NHS Resolution

18 September 2025

REF: SHA/26642

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APPEAL AGAINST BLACK COUNTRY ICB DECISION TO REFUSE AN APPLICATION BY GOODCURE LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT UNIT 25, DOULTON TRADING ESTATE, DOULTON ROAD, ROWLEY REGIS, B65 8JQ 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:

Goodcure Ltd
PCT Healthcare Ltd
Jhoots Pharmacy
PCSE on behalf of Black Country ICB

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1 The Application

By application dated 19 October 2024, Goodcure Ltd ("the Applicant") applied to Black Country ICB ("the Commissioner") for inclusion in the pharmaceutical list at Unit 25, Doulton Trading Estate, Doulton Road, Rowley Regis, B65 8JQ under Regulation 25. In support of the application it was stated:

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

1.1.1 "none.

1.1.2 The pharmacy will be providing Essential Services. It is not intended that appliances will be provided."

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

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

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

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

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

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

1.5 "The pharmacy will have all the necessary technical systems in place in working order to ensure that uninterrupted provision of essential services will take place during working hours.

1.6 Our essential services are only accessible at a distance - patients can contact us through phone, email, or through our website. Likewise healthcare professionals can issue prescriptions to us via the EPS system in place (which will be active after NHS contract is in place and the pharmacy obtains the ODS code). Both patients and healthcare professionals likewise can post physical prescriptions to our registered pharmacy address.

1.7 In terms of specific systems, we employ the use of Rx:Web which is a well known and reliable dispensing system used by thousands of pharmacies UK wide. This system will be used to dispense medication.

1.8 We also use the Trello work management software. This software allows us to Triage and organise all incoming patient requests and to deal with them in the most appropriate manner. We feel that this is important as it allows us to attend to the needs of our patient is the quickest, and most robust fashion. All channels of communication that we have available for the public will feed into this software.

1.9 We have clear guidelines in place in our SOPs to ensure that provision of services is carried out to the required standard during work hours.

1.10 We also provide clear guidance to service users on our website with respect to the services available from our pharmacy and how to access such services."

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

1.11 "The Premises is located within a secure unit that is not readily accessible to the general public. However should a patient attend the premises and requests an essential service face to face, they would be advised that this will contradict our contractual NHS agreement as we are a distance selling pharmacy. However as part of our duty of care, we would also liaise with the patient and arrange to provide the requested service at a distance if necessary. This would naturally depend on the specific situation and the specific service requested."

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

1.12 "We do not intend to provide any advanced services at the premises currently. However, should this change, we would endeavour to ensure any element of essential services are not provided face to face. This largely involves making the patient aware of what is defined as an essential service and an advance service and providing them with the necessary means to access any requested service in a practical manner. For example, if we decided to carry out advanced services in the future at the premises face to face (such as the NMS service as an example), and the patient happens to bring a prescription with them, we would advise that this prescription should be posted to our pharmacy address and we would deliver the treatment to your home (or chosen address) free of charge. We would also direct the patient to our website, specifically our "about us" section and the FAQs section which discusses what we can and cant do face to face as a distance selling pharmacy in detail."

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

1.13 "We have enclosed the SOPs for your reassurance. For further information please do not hesitate to get in touch.

1.14 Our website address is: www.goodcurepharmacy.co.uk

1.15 IMPORTANT NOTE: This website is password protected. This is because it advertises NHS services that we intend to provide after the NHS contractual agreement is in place. However, until then we are unable to advertise our services to the public.

1.16 Having said that if you wish to access the website to support our application, and to see the information and availability of services to patients, please do get in touch and we will provide you with the password to access it. (Note that the password is changed regularly for security purposes therefore if access is denied please let us know as it may be an old password that you are trying to use)."

2 The Decision

The Commissioner considered and decided to refuse the application. The decision letter dated 20 June 2025 states:

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

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

Extract from the Pharmacy Services Regulations Committee 8th April 20205

2.2 "Distance Selling Premises – excepted application

2.3 Goodcure Ltd CAS-334776-K1S4B9

2.4 Unit 25, First Floor, Doulton Trading Estate, Doulton Road, Rowley Regis, B65 8JQ

2.5 Decision:

Regulation 31 – refusal: same or adjacent premises

2.6 Regulation 31 (1) A routine or excepted application, other than a consolidation application, must be refused where paragraph (2) applies.

2.7 Regulation 31(2)(a) (i) (ii) There is no pharmacy providing pharmaceutical services at the same or adjacent premises.

2.8 As Regulation 31(2)(a) does not apply, the Committee is not required to consider Regulation 31(2) (b)

2.9 Therefore, the Committee concluded that it was not required to refuse the application under the provisions of Regulation 31.

2.10 The Committee then went on to consider Regulation 25.

Regulation 25 – Distance Selling Premises Applications

2.11 Regulation 25(2)(a) – The NHSCB must refuse an application to which paragraph 1 applies-

2.12 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.

2.13 The Committee was satisfied that the proposed premises are not on the same site or in the same building as the premises of a provider of primary medical services with a patient list.

2.14 The applicant did not provide details within the application form, however the proposed premises are not on the same site or in the same building as the premises of a provider of primary medical services with a patient list.

2.15 This is confirmed with information available on the NHS.UK website where the nearest general practice is located 1 mile away.

2.16 Therefore, the Committee concluded that it is not required to refuse the application under Regulation 25(2)(a).

2.17 Regulation 25(2)(b)(i) – The uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services.

2.18 The Committee was not satisfied that pharmacy procedures meet the standard required to satisfy the regulatory requirements of the uninterrupted provision of essential services to anyone in England who request such services. If CD items are to be delivered by the pharmacy driver, it will be impossible to provide a nationwide service, and therefore a breach of DSP regulations. There is no clear definition of what the local area is, so unclear how far the designated delivery driver would be expected to travel. The procedures adopted by the pharmacy are not likely to secure the safe and effective provision by the Applicant of Essential Services to persons anywhere in England.

2.19 Therefore, this regulation is deemed to have not been met.

2.20 Regulation 25(2)(b)(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.

2.21 The Committee was not satisfied that the pharmacy procedures meet the standard required to satisfy the regulatory requirements of the provision of essential services without face to face contact. The procedures adopted by the pharmacy are not likely to secure the safe and effective provision of Essential Services to persons anywhere in England. No information was available on how other Essential Services such as provision of health lifestyle advice or public health campaigns would be delivered. As no information provided, there is no assurance that these Essential Services would be provided.

