment only and no public access."* The Committee further noted the comments from the Applicant that if a patient did require a visit to the premises, for anything other than an essential service, then this would be by appointment only and they would be made aware that no essential services could be carried out.

6.22 The Committee noted the comment from interested parties regarding the reference in the SOPs to face to face contact which states "*For each patient, the pharmacist should clinically assess the prescription and using professional judgement consider whether it is necessary for face to face contact with the patient or their carer or if a direct conversation is required*." The Committee noted that the Applicant had responded to this and had confirmed that "*For each patient the pharmacist will clinically assess the prescription and where it is necessary to have a conversation with the patient it would be done via phone call, text, email or video call.*" The Committee considered that reference to "…face to face contact..." might be interpreted two ways, either a patient attending the premises or a patient using video call. The Committee considered it's everyday meaning would suggest the former and that updated SOPs had not been provided to confirm that the inclusion of "…face to face contact…" did not mean at the premises. .

6.23 The Committee noted the SOP "Delivering Controlled Drugs" under "Failure to deliver" states:

6.23.1 "*if the patient is not at home during the agreed slot – Complete a Not at home postcard detailing information about re-delivery or collection from the pharmacy …"*

6.24 Whilst the Applicant states that the SOPs have been updated and has responded to the particular point raised by parties, the Committee noted that they had not been provided within any revised SOPs. The Committee determined that reference to *"collection from the pharmacy…"* implied an option for patients which was not permitted under the Regulations.

6.25 Based on the information before it, the Committee was not satisfied that the provision of essential services would be without face to face contact.

6.26 The Committee noted the various references throughout the application and supporting information to prescriptions being received electronically as well as further confirmation from the Applicant that medications would be delivered by their own local delivery driver and that they would also be making use of Royal Mail and City Sprint. The Committee noted that the Applicant would have a fully functioning website and would be able to contact patients online as well as via email, video and telephone. The Applicant confirmed that they would be providing essential services to anyone anywhere in England.

6.27 Based on the information before it, the Committee was satisfied that the provision of essential services would be available to persons anywhere in England.

6.28 The Committee noted in the information provided, the Applicant refers to "*The online pharmacy will have at least one Responsible Pharmacist (RP) at the premises at all times during the contracted hours."* The Committee further noted in their appeal that the Applicant had stated "*Responsible Pharmacist (RP) Presence: We ensure that at least one Responsible Pharmacist (RP) will be on the premises during all contracted hours, guaranteeing the availability of essential services without disruption."*

6.29 The Committee noted that no further information had been provided by the Applicant in response to the queries regarding the Responsible Pharmacist that had been raised by Dean & Smedley in their representations. The Committee was of the view that it was not clear, from the information provided how essential services would be provided, should they be required, during the absence of the Responsible Pharmacist. Therefore the Applicant would be unable to provide all essential services without the presence of a pharmacist on site.

6.30 Based on the information before it, the Committee was not satisfied that the provision of services would be without interruption.

6.31 The Committee went on to consider whether safe and effective provision of essential services was likely to be secured.

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

6.33 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:

6.33.1 Dispensing of drugs and appliances

6.33.2 Urgent supply without a prescription

6.33.3 Preliminary matters before providing ordered drugs or appliances

6.33.4 Providing ordered drugs or appliances

6.33.5 Refusal to provide drugs or appliances ordered

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

6.33.7 Disposal service in respect of unwanted drugs

6.33.8 Promotion of healthy lifestyles

6.33.9 Prescription linked intervention

6.33.10 Health campaigns

6.33.11 Signposting

6.33.12 Support for self-care

6.33.13 Discharge medicines service

6.33.14 Websites and health promotion zones

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

Dispensing of drugs and appliances

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

6.36 The Committee noted that the SOP "Delivery of Medicines" stated under the heading "Collection":

6.36.1 *"For the collection of prescriptions from doctor's surgeries-2 address labels are generated. One is added to the branch record sheet, and collection is denoted by 'C'. The other is stuck to the delivery record book. The driver should sign the entry on the branch record sheet before leaving the pharmacy to ensure that they know a pickup is required. On arrival at the surgery for collection, prescriptions are placed in a bag, and the receptionist signs the delivery record book. The bag is returned to the pharmacy."*

6.37 However there was no further information provided by the Applicant as to how those patients who were not registered with surgeries local to the site of the pharmacy would be able to present non-electronic prescriptions to the pharmacy.

