15 May 2026

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REF: SHA/26849

APPEAL AGAINST BRISTOL, NORTH SOMERSET AND SOUTH GLOUCESTERSHIRE ICB DECISION TO REFUSE AN APPLICATION BY JOHN WARE LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT LEA HOUSE, UNIT 26 FROBISHER WAY, TAUNTON, SOMERSET, TA2 6BB UNDER REGULATION 25

1 Outcome

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

1.2 The Committee determined that the application should be granted.

A copy of this decision is being sent to:
Rushport Advisory LLP, on behalf of the Applicant
PCSE, on behalf of Bristol, North Somerset and South Gloucestershire ICB
Proheal Pharma
Healthcare Plus Consulting Ltd, on behalf of Vitastock Ltd

NHS Resolution

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1 The Application

By application dated 21 June 2025, John Ware Ltd ("the Applicant") applied to Bristol, North Somerset and South Gloucestershire ICB ("the Commissioner") for inclusion in the pharmaceutical list at Lea House, Unit 26 Frobisher Way, Taunton, Somerset, TA2 6BB 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 "Drug Tariff part IX* *EXCEPT items that require measuring or fitting."

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

1.2.1 "Not applicable as the nearest pharmacy provides different services and is a member of he [sic] same body corporate."

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

1.3.1 "Application is not on the same site or in the same building as the premises of a provider of primary medical services with a patient list."

Pharmacy procedures

1.4 Please explain how the pharmacy procedures used within the premises will secure:

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

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

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

1.6 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.

1.7 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.

1.8 "SEE ATTACHED INFORMATION"

1.9 [No information was attached.]

2 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 circulate these comments to parties for them to make observations on them if they so wished.

2.1 "Thank you for your letter of 15 September 2025. I act for John Ware Ltd in the above application and have been instructed by my client to submit the following reply to the consultation comments received.

2.2 Proheal Pharma comments that the proposed premises that my client would operate from are adjacent to their existing pharmacy. As there is no connection between my client's proposed pharmacy and the Proheal pharmacy and no shared employees, directors or shareholders, regulation 31 does not apply. Please note that my client was not aware of the location of Proheal Pharmacy and therefore indicated on their application form that there was no other pharmacy on either the same or adjacent premises as that proposed by my client. Despite this error, regulation 31 still does not apply for the reasons given above. The remainder of the comments from Proheal are not relevant to the legal test and we do not address them further.

2.3 Vitastock Ltd comments that the supporting information referenced in the application was not submitted by my client. This appears to be correct and my client apologises for this oversight.

2.4 Vitastock's representative then states,

2.4.1 *For these reasons we submit that the present purported application must be dismissed with no right to appeal.*

2.5 As the ICB will be aware, this is not the correct process to follow, nor would it be lawful as appeal rights are set out in the Regulations and are not discretionary.

2.6 My client has instructed me to submit their SOPs along with this reply and they are attached for the Committee's attention.

2.7 Vitastock's representative then states,

2.7.1 *"The applicant has confirmed that the existing distance selling pharmacy "is a member of [t]he same body corporate".*

2.8 My client has no idea what Vitastock is referring to. My client has not confirmed any such thing and the submission from Vitastock's representative is false. It is not clear why Vitastock's representative would make up false evidence.

2.9 We look forward to hearing from you in due course."

2.10 [SOPs at Appendix A for Committee]

3 The Decision

The Commissioner considered and decided to refuse the application. The decision letter dated 11 December 2025 states:

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

3.1 "Bristol, North Somerset and South Gloucestershire 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.

3.2 You have a right of appeal to the Secretary of State against Bristol, North Somerset and South Gloucestershire ICB's decision. Should you choose to appeal then you should either complete the online form available on the NHS Resolution website or send a concise and reasoned statement of the grounds for your appeal within 30 days of the date of this letter to nhsr.appeals@nhs.net or:

3.3 Primary Care Appeals, NHS Resolution, 8th Floor, 10 South Colonnade, Canary Wharf, London, E14 4PU"

South West Pharmaceutical Services Regulations Committee (PSRC) Decision report

3.4 "The SW Committee noted:

3.5 The applicant proposes opening a distance selling pharmacy in premises at 26 Frobisher Way, Taunton.

3.6 PRELIMINARY ISSUES

3.7 Nature of the application

3.8 This is application for a 'distance selling pharmacy' and is an excepted application and considered under regulation 25.