2.22 Therefore, this regulation is deemed to have not been met.

2.23 The Committee refused the application.

2.24 The Committee determined that the applicant has been granted appeal rights.

2.25 Specific conditions – Distance Selling Premises

2.26 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 Sandwell Health and Wellbeing board in respect of the premises included in the application, that inclusion will be subject to the following conditions:

2.26.1 The applicant must not offer to provide pharmaceutical services to persons who are present at (which includes in the vicinity of) the proposed premises.

2.26.2 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.

2.26.3 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.

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

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

2.26.4.2 – 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

2.26.5 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:

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

2.26.5.2 – 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 (eg because the availability of essential services from the applicant is limited to other categories of patients)."

3 The Appeal

Using the online form for pharmacy application appeals dated 24 June 2025, the Applicant appealed against the Commissioner's decision. The grounds of appeal are:

3.1 "We would like to appeal the decision of refusal made by the committee on the grounds that the following regulations we deemed not to have been met:

3.1.1 Regulation 25(2)(b)(i)

3.1.2 Regulation 25(2)(b)(ii)

3.2 With respect to Regulation 25(2)(b)(i) that was deemed not to have been met.

3.3 The Black Country ICB have stated that this regulation has not been met, siting the following reason:

"If CD items are to be delivered by the pharmacy driver, it will be impossible to provide a nationwide service, and therefore a breach of DSP regulations. There is no clear definition of what the local area is, so unclear how far the designated delivery driver would be expected to travel."

3.4 With the greatest respect to the BC ICB, we disagree with this statement and we believe that they have misunderstood the wording in the SOPs. They are under the assumption that the intent is that our "in house" pharmacy driver will be responsible for providing delivery of CD items all around the nation, which is not correct. The SOP 24 (Dispatch and Transport) [sic] states the following:

3.4.1 *"Items are delivered either by a local driver, courier, or an established delivery service such as Royal Mail.*

3.4.2 *Items within the local area (as determined by the Manager) should be delivered by the designated delivery driver.*

3.4.3 *All items (except controlled drugs (CDs) and refrigerated items) that are outside the local designated area should be delivered by Royal Mail.*

3.4.4 *Prescriptions containing CDs or refrigerated items that are to be delivered outside the local designated area should be delivered by designated delivery driver."*

3.5 This means that should a CD item need to be delivered outside of what is considered the "local vicinity" this would be delivered by a designated delivery driver. This involves the use of any courier service which is suitable to provide this treatment safely and securely. It is not to say that the pharmacy "in house" driver will be delivering the item, hence we have not used the word "local". A suitable courier driver service will be deemed one that provides a signed service and can return the product to the pharmacy in the event of a failed delivery.

3.6 We understand well that this may not be considered financially viable (for example, delivering just one item to another county for free), however we are prepared to do so since we are obliged to ensure provision of services nationwide. We are also aware that such requests are not likely to be plentiful in number and thus are prepared to cover the costs.

3.7 A specific "local" area has not been defined, since this will be reviewed on a case-by-case basis, considering the urgency of the request as well as the financial and practical implications. For example, it would be practical for the "in house" driver to deliver CD items to a location that is considered out of area (within reason) if there are other items that they are delivering other items in the local vicinity of the CD item location.

3.8 We respectfully disagree with the decision that the secure and safe provision has not been met with respect to this regulation due to the aforementioned reasons.

3.9 With respect to Regulation 25(2)(b)(ii) that was deemed not to have been met.

3.10 The notes provided from the committee meeting have not provided any clear specific reason why they feel that this provision of such services will not be possible to the required standard.

3.11 We would like to assure your good selves as well as the Committee that essential services such as promotion of healthy lifestyle choices, and the engagement in national public health campaigns would be carried out via our website (https://goodcure.co.uk) as well as secure means of contact that we have with patients and service users such as phone, email and WhatsApp. This has been stated in the original application.

3.12 I earnestly hope that you accept our appeal. We are eager to be a part of the NHS mission to provide healthcare to the public."

4 Comments to the Commissioner

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

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

4.1 THE APPLICANT

4.1.1 "Thank you for your letter dated 23rd December 2024 and for providing copies of the written representations regarding our application. We have reviewed the representations and would like to submit the following comments:

Our response to comments raised by Jhoots Pharmacy:

4.1.2 The guidance around refusal of face-to-face service to patients and explaining why we have done so is provided in light of the exceptional circumstance that a patient may present to the pharmacy. This is unlikely since our premises are located in a secure area, requiring patients to pass through multiple locked doors/ gates. Likewise it should be noted that the guidance is an explanation to the patient that we cannot provide face to-face service, not signposting as has been alluded to in the comment. We feel that this is not in breach of the guidance set for distance selling pharmacies, which stipulates that all essential services must be carried out at a distance and not face-to face. Rather, we feel that this is a duty and the only reasonable and professional action to be taken in such a scenario.

Our response to comments raised by PCT Healthcare Ltd:

4.1.3 With respect to the statement that the storage of medicines in the fridge may affect efficacy, we believe this is inaccurate since it is not in contradiction to the storage requirements set by manufacturers, which state that products must be stored at temperatures below 30 degrees Celsius. There is no stipulation for products to be stored in temperatures exceeding 8 degrees Celsius. This is in respect to the products that we have in stock currently and or will expect to have in stock.

4.1.4 Regarding the concerns raised about SOP 14, specifically concerning the supply of controlled drugs, it should be noted that the guidance is specifically regarding deliveries made by an employee of the pharmacy. It is not to suggest that we do not provide the same service to patients who do not live in the local vicinity. Where appropriate, we will deliver controlled drugs via reputable external postal services. In such situations, we will liaise with the patient before sending their treatment out for delivery to ensure that they will be present for collection. Where there is a collection failure, the items will be returned to the pharmacy in the same day. The only difference in such situations is that the medicines cannot be re-delivered to the patients, in keeping with regulations, as it has been outside of the possession of the pharmacy/pharmacy staff. Please note that such situations are expected to be rare and infrequent. We will always review our SOPs on a regular basis and, where necessary, adapt our policies to ensure that

service provision is safe, efficient, and in keeping with regulations and/or contractual obligations.