6.38 The Committee noted that the Applicant was proposing to use Royal Mail as well as City Sprint for the delivery of medication which was outside of the local area and where it was impractical to use their own local delivery driver.

6.39 Given the lack of information with regard to the receipt of non electronic prescriptions the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 5(2)(3) of Schedule 4.

Urgent supply without a prescription

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

6.41 Whilst the Committee noted the comments from the Applicant about "urgent" medication the Applicant had specifically referred to this as "antibiotics" or "end of life care" and that this would be delivered the same day. The Committee was of the view that whilst these may be considered "urgent" this was not the same as "urgent supply without a prescription".

6.42 The Committee noted that the Applicant had made no reference, either in the SOPs, in its original application form or subsequent representations as to how it would safely

and effectively receive requests from prescribers for urgent supplies of drugs and appliances.

6.43 The Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 6 of Schedule 4.

Preliminary matters before providing ordered drugs or appliances

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

6.45 The Committee noted that the SOP "Delivery Controlled Drugs" under "Procedure" it states:

6.45.1 *"Organise CD deliveries*

> *… Where the patient is exempt and wished further deliveries, record details of the exemption including the expiry date for any exemption certificate onto the PMR Where exemption status has expired contact the patient to provide new evidence of exemption status Where the patient is not exempt, mark 'to pay' on the prescription …"*

6.46 Whilst the information before it only demonstrated the evidence for exemption in relation to Controlled Drugs, it was probable that the same process for obtaining exemptions for Controlled Drugs would also be used for obtaining exemptions for any other medication which may be dispensed. However, the Committee noted that there was no information provided by the Applicant as to how the exemption would be obtained from the patient in the first instance.

6.47 Given the lack of information the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 7(3) of Schedule 4.

6.48 The Committee considered whether the Applicant had explained how charges will be paid and noted that whilst there was reference to "*where the patient is not exempt, mark 'to pay' on the prescription*" in the "*Delivering Controlled Drugs*" SOP, there was no further information as to how payment was to be taken by the Applicant or how they would ascertain that payment had then been made.

6.49 The Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 7(5)(b) of Schedule 4.

Providing ordered drugs or appliances

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

6.51 The Committee considered the information before it contained in the SOPs submitted by the Applicant.

6.52 The Committee noted the comments in the SOP "*If the person receiving the medicinal product is unhappy about the maintenance of the cold chain and the length of time in transit, they should refuse to accept the order and return it to the supplier."* The Committee was of the view that this process was concerned with the initial receipt of medications from suppliers, not from the pharmacy to patients, and, whilst it was important that the cold chain was maintained at all times in the supply chain, this was,

in essence, no different to how a standard bricks and mortar pharmacy would deal with the receipt of medications and therefore took no view on this.

6.53 The Committee's focus was on how the Applicant would ensure that the cold chain was maintained for the drugs that it was responsible for delivering to patients.

6.53.1 "3. Product dispatch.

If the product has been accepted into the service as per the Cold Chain SOP, it should be at the start of this process located within the temperature-controlled, pharmacy grade refrigerator. The process of the product leaving the pharmacy should be documented in the delivery log. On removal of any item from the base drug refrigerator, there will be a visual inspection of the product to ensure that it meets with the described physical appearance.

4. Delivery requirements

A regulated cold chain delivery firm should be used to deliver regular medicines. If this is not available, a cool pack/box must be used for transporting drugs requiring cold storage in conjunction with a validated minimum/maximum thermometer must be used for transporting vaccines requiring cold storage. Domestic cool boxes must not be used.

Medicines must be kept in their original packaging, wrapped in bubble wrap (or similar insulation material) and placed in the coolbox with cool packs as recommended by the manufacturer. This prevents direct contact between medicines and the cool packs and protects them from damage. The time between removing medicines from cool storage and use must be kept to a minimum.

Delivery Temperature Deviation Procedure

If it is found during delivery that the maximum/minimum thermometer readings are outside the ideal 8C and 2C and there is a concern that there has been a breach in the cold chain then this should be brought to the attention of the named person responsible for the storage of medicines. In this event, please follow these procedures.