3.9 Regulation 31 (same or adjacent premises)

3.10 Regulation 31 states: [quotes Regulation 31]

3.11 The SW Committee noted there is another DSP in premises very near to the proposed premises and in considering Part 2 a) and b) of Regulation 31 noted part a) may be met, however, the DSP already operating nearby is a different company with different directors therefore it is not reasonable to treat the services as the same services so part b) is not met. The SW Committee agreed it ought not to matter if both providers are providing services nationally to patients. ***The SW Committee was satisfied it is not required to refuse the application by virtue of Regulation 31***.

3.12 Representations received

3.13 Representation was received from:

3.14 Proheal Pharma objects to the application and comment on the physical proximity of premises, existing provision of services, regulatory grounds, duplication and fragmentation risk, no demonstrable need or public benefit, impact on quality and continuity of patient care, confusion among GP's and NHS systems, operational risk and supplier confusion, business harm and commercial threat, impact on staff and management and regulatory exploitation. They ask the ICB to reject the application on grounds of conflict, confusion, operational risk and patient safety and to recognise the regulatory intent of Reg 25 is being comprised and prevent a situation that will cause long term logistical disruption and distress to an existing provider, concluding:

3.14.1 "*13. Conclusion*

3.14.2 *Approving this application would:*

3.14.2.1 *Create delivery chaos, customer confusion and long-term rivalry.*

3.14.2.2 *Risk misdelivered medications and associated clinical and reputational harm.*

3.14.2.3 *Completely undermine the sustainability of a newly launched NHS service provider (Proheal Pharma).*

3.14.3 *This is a critical moment to uphold fairness, integrity and patient safety.*

3.14.4 *We respectfully request that NHS England reject their application immediately in order to protect the existing distance selling pharmacy located adjacent to the proposed premises. Approving this application would not lead to improved outcomes for the public and would undermine both existing NHS investment and our own investment in pharmaceutical services in the area.*

3.14.5 *We kindly urge you to protect the trust placed in the NHS and reject this application.*"

3.15 Community Pharmacy Somerset acknowledges the application but neither supports nor opposes it.

3.16 Healthcare Plus Consulting Ltd, on behalf of Vitastock Ltd, object to the application noting the application must be refused under certain circumstances and submit the application fails to comply with the regulations stating:

3.16.1 *"Issues with the present purported application*

3.16.2 *The present purported application fails to make any attempt to make clear how the applicant will comply with the provisions in regulation 25(2)(b). The application references "ATTACHED INFORMATION" but we do not believe that any additional information has been attached. This has been confirmed to us by an email sent 10th August 2025 from PCSE. We believe that the present application should be dismissed as simply not being an application within the meaning of the regulations as it makes no attempt whatsoever to provide the necessary information.*

3.16.3 *For these reasons we submit that the present purported application must be dismissed with no right to appeal.*

3.16.4 *Even if the purported application is to be considered a valid application, there no reason to believe that regulation 25(2)(b) is complied with. Explicitly, there is no information as to how the uninterrupted provision of essential services will be provided to persons anywhere in England. There is no information as to how essential services will be conducted without face to face contact.*

3.16.5 *Additionally, no floorplan has been provided. This makes it impossible for the Committee to verify that the applicant has a place to make confidential video and phone calls as required by Schedule 4 paragraph 28B with regard to distance selling applications.*

3.16.6 *We also note that all routine applications must comply with regulation 31. In this regard we note that the applicant is applying to open in Unit 26 while Unit 27 is presently a distance selling pharmacy.*

3.16.7 *The applicant has confirmed that the existing distance selling pharmacy "is a member of [t]he same body corporate". It is established that where ownership is linked, a routine application falls foul of Regulation 31(2)(b).*

3.16.8 *Based on the above, we submit that this application should be dismissed/ refused as it makes no attempt to comply with the provisions of Regulation 25(2)(b) and does not satisfy the provision of Regulation 31."*

3.17 The applicant responded and addressed matters raised by each of the interested party responses, offering explanation on each point raised,

submitting the objections should be dismissed. They forward their SOP's noting these were omitted from the application when it was first submitted.