Response to comments Raised by CPS:

4.1.5 Regarding the statement that the Black Country ICB must assure itself that the applicant is able to meet the requirements of regulation 9 should the applicant wish to provide advanced services at the premises, we wish to note that it is not intended that advanced services will be provided at the premises. We intend to provide advanced services at a distance, just like essential services, where this is practical and clinically appropriate. We are aware that should advanced services be provided on site, care must be taken to avoid the provision of essential services, such as the dispensing of prescription, signposting and the like.

4.1.6 Should you require any further information or clarification, please do not hesitate to contact us."

5 Amendments to Regulation 25

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

5.1 THE APPLICANT

5.1.1 "Thank you for your letter dated 1 July 2025 regarding the amendments to Regulation 25 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, which came into force on 23 June 2025, and the impact of these changes on our application currently under appeal.

5.1.2 We welcome the opportunity to provide the following comments in support of our application, which we believe remains fully compliant with the revised requirements for distance selling pharmacies (DSPs).

Nationwide Provision of Essential and Public Health Services

5.1.3 I can confirm that Goodcure Ltd will ensure the uninterrupted provision of pharmaceutical services to individuals anywhere in England, as required under Regulation 25(2)(b)(i). This includes not only the core dispensing and clinical advisory functions but also participation in relevant public health initiatives.

5.1.4 Specifically, we confirm that our service offering includes:

5.1.4.1 Engagement with Healthy Living Pharmacy (HLP) principles, including health promotion campaigns, self-care education, and signposting.

5.1.4.2 Delivery of current NHS initiatives such as the Smoking Cessation Service, Hypertension Case-Finding, and weight management referrals, as well as the promotion of flu and COVID-19 vaccination information, sexual health guidance, and more.

5.1.4.3 The provision of medication dispensed against a valid prescription to all patients and service users in England.

5.1.5 To support this, our public-facing website will serve as a key access point for the public, featuring:

5.1.5.1 Regularly updated health education content, articles, and NHS resource links.

5.1.5.2 A secure and easy-to-use online form through which patients may request counselling or healthy living advice from a pharmacist.

5.1.5.3 Clear contact details, including telephone access for real-time advice and support.

5.1.6 All services will be provided uniformly across England and not limited to any particular region or locality, in line with the fundamental requirements of a DSP.

Remote-Only, Safe and Effective Service Delivery

5.1.7 In compliance with Regulation 25(2)(b)(ii) we can confirm that no services will be provided to patients/ service users face-to-face at the pharmacy premises. Our service model is fully remote and operates through telephone, secure digital channels, and reliable postal or courier delivery services.

5.1.8 Robust standard operating procedures (SOPs), professional training, and IT infrastructure are in place to ensure that all services are delivered safely, effectively, and in full compliance with DSP regulations.

5.1.9 Updated SOP for Controlled Drug Deliveries

5.1.10 For your knowledge, I wish to inform you that as per routine review of our SOPs, we have made several updates. From them are the following:

5.1.10.1 the section relating to the delivery of Controlled Drugs (CDs) to reflect best practices and regulatory expectations. The updated wording now states:

"*A suitable postage method that can provide a tracked and signed service and will return the items in the event of failed delivery, will be used to deliver CDs.*"

5.1.10.2 This revision clarifies that the handling of CDs is secure, accountable, and patient-focused, with contingencies in place for non-delivery. It also demonstrates that service provision is applicable to the whole of England as per regulatory requirements.

5.1.10.3 Changes to the wording “Essential services” to pharmaceutical services in line with the changes in regulations.

5.1.11 We believe the above demonstrates that our application remains compliant with the amended requirements of Regulation 25. We respectfully request that the appeal process continues on this basis and would be happy to provide any additional information if required.”

6 Summary of Representations

This is a summary of representations received on the appeal.

6.1 THE COMMISSIONER

6.1.1 “The Committee considered the appeal received and felt that the additional information provided from the applicant to NHS Resolution in relation to the provision of Essential Services, is new information that was not available to Committee at the time a decision was made. If that information was available, the Committee may have come to a different conclusion. It is accepted that it was not a requirement of the Regulations at the time of determination to provide information in relation to provision of Advanced and Enhanced Services.”

6.2 PCT HEALTHCARE LTD

6.2.1 “Further to the letter dated 15 July 2025 regarding the above application. PCT Healthcare Ltd, trading as Peak Pharmacy in this locality, wish to submit the following representations.

6.2.2 PCT Healthcare Limited supports the decision made by Black Country ICB to refuse the above application as the applicant failed to meet the requirements of:

6.2.2.1 Regulation 25(2)(b)(i)

6.2.2.2 Regulation 25(2)(b)(ii)

6.2.3 Regulation 64(3) sets out conditions that distance selling premises must comply with. One of those is that the pharmacy procedures for the premises must secure the uninterrupted provision of essential services during core and supplementary opening hours to persons anywhere in England who request those services, the application does not fully explain how this will take place.

6.2.4 Essential pharmacy services cannot be provided to patients who are present at a distance selling pharmacy premises. This applicant does

not satisfy the criteria, that there would be safe and effective provision of essential services without face-to-face contact with patients or carers.

6.2.5 Regarding the Standard Operating Procedures (SOPs) provided by the applicant which outline how the NHS Regulations shall be met, PCT Healthcare Limited submit following observations.

6.2.6 Within SOP 1 – General Working Practices: on page 11

6.2.7 Fridge items and Controlled Drugs

"All Fridge items must be stored in the fridge at any stage of the process. The Fridge compartments are divided into "stock items", "Awaiting Final Check" and "Awaiting Delivery". The prescription products must be stored in the appropriate place. The whole prescription must be placed in the fridge if there is least one fridge item in it."

6.2.8 Note: The storage of non-fridge items in a fridge can affect their efficacy.

6.2.9 PCT Healthcare Limited advises that the incorrect temperature storage of medication can affect their efficacy. Medication that should not be refrigerateed [sic] to name a few are Adrenaline Auto-injetors [sic], EpiPens, and certain Nitroglycerin Tablets, full details are available in the indidividual [sic] drug SPCs, the medications listed here are used in emergency situations and it is a concern that the applicant is unaware of these storage conditions.