5. Temperature deviation due to freezer malfunction

If the temperature has deviated during a freezer malfunction, move the samples to an alternate freezer and give a list of the affected boxes, and the temperature at the time of the move then document this discrepancy in the hubnet.io error log and follow the steps below.

6. Temperature deviation due to power outage

If a power outage occurs, and the generator (if available) does not kick in to restore power to the freezers, alternative arrangements for cold storage must be deployed. This includes, but is not limited to, finding another facility with suitable cold chain maintenance ability to house the product temporarily.

This error will need to be logged in the hubnet.io error log and follow the subsequent steps below.

7. Temperature deviation due to dry ice

If a shipment temperature has deviated during shipment (i.e. shipment has warmed because all of the dry ice has sublimated due to a delayed shipment) document this discrepancy in the error log and follow the steps below.

Processing of temperature damaged items

8. Immediate action upon identification of damaged items

Should the minimum recording of the temperature be less than 0C then the stock in the refrigerator should be quarantined by placing it into an appropriate container or bag and labelling the container or bag 'DO NOT USE'. The stock will be then disposed of according to the Standard Operating Procedure on the disposal of unwanted medicines.

9. Identification of temperature deviation post-delivery

If the breach of the cold chain is discovered after the vaccine has been given to the patient, then the Incident Reporting Policy should be followed. The patient must be referred to the responsible pharmacist for review."

6.54 In addition to the SOP, the Committee noted the comments from the Applicant in response to the representations in which they expanded upon the process for "Handling Missed Deliveries" and stated:

6.54.1 "*Handling Missed Deliveries: Safe Place or Neighbour Delivery: Due to the temperature-sensitive nature of fridge lines, leaving the package in a safe place or with a neighbour is not part of our protocol. However, if absolutely necessary and pre-arranged with the patient, ensure the designated person can store the medicine within the required temperature range.*

Reattempting Delivery: If the patient is not available, arrange an immediate reattempt of the delivery. The urgency of fridge line deliveries means this should be prioritized.

Immediate Pharmacy Return Protocol: If delivery is unsuccessful and a reattempt is not possible, we have a protocol in place for the immediate return of the fridge lines to the pharmacy. The courier should ensure the medicines are kept within the correct temperature range during return transit. Once returned, the fridge lines should be immediately placed in a dedicated pharmacy refrigerator to maintain their integrity."

6.55 The Committee noted the comment from the Applicant that they had updated their SOPs and confirmed that "*we won't be needing a freezer as we won't be storing any medicines or vaccines that require a freezer*" however no updated SOPs have been provided by the Applicant and therefore the Committee was only able to consider the information which was before it.

6.56 The Committee noted the comment that "a regulated cold chain delivery firm should be used" however there was nothing further provided as to how the Applicant would ensure that the cold chain would be maintained by the specialised delivery firm or what should happen if they were unable to deliver the medication. Further the Committee was unsure how, if the specialist company was not available, patients who were not local would be able to receive their medication.

6.57 With regard to local deliveries, the Committee noted that the Applicant was proposing to use their own delivery driver. The Committee noted that domestic cool boxes would not be used and the Applicant was proposing to use a "*cool pack/box in conjunction with a validated minimum maximum thermometer*". The Committee noted that the SOP went on to state "*If it is found during delivery that the maximum/minimum thermometer readings are outside the ideal 8C and 2C and there is a concern that there has been a breach in the cold chain then this should be brought to the attention of the named person responsible for the storage of medicines."* The Committee noted that no information was provided as to how the local delivery driver would audit and monitor the temperature whilst the medication was out for delivery.

6.58 Whilst the Committee had been provided with information as to what would happen if there was a failed delivery by the pharmacy's own delivery driver, there was very little information provided as to what would happen if there was a failed delivery for those further afield whose medication was being delivery by courier.

6.59 In addition to the SOP "Delivering Controlled Drugs" the Committee noted that the Applicant had also set out an overview of their procedures in subsequent representations.

6.60 The Committee noted that some of these procedures referred to how the Applicant would deal with Controlled Drugs within the pharmacy premises. The Committee took no view on this as the Committee's focus was on how the Applicant would ensure that drugs would be provided and the requirements of the Misuse of Drugs Regulations 2001 were maintained.

6.61 The Committee noted the SOP states:

6.61.1 "3. Dispatch the item.