3.18 When comments are circulated to the applicant and interest parties the covering letter states:

3.19 *Please note that any new information that you submit at this stage will have little or no weight placed upon it unless it can be demonstrated that you are presenting it in response to representations submitted by another party that you believe are not true or are incorrect.*

3.20 The SW Committee discussed the provision of SOPs after the 45-day circulation and noted it is new information that interested parties will not have been sighted on and therefore could not place significant weight on them as this was new information.

3.21 <u>REGULATION 25(2) – requirements for distance selling pharmacies</u>

3.22 An application for distance selling premises is, by virtue of regulation 25(1), not subject to the market entry test.

3.23 Regulation 25(2) states:

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

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

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

in respect of pharmacy premises that are distance selling premises.

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

(a) if the premises in respect of which the application is made are on the same site or in the same building as the premises of a provider of primary medical services with a patient list; and (b)unless the NHSCB is satisfied that the pharmacy procedures for the pharmacy premises are likely to secure— (i) the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services, and

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

3.24 <u>Reg 25(2)(a) – same site as a provider of primary medical services</u>

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

3.26 <u>Reg 25(2)(b) – the pharmacy procedures</u>

3.27 Information about how the applicant would operate the proposed pharmacy is provided by way of the submission of SOP's lodged with the applicant's response to the notification responses.

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

3.29 *Services available without interruption*

3.30 In the application form, the applicant has proposed core hours of 9am – 1pm and 1.30pm – 5.30pm Monday to Friday. Closed Saturdays and Sundays. No additional supplementary hours are proposed.

3.31 In the SOP's at page 14 it says:

3.31.1 *"All pharmacy staff must note that this pharmacy operates in accordance with specific approval under the Regulations and these premises are 'Distance Selling Premises'. In order to comply with our terms of service, this pharmacy will provide;*

- *The uninterrupted provision of pharmaceutical services, during the opening hours of the premises, to persons anywhere in England who request those services."*

3.32 And on page 105:

3.32.1 *"Advice and help will be available to patients during opening hours of the pharmacy and patients can access information on our pharmacy website at all times. This ensures the uninterrupted provision of the service to patients across England."*

3.33 The SW Committee noted that there was little about how the pharmacy would be staffed, there was nothing about sickness, leave or absences of the responsible pharmacist. On page 14 it states service provision will be uninterrupted but there is no explanation on how emergency situations will be approached or clarity on a business continuity plan.

3.34 The SW Committee was not satisfied that services will be provided without interruption.

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

3.36 In the SOP's on page 17 it states:

3.36.1 *"Communication Channels*

3.36.2 *All communication regarding NHS Pharmaceutical Services should be carried out using the most suitable non face to face method for the patient and the service being provided with particular consideration to maintaining confidentiality. This may be telephone, email, video-*

conferencing or other types of non face to face communications such as text messages.

3.36.3 *The pharmacy has provision for both live audio and live video communication with patients and this must always be carried out in the specified confidential area of the pharmacy premises.*

3.36.4 *Request for face-to-face service provision*

3.36.5 *OUR PHARMACY OPERATES FROM SELF-CONTAINED PREMISES THAT USE A CONTROLLED ACCESS SYSTEM. MEMBERS OF THE PUBLIC ARE NOT ABLE TO ATTEND THE PREMISES TO RECEIVE ANY NHS SERVICES*

3.36.6 *If any member of staff receives a query from any member of the public, or patient or their carers that requests the provision of any pharmaceutical service face to face on or in the vicinity of the premises then they must;*

3.36.6.1 *Inform the person that, we cannot provide any face to face NHS services*

3.36.6.2 *Refer the person to the Responsible Pharmacist if they require any further explanation.*