6.2.10 On page 63 as part of the SOP 14 – Processing FP10MDA Prescriptions

FP10MDA prescriptions will be collected by the driver from local drugs and Alcohol services in a weekly manner

In the event that the presecription [sic] is not delivered. The driver will bring the item back. The item should then be stored in the CD cupboard, as it has been under the possession of pharmacy staff, in a controlled environment (ie the delivery van) and remained in a sealed, tamperproof bag.

FP109MDA presecriptions [sic] are not to be sent by external postal services.

6.2.11 How shall Regulation 64(3) be complied with regarding the provision of services to persons anywhere in England who request this service? What about an FP10MDA prescription for a patient in Plymouth or Truro, for example.

6.2.12 As a Distance Selling Pharmacy the services offered must be comparable to every patient throughout England, irrespective of their location. The disparity of service for patients close to Rowley Regis versus those outside the applicant's description of "local" implies that the applicant will offer differing essential service provision to patients

based on their geography which is clearly against the Regulations for a Distance Selling Pharmacy.

6.2.13 As a Distance Selling Pharmacy services cannot be limited to a locality and must be available on a nationwide basis, once again there are no specifics within the application indicating how this requirement shall be met.

6.2.14 In addition, Supervised Consumption contracts are set up to be operated by an accredited pharmacist who is responsible for providing the services within a pharmacy in keeping with the published guidelines of the commissioner and the Service Specification. A delivery driver is not an accredited pharmacist.

6.2.15 In the original application on page 63 it states that:

" FP10MDA presriptions [sic] *are not to be sent by external postal services."*

6.2.16 In the applicant's appeal letter dated 25th December 2024, they clearly state with regards to SOP 14 (processsing FP10MDA) [sic] "delivery of controlled drugs will only be made by an employee of the pharmacy." This appeal letter then goes on to state that delivers of controlled drugs shall be delivered via reputable external postal service referring to SOP 14.

6.2.17 Additionally the letter states referring to SOP 14 "where there is a collection failure, the items will be returned to the pharmacy the same day." Once again we respectfully ask NHS Resolution to review how an item shall be returned the same day to the pharmacy where there is a delvery [sic] failure in Truro when the pharmacy closes at 5pm each day.

6.2.18 This application does not fully explain how this will take place.

6.2.19 Within SOP 12 Management of Controlled Drugs (CDs) in Pharmacy Operations

6.2.20 On page 84 there is a section that states:

When a CD contained prescription is made up and awaiting delivery, the CD is stored in the CD cabinet and a CD sticker is placed on the bag, such that the driver is aware that there is a CD that needs to be collected from the CD cabinet. Likewise the case for Fridge items.

Where the prescription only contains a CD, a bag label and a CD sticker is attached to the delivery sheet so that the driver is aware of the prescription.

6.2.21 The nature of how this SOP is written once again suggests that the Management of Controlled Drugs is undertaken by a delivery driver covering a "local area" once again with no detail as to how the more distant areas of England are dealt with. This SOP indicates a two tier

system within the SOPs of this application for those close to the pharmacy and those wwho [sic] live further away.

6.2.22 PCT Healthcare Limited request the NHS Resolution review the revised SOP comments from the applicant with regards to deliveries for those patients within Rowley Regis and then for pateints [sic] further afield e.g. Truro for general prescriptions items, those items requiring special storage conditions, and controlled drugs.

6.2.23 Within SOP 19 Temperature and Environmental Control

6.2.24 On page 78 there is a section that states:

If the fridge temperature likewise falls below the recommended range, then in the first instance the medication should be clearly segregated by placing in a clear plastic bag, ensuring to write on the bag "QUARANTINED (and include the date). Advice should be sought from the manufacturer regarding this medication. The temperature excursion should be raised to the pharmacy manager.

It is upon the SP to investigate whether there is a fault with the fridge which means that this is likely to happen again. If so, arrangements must be made as soon as possible to fix the fridge/ obtain a new one.

6.2.25 There is however no detail within the SOPs to indicate the action that would be taken by the pharmacy team should the fridge temperature deviate above 8 celsius [sic].

6.2.26 Within SOP 24 Dispatch and Transport

6.2.27 On page 94, there is no detail regarding the assurance of the "cold-chain" being maintained and monitored from the pharmacy to the patient. Neither for deliveries in the local environ of Rowley Regis nor on a national basis. Within this SOP there is this statement:

All items (except controlled drugs CDs) and refrigerated items) that are outside the local designated area should be delivered by Royal Mail.

6.2.28 This application is required to fully meet the criteria within Regulation 25, and we wish NHS Resolution to specifically consider Regulation 25(2)(b)(ii) regarding this application.

6.2.29 Additionally, we trust that the SOPs will satisfy NHS Resolution in other key areas such as:

The manner in which the applicant would communicate and action drug recalls and alerts.

Action the applicant will take in the event of being unable to fulfil a prescription completely (i.e., how they will deal with 'owings').

6.2.30 We also ask NHS Resolution to satisfy themselves that the applicant, from the evidence within the application will ensure that all

communication, whether on their website, practice leaflet or via mailshots / local advertising and the like, complies with GPhC's "Guidance for Registered Pharmacies Providing Pharmacy Services at a Distance, Including on the Internet" Principle 4.1 in relation to transparency and choice.

6.2.31 PCT Healthcare Limited t/a Peak Pharmacy would like to be informed of the outcome of this appeal, and we would wish to attend the Oral Hearing, should one be deemed necessary."

7 Late Representations

7.1 JHOOTS PHARMACY

7.1.1 "Thank you for your letter dated 15th July 2025 enclosing the appeal with regards to the above application that was refused by NHS England.

7.1.2 For consideration we enclose a copy of the representations we sent to the NHS Primary Care Team dated 16th December 2024 as part of the original consultation. We believe those comments remain applicable and stand by these for your consideration."

In a letter dated 16 December 2024 addressed to the Commissioner, Jhoots Pharmacy stated:

7.1.3 "Thank you for your letter dated 25th November 2024 enclosing a copy of the application listed, to provide pharmaceutical services under Regulation 25 as a Distant Selling Pharmacy. As an interested party Jhoots pharmacy would like to submit the following response to be taken into consideration.