Give the correctly labelled and bagged item to the driver along with the drop sheet. Make sure that the driver understands that this is not a regular delivery and needs to be signed for. Make sure that the deliverer understands that the item has to remain secure and should not be left alone or out of sight.

4. Driver delivers the item.

The person who is delivering the controlled drug should double-check the address to be delivered to and ask the person who is present for identification if necessary. A signature should be obtained from the patient who receives their item. If the patient has a carer and is incapable of signing then their signature would be acceptable if all necessary parameters are checked. In the event that neither the carer nor the patient is present the pharmacist should be contacted immediately.

5. Report back to the pharmacist.

The pharmacist has a legal responsibility to make sure that the patient has received their medication. Therefore the driver needs to contact the pharmacist to confirm delivery. The best way to do this is to return with the drop sheet which is signed by the patient if this is not possible on the same day (although the drop sheet must be returned) then a phone call would suffice.

…

7. Failure to Deliver

If the patient is not home during the agreed delivery slot– Complete a Not at home postcard detailing information about re-delivery or collection from the pharmacy Post the pharmacy card through the letterbox Do NOT push the medicines through the letterbox Do NOT leave the medicines outside the door Inform the authorised pharmacy staff upon return to the pharmacy Where schedule 2 or 3 CDs are not delivered inform the pharmacist upon return to the pharmacy The pharmacist should then do the following: For controlled drugs subject to safe custody Return undelivered controlled drugs to the controlled drugs cabinet For schedule 2 CDs re-enter the drug back into the CD register with an explanation.

8. Following delivery or attempted delivery

Check the Driver's delivery schedule against the detached prescriptions. Prescriptions for packages which been successfully delivered may be treated as completed and filed. Prescriptions for packages which have not been delivered should be reattached to the package. Contact the patient to confirm the next details for the next delivery. Return the prescription and package to the delivery storage area or the fridge if applicable."

6.62 Under the SOP "The Delivery of Medicines" the Committee noted it stated:

6.62.1 "*5. Driver arrival.*

When the driver arrives, check the label on the bag against the prescription, branch record sheet and book. File prescriptions. Complete as necessary with fridge and CD items. Check and tick against the branch record sheet label when transferring items to the delivery driver. The driver signs and dates the branch record sheet at this stage to confirm the pickup.

6. Controlled drugs delivery.

If a CD is included, phone the patient beforehand to confirm they are in. The driver should sign the blue box on the back of the script and write 'delivery' to complete the audit trail. The driver's name and 'delivery' is written in the CD register as the person collecting the medication. If delivery is unsuccessful, the CD is returned to the pharmacy, booked back into the CD register and signed out again on retry.

7. Driver departure.

Ensure that the driver takes the delivery record book with them. The branch record sheet stays in the pharmacy as a record of which items have been taken by driver. On delivery at the appropriate address, the driver should give the patient every opportunity to answer the door.

IF THE PATIENT IS IN:

1. The driver should state that he is delivering medication from the pharmacy and check the patient's name and address. The number of packages to be delivered should be confirmed against the entry in the delivery record book.

2. The patient must sign the delivery record book on receipt of their medication. The driver should not enter the patient's house if possible.

3. The book must be returned to the pharmacy as proof of delivery before the close of business that day.

4. The driver should not offer medical advice unless qualified to do so. If the patient has a query about their delivered medication, the driver can provide the telephone number of the pharmacy (which is printed on all medication labels) and ask the patient to phone the pharmacy for advice. If the driver is asked to give written advice to a patient in the form of a note or letter from the pharmacy, then the pharmacy should phone the patient after delivery to ensure the note has been received and understood. Medicines should be kept securely in the vehicle, and doors and windows are closed/locked at all times. The medication should be kept out of sight, e.g. in the boot.

IF THE PATIENT IS OUT:

1. The driver leaves a failed delivery card (available from NPA).

2. The driver returns to the pharmacy with any undelivered medication and the delivery record book.

DO NOT- Leave the delivery items.

- *unattended in porches or on doorsteps*
- *with children*
- *neighbours - Unless arrangements have been made by the patient/carer"*

6.63 Whilst the Committee noted the information in the SOP with regard to the delivery and non delivery of controlled drugs this all appeared to be with reference to the Applicant's own delivery driver.