3.36.7 *Provision of Advanced or Enhanced Services*

3.36.8 *The Pharmacy does not provide advanced or enhanced services to patients on the premises. NMS will be conducted remotely with no patients accessing the service at the premises (see NMS SOP).*

3.36.9 *Pharmacy First will be provided remotely if the pharmacy has been approved to provide the service (see Pharmacy First SOP)."*

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

3.38 On page 17 of the SOP's it states:

3.38.1 *"Procedures for NHS Pharmaceutical Services*

3.38.2 *NHS Pharmaceutical Services will be provided to any patient living in England who requests such services, this is made clear on the website and in the Practice leaflet. Patients who wish to send paper prescriptions to the pharmacy by post should be sent stamped addressed envelopes to enable them to do so.*

3.38.3 *Communication Channels*

3.38.4 *All communication regarding NHS Pharmaceutical Services should be carried out using the most suitable non face to face method for the patient and the service being provided with particular consideration to maintaining confidentiality. This may be telephone, email, video-*

conferencing or other types of non face to face communications such as text messages.

3.38.5 *The pharmacy has provision for both live audio and live video communication with patients and this must always be carried out in the specified confidential area of the pharmacy premises."*

3.39 At parts 12 and 13 of the SOPs there are sections that discuss the management of nominations and electronic prescriptions.

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

3.41 To establish if services will be provided without face-to-face contact it is useful to examine the Terms of Service (Schedule 4 Part 2 essential services) where compliance would ordinarily require face to face contact and assess if the applicant has explained how they will achieve it. The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (legislation.gov.uk)

3.42 Paragraph 6 – Urgent supply without a prescription

3.43 From page 65 of the SOP's under 'Emergency Supply and Urgent Supply' there is information on the process for this with the objective stating:

3.43.1 *"Emergency Supply and Urgent Supply*

3.43.2 *Whilst the Distance Selling nature of the pharmacy is such that Emergency Supply is unlikely to occur as often as in a retail pharmacy, all staff must be aware of the procedures to be followed in the event of such a request.*

3.43.3 *Objectives*

3.43.4 *In an emergency Pharmacists are able to supply a POM without a prescription to a patient if requested by the following:*

3.43.4.1*Prescriber (Urgent supply at the request of the prescriber).*

3.43.4.2*Patient (Emergency supply at the request of the patient)."*

3.44 16.11 of the SOPs also describes how delivery of urgent items should be expedited.

3.45 The SW Committee was satisfied that the pharmacy has suitable arrangements in place for dealing with urgent requests.

3.46 Paragraph 7 – Exemption Checking and payment

3.47 On page 25 of the SOP's under 'Online Order Receipt & Exemption Checking' there is information on the process for this with the objective stating:

3.47.1 *"Online Order Receipt & Exemption Checking*

3.47.2 *Objective*

3.47.3 *To capture all orders, to then process promptly and professionally to ensure:*

3.47.3.1 *Patient details are complete and accurate on registration.*

3.47.3.2 *The order on the administration screen matches with the original prescriptions once received.*

3.47.3.3 *Prescription charges have been collected and processed where they are due.*

3.47.3.4 *Prescription charge exemption is verified with scanned/posted evidence and records maintained.*

3.47.3.5 *A message is sent to advise the patient the order has been received and is being dealt with.*

3.47.3.6 *Orders are all captured and not missed.*

3.47.3.7 *Prioritising of orders by their despatch date. Dependent on the patients chosen delivery date."*

3.48 6.8 of the SOPs provides more detail on how exemption status can be checked including mention of the real time exemption checking system.

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

3.50 <u>Paragraph 8 providing ordered drugs or appliances</u>

3.51 On page 73 of the SOP's under 'Online Order Receipt & Exemption Checking' there is information on the process for this with the objective stating:

3.51.1 *"Order Delivery*

3.51.2 *Scope*

3.51.3 *The process for delivery of prescriptions to the patient's chosen address and the provision of information and advice to patients to whom drugs are supplied about the safe keeping of drugs and return of unwanted medicines.*

3.51.4 *Objective*

3.51.5 *This SOP will ensure that:*

3.51.5.1 *Prescriptions are delivered safely and securely*

3.51.5.2 *A robust audit trail is maintained*

3.51.5.3 *Medication is properly delivered*

3.51.5.4 *Patients are aware of missed deliveries and can easily arrange re-delivery.*