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

7.1.5 The application does not provide sufficient evidence as to how the provision of essential services will be provided without face to face contact. We note the application does say "should a patient attend the premises and requests an essential service face to face they would be advised that it would contradict…" this would imply patients may be advised or signposted on the premises.

7.1.6 We submit this application does not meet Regulation 25."

8 Summary of Observations

This is summary of observations received.

8.1 THE APPLICANT

8.1.1 "I write on behalf of Goodcure Ltd to provide our rebuttal to the representations submitted in response to our appeal, as invited by NHS Resolution's letter of 18 August 2025. In accordance with the guidance,

this rebuttal is confined solely to addressing the matters raised by the parties, without introducing new issues.

Response to PCT Healthcare Ltd / Murrays Healthcare (7 August 2025)

8.1.2 PCT Healthcare suggest that our Standard Operating Procedures (SOPs) and processes fail to demonstrate compliance with Regulations 25(2)(b)(i), 25(2)(b)(ii) and 64(3). We respectfully rebut these assertions as follows:

8.1.3 Provision of Services Nationally (Reg 64(3))

8.1.4 Our application makes clear that essential services will be provided to any patient in England without geographical restriction. References within SOPs to “local” arrangements describe operational logistics, not service limitations.

8.1.5 Patients in Truro, Plymouth, or elsewhere will receive the same uninterrupted service as those in Rowley Regis.

8.1.6 Safe and Effective Delivery Without Face-to-Face Contact (Reg 25)

8.1.7 The model of a Distance Selling Pharmacy necessarily excludes provision of essential services to walk-in patients. Our SOPs explicitly state that face-to face services will not be provided at the premises. Patients who attend in person will be signposted appropriately, consistent with regulatory requirements

8.1.8 Storage and Cold Chain Management

8.1.9 PCT Healthcare highlight concerns about fridge storage and cold chain maintenance. Our SOPs require separation of fridge and ambient items within prescriptions, in line with clinical safety standards. Medicines unsuitable for refrigeration (e.g. adrenaline auto-injectors, nitroglycerin tablets) will not be stored in a fridge. The SOP wording may have been misunderstood, but our operational procedures comply fully with manufacturers’ SPCs and GPhC standards. In addition, our cold chain SOP includes continuous monitoring, with contingency measures if temperatures exceed 8°C, ensuring medicine integrity at all times.

8.1.10 Controlled Drugs (CDs)

8.1.11 Our SOPs state that CDs will not be sent via standard external postal services. Instead, CDs will be provided either by appropriately trained Goodcure Ltd staff or via a specialist courier service suitable to provide this treatment safely and securely. Such deliveries will always require signed receipt to ensure a full audit trail, and in the event of a missed delivery, items will be returned to the pharmacy. Responsibility for CDs will always remain with the Responsible Pharmacist, ensuring full compliance with legal and professional requirements, whist maintaining adequate service provision nationwide.

8.1.12 Service Failures and Recalls

8.1.13 PCT Healthcare suggest insufficient clarity on recalls, alerts, and 'owings'. These matters are addressed comprehensively within our SOPs, which include escalation protocols and communication procedures in line with NHS and MHRA requirements.

8.1.14 In summary, PCT Healthcare's concerns are either based on misinterpretations of the SOPs or matters already addressed. We also respectfully note that as a large, established operator in the locality, PCT Healthcare has a direct commercial interest in preventing a new entrant, which may explain the nature of some of the points raised.

Response to West Midlands ICB (14 August 2025)

8.1.15 We welcome the acknowledgement by the West Midlands ICB that information subsequently provided "*may have led the Committee to a different conclusion*" had it been available at the time of the original decision. This directly supports the appropriateness of allowing our appeal.

8.1.16 Furthermore, the ICB confirmed that it was not a requirement under the Regulations at the time of determination to provide information on Advanced and Enhanced Services. This validates that our original application was compliant with the Regulations in force.

Response to Jhoots Pharmacy (15 August 2025)

8.1.17 Jhoots Pharmacy repeat their earlier objection that essential services cannot be provided without face-to-face contact. This is a clear misunderstanding of the Distance Selling Pharmacy model as well as our operational model and Standard Operating Procedures. By law, essential services must be provided without requiring patients to attend the premises, and our SOPs set out precisely how this is achieved.

8.1.18 We have made it very clear that in the very unlikely event that patients mistakenly attend the premises, our SOPs specify that no essential services will be provided face-to-face; instead, patients will be advised with respect to this in compliance with Regulation 25. This approach aligns fully with NHS and GPhC requirements.

8.1.19 We also observe that Jhoots' representations largely repeat earlier consultation responses and are made by another local competitor with a clear financial interest. This context should be borne in mind when weighing the weight and substance of their objections.

Conclusion

8.1.20 The objections raised do not demonstrate any failure by Goodcure Ltd to meet the requirements of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013. On the contrary, our SOPs and operating model are fully compliant, ensuring safe, effective, and nationwide delivery of pharmaceutical services.

8.1.21 It is also noted that the objections from existing local contractors are primarily made by competitors with an evident commercial interest in restricting market entry. While we acknowledge their right to comment, such financial motivations should not outweigh the clear regulatory compliance and robust patient safeguards demonstrated in our application.

8.1.22 Above all, Goodcure Ltd.'s entry onto the NHS Pharmaceutical List will improve patient safety, access, and choice, ensuring equitable availability of essential services for all patients in England, regardless of location. This outcome aligns squarely with the objectives of the NHS to protect patients, expand access, and support modern models of care.

8.1.23 We therefore respectfully submit that the Pharmacy Appeals Committee should allow this appeal and grant inclusion of Goodcure Ltd in the NHS Pharmaceutical List as a Distance Selling Pharmacy."

9 Consideration

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

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

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

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

Regulation 31

9.5 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).

9.6 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.

9.7 The Committee noted the conclusion of the Commissioner that "*there is no pharmacy providing pharmaceutical services at the same or adjacent premises*" and "*therefore it was not required to refuse the application under the provisions of Regulation 31"*. The Committee noted that this had not been disputed either on appeal or in subsequent representations. The Committee therefore determined that it was not required to refuse the application under the provisions of Regulation 31.