6.64 The Committee noted the additional information provided by the Applicant in which they make reference to deliveries being made by couriers and state:

6.64.1 "*Authorized Personnel: Only authorized and trained personnel are involved in the handling and delivery of controlled drugs. This includes pharmacists and pharmacy staff who have undergone specialized training in compliance with regulatory requirements. All the controlled drugs medicines are sent by tracked and signed for delivery service.*

Secure Storage Facilities: Controlled drugs are stored in secure, access-restricted areas within our pharmacy. These areas are equipped with additional security measures to prevent unauthorized access.

Real-Time Monitoring and Surveillance: Our storage facilities and in-house delivery vehicles are equipped with advanced security and surveillance systems to monitor and record activities in real time, ensuring the integrity and security of controlled drugs. The courier used for CD deliveries provides real time tracking service.

Chain of Custody Protocols: We have established rigorous chain of custody protocols to track the movement of controlled drugs from the point of receipt to the final delivery. This includes detailed documentation at each stage of the process. "

6.65 The Committee noted that there was very little information provided as to what would happen if there was a missed delivery for those who lived further afield and whose medication was being delivered by the courier.

6.66 Taking all of the information into account, including the additional information regarding the delivery of controlled drugs, the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 8(1) of Schedule 4.

6.67 The Committee noted that the Applicant had not provided any information on the application form with regard to the provision of appliances and had left this blank. The Committee was therefore unsure if the Applicant was or was not proposing to provide appliances, however given that no further information had been provided to show that there would be compliance with paragraph 8(4) of Schedule 2, the Committee was of the view that, if the application was to be granted, the Applicant would not be able to provide any appliances.

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

6.69 The Committee noted that the Applicant had provided no information with regard to this aspect of the Terms of Service in either the original application form, the SOPs or subsequent representations.

6.70 Given the lack of information the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 8(15) of Schedule 4.

Refusal to provide drugs or appliances ordered

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

6.72 The Committee noted that no information had been provided either in the original application from, on appeal or in subsequent representations.

6.73 Therefore the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 9(4) of Schedule 4.

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

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

6.75 The Committee noted that there was no mention in the SOPs, or supporting information from the Applicant with regard to how they would provide appropriate advice about the benefits of repeat dispensing.

6.76 The Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 10(1) of Schedule 4.

Disposal service in respect of unwanted drugs

6.77 The Committee considered whether the Applicant had explained how it will safely and effectively accept and dispose of unwanted drugs presented to it for disposal.

6.78 The Committee noted the various comments regarding the disposal service in respect of unwanted drugs in both the application, subsequent representations to the Commissioner as well as on appeal and in response to the representations received on the appeal.

6.79 The Committee noted the contradictory information provided by the Applicant as in the original application form it is stated "…*any unwanted medicines should be arrange to be collected from their house*", however the Commissioner's decision letter had stated that when this had been questioned by Community Pharmacy Staffordshire and Stoke on Trent, the Applicant had confirmed that *"Medicines disposal units within the pharmacy are for internal medicines waste only. For patients to dispose of medicinal waste they are sign-posted to local services around them where medicines can be disposed of. If this is not an option, we notify patients of the possibility of collection, however this would be arranged via their local health authority"*

6.80 In the appeal, the Applicant had confirmed that "*any unwanted medicines should be taken to their nearest NHS commissioner pharmacy or GP surgery for disposal."* The

Applicant had gone on to state "*We acknowledge the confusion caused by the previous wording and have clarified this in our SOP."*

6.81 The Applicant further stated, in its appeal *"Clarification on Waste Disposal: All patients will be advised to use their nearest NHS pharmacy or GP surgery for medicine returns. Our floor plans' waste section is intended for internal use only*."

6.82 The Committee noted that the process regarding the disposal of unwanted medicines has been raised by parties in representations in which it was stated by Pharmacy Sales & Consultancy on behalf of Dean and Smedley that "*should the application be granted the appellant will be contractually obliged to provide this essential service for anyone in England who wishes to use it."* Further, Community Pharmacy Staffordshire and Stoke on Trent had made reference to the collection of unwanted medicines and stated "*it is not clear that the applicant is aware that patients should have several options for disposal of unwanted medicines"* and concluded that "*the disposal service should be advertised on the website/app and marketing leaflets."*

6.83 The Applicant had responded to these points and stated "*Medical waste disposal: Patients will be reminded that any unwanted medication should be taken to their nearest NHS commissioner pharmacy or GP surgery for disposal. We will have a dedicated page on our website to signpost patients to their nearest NHS commissioned pharmacy for safe disposal of medication. Patients have several options available as there are many places across the UK that provide this service. Just to give an example there are around 12 different pharmacies in Burton on Trent that provide safe disposal of medication hence this gives patients lots of options"*.