3.51.5.5 *Patients receive information on safe keeping and return of unwanted medicines."*

3.52 On page 76 and 77 of the SOP's the process for cold chain delivery is described. On page 72 it discusses packaging and mentions things like padded envelopes, bubble wrap etc. Regarding delivery services, there is no explanation on how the Superintendent will maintain oversight of the person/company doing delivery on their behalf and how training for the courier process will be delivered. There is little information provided on how an unsuccessful delivery by Royal Mail will be dealt with particularly as meds are likely to be taken back to a sorting office and how they will guarantee getting it back to the pharmacy.

3.53 The SW Committee was NOT satisfied that suitable arrangements are in place for the delivery of items including temperature controlled and CD items.

3.54 Paragraph 8(4)

3.55 Part 4 of the application form states appliances will be provided as described in Part IX of the Drug Tariff, except items that require measuring or fitting.

3.56 The SW Committee therefore did not need to consider measuring and fitting of appliances.

3.57 Paragraph 9(4) – Repeat Dispensing

3.58 On page 135 - 136 it details how patients must be advised to only order items they need, check there are no side effects such that a medication review is required, and confirm there have been no changes in therapy.

3.59 On page 134 of the SOP's there is a description of the Repeat Dispensing process, including:

3.59.1 "*Repeat Dispensing*

3.59.2 *Repeat Dispensing is a process by which patients are able to obtain repeat medicines without the need to contact their GP on each occasion. The supplies of medicines are managed by the patient's pharmacy of choice and the patient or representative must visit the same pharmacy for each supply under the service.*

3.59.3 *The prescriber produces a master 'repeatable' authorising prescription (annotated with RA) on a standard FP10 form and a set of identical 'batch' prescriptions on a standard FP10 form (annotated with RD).*

3.59.4 *Both forms must be computer generated. Any handwritten amendments, including any additional medication added will invalidate the prescription.*

3.59.1 *Objectives*

3.59.1.1 *To provide a framework for a safe on going repeat dispensing service which includes prompt attention to medication change or any other known changes in patient need.*

3.59.1.2 *To promote the service to relevant patients*

3.59.1.3 *To ensure that the master repeatable prescription and batch issues are stored safely.*

3.59.1.4 *To ensure there is an effective audit trail for each master repeatable prescription and its associated batch issues.*

3.59.1.5 *To ensure that all regular dispensary staff are appropriately trained in accordance with the local PCO arrangements, and that all part-time pharmacists, relief pharmacists and locum pharmacists who work in the pharmacy have also received appropriate training.*

3.59.1.6 *To meet the legal requirements of the Repeat Dispensing service*

3.59.1.7 *To offer a safe and effective service to patients without face to face contact*

3.59.1.8 *Ensure that patients gain maximum benefit from their medication and reduce wastage of medicines."*

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

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

3.62 At part 5 of the SOPS, it details how remote means of communication will be used (phone, email etc.) will be used to contact patients without face to face contact.

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

3.64 <u>Paragraph 10(1)(da) – benefits of repeat dispensing</u>

3.65 On page 135 of the SOP's it states:

3.65.1 *"Prescription Reception*

3.65.2 *Appropriate advice about the benefits of repeat dispensing must be given to any patient who:*

3.65.2.1 *has a long term, stable medical condition (that is, a medical condition that is unlikely to change in the short to medium term); and,*

3.65.2.2 *requires regular medicine in respect of that medical condition, including, where appropriate, advice that encourages the patient to discuss repeat dispensing of that medicine with a prescriber at the provider of primary medical services whose patient list the patient is on.*

3.65.3 *Such advice will be provided by the Pharmacy using its permissible methods of non face-to-face contact with patients.*

3.65.4 *On receipt of a repeatable prescription from the patient, either in the post or collected from the surgery for the first time, the pharmacy staff should ensure that the patient fully understands the Repeat Dispensing Process and is provided with a patient information leaflet that outlines the benefits of the service.*