Regulation 25

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

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

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

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

in respect of pharmacy premises that are distance selling premises.

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

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

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

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

(ii) the safe and effective provision of pharmaceutical services without face to face contact at the pharmacy

premises between any person receiving the services, whether on their own or on someone else's behalf, and the applicant or the applicant's staff.

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

Additional information to be included with excepted applications

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

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

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

Nature of details to be supplied

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

Regulation 25(1)

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

Regulation 25(2)(a)

9.11 The Committee noted that the Applicant had not included any information in the relevant section of the application form that deals with this point. The Committee noted that the application form states that the relevant section should only be completed if the proposed premises are on the same site or in the same building as the premises of a provider of primary medical services with a patient list. The Committee considered that, where the Applicant did not include any information in this section, it was reasonable to consider that the Applicant was indicating that the proposed premises were not on the same site or in the same building as the premises of a provider of primary medical services with a patient list. The Commissioner in its decision report stated "*this is confirmed with information available on the NHS.uk website where the nearest general practice is located 1 mile away*". The Committee noted that

this had not been disputed either on appeal or in subsequent representations so, 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)

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

9.13 The Regulations require the Committee to be satisfied as to a number of matters, including that essential services will be provided on an uninterrupted basis, across England, and that pharmaceutical services will be provided in a safe and effective way without face to face contact.

9.14 Paragraph 8 of Schedule 2 requires an applicant to provide details in relation to an application, and paragraph 10 of Schedule 2 indicates that the obligation is only discharged if the information or documentation provided is sufficient to satisfy the Commissioner in receipt of it, with good cause, that no relevant information or documentation is missing, having regard to the uses that the Commissioner may need to make of the information or documentation when carrying out its functions.

9.15 The Committee has asked itself whether it has sufficient information and documentation which would address the criteria in Regulation 25(2)(b). If the Committee is to be satisfied of the matters in that paragraph, the Committee must be provided with evidence to demonstrate these matters. In this case, that evidence put forward has taken the form of the original application and the SOPs which the Applicant has prepared or commissioned.

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

9.17 In respect of uninterrupted provision, the Committee noted the conclusion of the Commissioner that it "*was not satisfied that pharmacy procedures meet the standard required to satisfy the regulatory requirements of the uninterrupted provision of essential services to anyone in England who request such services"* and had gone on to state "*The procedures adopted by the pharmacy are not likely to secure the safe and effective provision by the Applicant of Essential Services to persons anywhere in England."*

9.18 The Committee noted that the Commissioner had gone on to conclude that it "*was not satisfied that the pharmacy procedures meet the standard required to*

satisfy the regulatory requirements of the provision of essential services without face to face contact."

9.19 The Committee noted, in the information provided, the Applicant states:

9.19.1 "*Our essential services are only accessible at a distance - patients can contact us through phone, email, or through our website. Likewise healthcare professionals can issue prescriptions to us via the EPS system in place (which will be active after NHS contract is in place and the pharmacy obtains the ODS code). Both patients and healthcare professionals likewise can post physical prescriptions to our registered pharmacy address."*

9.20 The Committee further noted the comments from the Applicant with regard to the delivery of medication and SOP 24 "Dispatch and Transport" states "*Items are delivered either by a local driver, courier or an established delivery service such as Royal Mail."* The Committee was of the view that this would ensure that the provision of services was to all of England.

9.21 The Committee noted the comments from PCT Healthcare with regard to a nationwide service and in particular SOP 14 "Processing FP10MDA Prescriptions" which states:

9.21.1 "*FP10MDA prescriptions will be collected by the driver from local Drugs and Alcohol services in a weekly manner*."

9.22 The Committee noted the response from the Applicant which states:

9.22.1 *"Our application makes clear that essential services will be provided to any patient in England without geographical restriction. References within SOPs to "local" arrangements describe operational logistics, not service limitations.*

Patients in Truro, Plymouth, or elsewhere will receive the same uninterrupted service as those in Rowley Regis."

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

9.24 The Committee went on to consider the uninterrupted provision of essential services. The Committee noted the comment from the Applicant that:

9.24.1 "*The pharmacy will have all the necessary technical systems in place in working order to ensure that uninterrupted provision of essential services will take place during working hours*."

9.25 Apart from this statement, the Committee noted that there was no further information provided by the Applicant with regard to the absence of the Responsible Pharmacist. The Committee was of the view that it was not clear, due to the lack of information 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.

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

9.27 The Committee noted the statement from the Applicant that:

9.27.1 *"The Premises is located within a secure unit that is not readily accessible to the general public. However should a patient attend the premises and requests an essential service face to face, they would be advised that this will contradict our contractual NHS agreement as we are a distance selling pharmacy. However as part of our duty of care, we would also liaise with the patient and arrange to provide the requested service at a distance if necessary. This would naturally depend on the specific situation and the specific service requested*."

9.28 The Committee further noted the comments from Jhoots Pharmacy with regard to face to face contact and that this could imply that patients may be advised or signposted on the premises.

9.29 The Committee noted the further comments from the Applicant that:

9.29.1 *"…By law, essential services must be provided without requiring patients to attend the premises, and our SOPs set out precisely how this is achieved.*

We have made it very clear that in the very unlikely event that patients mistakenly attend the premises, our SOPs specify that no essential services will be provided face-to-face; instead, patients will be advised with respect to this in compliance with Regulation 25. This approach aligns fully with NHS and GPhC requirements."

9.30 The Committee was of the view, based on the information before it, that the provision of pharmaceutical services would be without face to face contact.

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

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

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

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

9.34.1 Dispensing of drugs and appliances

9.34.2 Urgent supply without a prescription

9.34.3 Preliminary matters before providing ordered drugs or appliances

9.34.4 Providing ordered drugs or appliances

9.34.5 Refusal to provide drugs or appliances ordered

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

9.34.7 Disposal service in respect of unwanted drugs

9.34.8 Promotion of healthy lifestyles

9.34.9 Prescription linked intervention

9.34.10 Health campaigns

9.34.11 Signposting

9.34.12 Support for self-care

9.34.13 Discharge medicines service

9.34.14 Websites and health promotion zones

9.35 The Committee noted that the Applicant in response to the question on the application form as to whether they were undertaking to provide appliances, stated *"none"* and further *"it is not intended that appliances will be provided".* The Committee was therefore of the view that, if the application was to be granted, the Applicant would not be able to provide any appliances.