6.84 The Committee was mindful of the Terms of Service as set out in paragraphs 13-15 of Schedule 4 for the Applicant to accept and dispose of unwanted drugs presented to it. Given that the Applicant was not proposing to accept any unwanted drugs, the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 13-15 of Schedule 4.

Promotion of healthy lifestyles

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

6.86 The Committee noted that no information on this had been provided by the Applicant either in the original application form, in the form of SOPs, on appeal or in subsequent representations.

6.87 The Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 16-18 of Schedule 4.

Prescription linked intervention

6.88 The Committee considered whether the Applicant had explained how it will assess whether persons require prescription linked intervention advice because they have diabetes, are at risk of coronary heart disease, smoke or are overweight.

6.89 The Committee noted that no information had been provided by the Applicant either in their original application form, on appeal or in subsequent representations.

6.90 Therefore the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 17 of Schedule 4.

Health campaigns

6.91 The Committee considered whether the Applicant had explained how it will safely and effectively participate in health campaigns, if and to the extent required by the Commissioner.

6.92 The Committee noted the statement from the Applicant that "*we will have a dedicated page on our website that promotes Public Health. This ensures that the patient receives the necessary support without breaching regulations."* The Committee noted that there was no further information provided as to how the pharmacy would safely and effectively participate in health campaigns.

6.93 The Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 18 of Schedule 4.

Signposting

6.94 The Committee considered whether the Applicant had explained how it will provide information to users of the pharmacy about other health and social care providers and support organisations.

6.95 The Committee noted that apart from the statement from the Applicant that "*we will have a dedicated page on our website to signpost patients to their nearest NHS commissioned pharmacy for safe disposal of medication*" there was nothing further provided with regard to how the Applicant was proposing to provide information to users about other health and social care providers and support organisations.

6.96 The Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 19-20 of Schedule 4.

Support for self-care

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

6.98 The Committee noted that no information had been provided either in the initial application form, on appeal or in subsequent representations.

6.99 Given the lack of information the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 21-22 of Schedule 4.

Discharge medicines service

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

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

6.102 The Committee noted that the Applicant had provided no information either in its initial application, subsequent appeal or representations with regard to the Discharge Medicines Service. Given the lack of information the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 22B and 22C of Schedule 4.

Website health and promotion zones

6.103 The Committee considered whether the Applicant had explained how it will ensure that it has a website for us by the public for the purpose of accessing pharmaceutical services from those premises, on which there is an interactive page, clearly promoted to any user of the website when they first access it, which provides public access to a reasonable range of up to date materials that promote healthy lifestyles by addressing a reasonable range of health issues.

6.104 The Committee noted references by the Applicant to use of the website and that there would be a "*dedicated page that promotes public health*" as well as being able to "*signpost patients who needed to dispose of medication*", however there was no further reference to the Applicant's website including an interactive web page for patients to access nor the services provided by the Applicant.

6.105 Given the lack of information the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 28C of Schedule 4.

Summary

6.106 On the information before it, the Committee could not be satisfied that there are procedures likely to secure the safe and effective provision of essential services as required by Regulation 25(2)(b).

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

6.107.1 confirm the Commissioner's decision;

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

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

6.108 Given that the Commissioner had not considered all aspects of the Regulations, the Committee determined that the decision of the Commissioner must be quashed.

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

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

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

7 Decision

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

7.2 Accordingly, the Committee:

7.2.1 quashes the decision of the Commissioner; and

7.2.2 redetermines the application as follows -

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

7.2.2.2 the Committee was satisfied that the premises of the Applicant are not on the same site or in the same building as the premises of a provider of primary medical services with a patient list,

7.2.2.3 the Committee was not satisfied that all essential services were likely to be secured without interruption during the opening hours,

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

7.2.2.5 the Committee was not satisfied that all essential services were likely to be secured in a safe and effective manner,

7.2.2.6 the Committee was not satisfied that all essential services were likely to be secured without face to face contact;

7.2.3 The application is refused.

Case Manager
Primary Care Appeals