9.36 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:

Urgent supply without a prescription

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

9.38 The Committee noted that the Applicant had made no reference, either in the SOPs, 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.

9.39 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

Preliminary matters before providing ordered drugs or appliances

9.40 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.

9.41 The Committee noted that there was no information provided by the Applicant, in the application form or SOPs, as to how the Applicant was going to obtain the evidence initially from the patient regarding their exemption status.

9.42 Given the lack of information the Committee was not satisfied that there would be compliance with paragraph 7(3) of Schedule 4.

Providing ordered drugs or appliances

9.43 The Committee considered whether the Applicant had explained how drugs/appliances will be provided to the patient (including to ensure that (i) that 'cold chain' is maintained, where relevant and (ii) that the requirements of the Misuse of Drugs Regulations 2011 and, in particular, Regulations 14 and 16, are met).

9.44 The Committee noted the comments from PCT Healthcare with regard to the fridge temperatures for cold chain medicines. The Committee noted that this was contained within the pharmacy procedures for when the medication was stored in the pharmacy. The Committee was of the view that this was no different for a distance selling pharmacy than it was for a standard "bricks and mortar" pharmacy and therefore took no view on this.

9.45 The Committee did however go on to consider whether the Applicant had explained how the "cold chain" is maintained for the delivery of thermolabile medications.

9.46 The Committee noted under SOP 24 "Dispatch and Transport" it states:

9.46.1 *1. Delivery Methods*

Items are delivered either by a local driver, courier, or an established delivery service such as Royal Mail.

Items within the local area (as determined by the Manager) should be delivered by the designated delivery driver.

All items (except controlled drugs (CDs) and refrigerated items) that are outside the local designated area should be delivered by Royal Mail.

Prescriptions containing CDs or refrigerated items that are to be delivered outside the local designated area should be delivered by designated delivery driver.

2. Daily Operations:

Items are taken from the pharmacy premises daily by the delivery driver, who will deliver the items to patients, the Royal Mail drop-off point, or the Courier service drop-off point.

The delivery driver will scan the items again when collecting them. This will highlight on the system that they have been sent for delivery, as well as send an SMS/ Message to the patient. All items can be tracked via a tracking number in the Royal Mail R website. [sic] *This number should be sent to the patient so that they can track their items.*

Once items are delivered, the Driver will scan the appropriate barcode to register the items as delivered to either the patient, Royal Mail, or the Courier.

The Driver will also collect any failed deliveries from Royal Mail or the courier and deliver them back to the pharmacy.

Once items are back in the pharmacy, they will be registered as missed deliveries. An SMS/email must be sent to the patient to highlight this.

Items must then be stored appropriately in the pharmacy (i.e., in the missed deliveries area, the fridge, or the CD cupboard).

Staff must liaise with patients to arrange for a future delivery and an agreed date."

9.47 Whilst the Committee noted the comment "*the Driver will also collect any failed deliveries from Royal Mail or the courier and deliver them back to the pharmacy"* there was no information provided as to how the pharmacy would know that there had been a missed delivery by either the courier or Royal Mail. Further, there was no information as to how the temperature for any thermolabile medication would be maintained or monitored once the medication left the pharmacy either where this was being delivered by the pharmacy's own delivery driver or where they were using a courier. The Committee noted that there was no information provided to show what would happen for a missed or failed delivery of a thermolabile medicine.

9.48 The Committee noted the contradictory information from the Applicant with regard to controlled drugs and how they would be delivered. The Committee noted in further representations the Applicant states:

9.48.1 *"Our SOPs state that CDs will not be sent via standard external postal services. Instead, CDs will be provided either by appropriately trained Goodcure Ltd staff or via a specialist courier service suitable to provide this treatment safely and securely. Such deliveries will always require signed receipt to ensure a full audit trail, and in the event of a missed delivery, items will be returned to the pharmacy. Responsibility for CDs will always remain with the Responsible Pharmacist, ensuring full compliance with legal and professional requirements, whist maintaining adequate service provision nationwide."*

9.49 The Committee noted that whilst the Applicant had confirmed that controlled drugs would be delivered by courier, there was no information provided as to how the pharmacy would know that there had been a missed delivery and that they would need to "*collect any failed deliveries from Royal Mail or the courier and deliver them back to the pharmacy*". The Committee further noted that whilst the Applicant had stated "*once items are delivered, the Driver will scan*

the appropriate bar code to register the item as delivered to either the patient, Royal Mail or courier" there was no information provided as to what the pharmacy's own delivery driver would do if there was a missed delivery.

9.50 The Committee was of the view that, apart from its own delivery driver going to pick up a failed delivery from a "*courier collection point"* it had not been provided with any information as to how it would be made aware that there had been a failed delivery of controlled drugs by either the courier or Royal Mail.

9.51 Taking all of the information before it into account the Committee was not satisfied that the Applicant had provided information sufficient to show that there would be compliance with paragraph 8(1) of Schedule 4.

9.52 The Committee considered if the Applicant had explained what containers will be "suitable" for posted/delivered items.

9.53 The Committee noted in "Definitions" in the SOPs it states:

9.53.1 *"Packaging material: Any material, including printed material, employed in the packaging of a pharmaceutical product, but excluding any outer packaging used for transportation or shipment. Packaging materials are referred to as primary or secondary, according to whether or not they are intended to be in direct contact with the product*."

9.54 And further states:

9.54.1 "Picking/ preparing: The process of physically preparing the pharmaceutical products and sticking the pharmacy labels on the packaging as appropriate."

9.55 The Committee also noted the references to packaging within SOP 13 "Processing Prescriptions" however noted that this was in respect of the original packaging used rather than an explanation with regard to the packaging that should be used for items that are to be posted or delivered.

9.56 The Committee was of the view that there was no information provided by the Applicant with regard to what containers will be "suitable" for posted/delivered items. Based on the lack of information, the Committee was not satisfied there would be compliance with paragraph 8(15) of Schedule 4.

Refusal to provide drugs or appliances ordered

9.57 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.

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

9.59 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

9.60 The Committee considered whether the Applicant had indicated 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.

9.61 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.

9.62 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

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

9.64 The Committee noted the comments in the various SOPs regarding the disposal of unwanted drugs including SOP 12 "Management of Controlled Drugs (CDs) in Pharmacy Operations" which states:

9.64.1 "*Schedule 2 CDs which are returned from patients can be destroyed by the responsible pharmacist. Any returned CDs must be recorded in full in the CD patient returns register. This register must be kept for a minimum of 7 years."*

9.65 The Committee further noted SOP 23 "Destruction and Disposal of Pharmaceutical Products" which states:

9.65.1 "*Procedure*

Pharmaceutical products require destruction or disposal in the following scenarios

1) Once currently stocked items reach their expiry date

2) Any unwanted pharmaceutical products are delivered to the pharmacy of the purpose of disposal.

…

Receipt of unwanted pharmaceutical products for disposal

Receiving and disposing of pharmaceutical products is an essential service which all pharmacies in the United Kingdom (including DSPs) must provide. However, as a DSP this service cannot be provided face to face since it is an essential service. Therefore patients must be informed that they cannot come to the pharmacy premises and drop off unwanted goods by hand. Rather this should be delivered to the pharmacy.

The Pharmacy must not accept needles/ sharps as this should be disposed of as per the local council guidelines.

If controlled drugs are received, they should be recorded in the CD patient returns Folder. Items should ideally be disposed of there and then, in the presence of the RP and another member of staff. However if this is not practical, then items should be bagged and labelled as a patient return, as well as the corresponding reference number relating to the folder entry. The item should be stored in the CD cupboard and destroyed as soon as is practical.

CDs must be destroyed via the CD denaturing kits available, in accordance with MHRA guidance."

9.66 However, the Committee noted that whilst the Applicant had stated how they would dispose of any returned medication and that they would not accept medication from patients on a face to face basis and that it "*should be delivered to the pharmacy"* there was no information provided as to how patients would arrange to deliver the medication to the pharmacy.

9.67 Based on the information before it, 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.

Prescription linked intervention

9.68 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.

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

9.70 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

9.71 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.

9.72 The Committee noted the statement from the Applicant that "*we confirm that our service offering includes … Engagement with Healthy Living Pharmacy (HLP) principles; including health promotion campaigns.*" and that to support this "*the public facing website will serve as a key access point for the public, featuring: Regularly updated health education content, articles and NHS resource links …*" The Committee considered that participating in health campaigns was not solely about placing material on-line. The Committee noted that there was no further information provided as to how the pharmacy would safely and effectively participate in health campaigns.

9.73 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

9.74 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.

9.75 The Committee noted the statement from the Applicant that "*we confirm that our service offering includes … Engagement with Healthy Living Pharmacy (HLP) principles; including … signposting*" and that to support this "*the public facing website will serve as a key access point for the public, featuring: Regularly updated health education content, articles and NHS resource links; Clear contact details, including telephone access of real time advice and support…*" The Committee considered that signposting was not solely about placing material on-line. The Committee noted that apart from these statements 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.

9.76 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

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

9.78 The Committee noted the statement from the Applicant that "*we confirm that our service offering includes … Engagement with Healthy Living Pharmacy (HLP) principles; including …self-care education …*" and that to support this "*the public facing website will serve as a key access point for the public, featuring: Regularly updated health education content, articles and NHS resource links; A secure and easy to use online form through which patients may request counselling or health living advice from a pharmacist…*" The Committee considered that support for self-care was not solely about placing material on-line. The Committee noted that apart from these statements 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.

9.79 The Committee noted that no further information had been provided to demonstrate how the Applicant would be providing information about advice and support to people caring for their families.

9.80 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

9.81 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.

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

9.83 The Committee noted that no information had been provided by the Applicant either in its original application and SOPs or in its subsequent appeal with regard to the Discharge Medicine Service and no explanation had been given as to how the Applicant was proposing to provide advice, assistance or support and that there was also no explanation regarding any procedures in place for checking referrals for the discharge medicine service.

9.84 The Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 22B & 22C of Schedule 4.

Other considerations

9.85 The Committee noted the comments from PCT Healthcare with regard to

9.85.1 The manner in which the Applicant would communicate and action drug recalls and alerts; and

9.85.2 Action the applicant will take in the event of being unable to fulfil a prescription completely (i.e., how they will deal with 'owings').

9.86 The Committee was mindful that the Applicant did not need to provide information as to how it would carry out all of the procedures that a pharmacy would carry out during the everyday business of running a pharmacy. The Committee was mindful that it did have to be satisfied that essential services would be provided on an uninterrupted basis across England and that it had the information before it which would address the criteria in Regulation 25(2)(b).

9.87 The Committee was of the view that how the Applicant would communicate and action a drug recall or how it would deal with 'owings' are in essence no different as to how a standard 'bricks and mortar' pharmacy would deal with these processes. The Committee had noted that throughout the SOPs and supporting information the Applicant had confirmed that all correspondence would be via means other than by face to face communication which included the use of email, phone as well as video conferencing. The Committee noted that "owings" as well as "drug recalls" were not specifically listed within Schedule 4 "Terms of Service" and was therefore of the view that this was not something to which it had to have specific regard. However, on the basis of the information provided to it the Committee was satisfied that the Applicant would comply with the Regulations and criteria in respect of these terms of service.

9.88 In relation to all other essential services, the Committee was, on balance, satisfied that procedures adopted by the pharmacy (and general adherence to the Terms of Service) would be "likely to secure" safe and effective provision.

Summary

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

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

9.90.1 confirm the Commissioner's decision;

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

9.90.3 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.

9.91 In those circumstances, given the change in wording to the Regulations since the Commissioner made its decision and based on additional information provided by the Applicant, the Committee determined that the decision of the Commissioner must be quashed.

9.92 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.

9.93 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.

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

10 Decision

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

10.2 The Committee:

10.2.1 quashes the decision of the Commissioner; and

10.2.2 redetermines the application as follows -

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

10.2.2.2 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;

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

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

10.2.2.5 the Committee was not satisfied that pharmaceutical services were likely to be secured in a safe and effective manner; and

10.2.2.6 the Committee was satisfied that pharmaceutical services were likely to be secured without face to face contact.

10.2.3 The application is refused.

Case Manager
Primary Care Appeals