3.65.4.1 *Check to confirm if the patient has a long term, stable medical condition that requires regular medicine in the short to medium term and ensure relevant patients have the scheme explained to them.*

3.65.4.2 *The pharmacy record card must be completed and attached to a RA and an entry made on each occasion a dispensing takes place.*

3.65.4.3 *Any amendments to the RD, e.g. items not issued or change to expected interval must be recorded in the comment section of the pharmacy copy of the card.*

3.65.4.4 *When a RA is accepted the details should be checked thoroughly to ensure that there are no omissions or errors which could prevent the dispensing of all the batch prescriptions.*

3.65.4.5 *The RA should be retained in the pharmacy although it is the patient's choice whether they leave the RD with the pharmacy or retain them."*

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

3.67 <u>Paragraph 13 – Disposal service in respect of unwanted drugs</u>

3.68 On page 90 of the SOP's it states:

3.68.1 *"Patient Returned Medication*

3.68.2 *This service is available to all patients living in England.*

3.68.3 *Patients or their representatives may not return and medicines directly to the pharmacy and must follow the procedures set out in this SOP.*

3.68.4 *Patients should be referred to the 'Returning unwanted medication' page on the website for information.*

3.68.5 *To arrange the return of unwanted medicines to the Pharmacy the patient must telephone and speak to a member of the dispensary team. For controlled drugs this must always be the pharmacist on duty.*

3.68.6 *The process for returning medication must be explained to the patient.*

3.68.7 *Each return will be made by booking an appointment for the pharmacy's driver to visit the patient's home to collect the returned medication or by sending the appropriate packaging to the patient to arrange for return by Royal Mail – Note the Royal Mail website refers to a prohibition on carrying "controlled drugs" but this refers only to illicit controlled drugs and not those supplied under the direction of a physician.*

3.68.8 *Ensure the patient understands that any sharps and clinical/contaminated waste cannot be returned and they should follow local procedures for disposing of them.*

3.68.9 *Ensure the patient knows that cytotoxic and hazardous waste, as well as CDs, must be separated if possible before returning to pharmacy.*

3.68.10 *Patients should be advised to mark the package of unwanted medication "Z Returns" to allow them to be easily identified. The packaging must not identify the contents as being controlled drugs (or any other drugs).*

3.68.11 *Appropriate packaging must be sent to patients to return hazardous medicines as return of such medicines in inadequate packaging may be unsafe.*

3.68.12 *Advise patient of their other options to dispose of unwanted or expired medication if they cannot arrange a suitable time for collection. Patients are permitted to return medication to their local pharmacy if required."*

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

3.70 <u>Paragraph 17 – prescription linked interventions</u>

3.71 On page 39 of the SOP's it states:

3.71.1 *"Interventions and Problem Solving*

3.71.2 *Objectives*

3.71.3 *This SOP is designed to ensure that any interventions that are identified in the Pharmaceutical & Legal assessment SOP are dealt with promptly, professionally and appropriately. Always be aware that:*

3.71.3.1 *Patient safety must always be the priority.*

3.71.3.2 *The nature of the pharmacy as a Distance Selling Pharmacy means that it is not always possible to provide the same services as normal retail pharmacies.*

3.71.3.3 *Customer confidence and good patient relationships should always be maintained.*

3.71.3.4 *Good working relationships with other health care professionals should always be maintained.*

3.71.4 *Scope*

3.71.5 *This SOP covers the events that may occur during the dispensing process."*

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

3.73 Paragraph 18 - Public health campaigns

3.74 On pages 105 and 106 there is a description of the process for participation in Health Campaigns and patient engagement:

3.74.1 *"Health Campaigns & Community Engagement Exercise*

3.74.2 *Terms of Service require participation in a maximum of 2 campaigns per financial year, but you should agree to take part in all campaigns where practicable.*

3.74.3 *The Pharmacy will take part in national health campaigns to promote public health messages to patients across England. This will be achieved by sending out leaflets with prescriptions during specific targeted campaign periods and providing additional advice and learning resources via the website on the health promotion zone.*

3.74.4 *The pharmacy will also take part in at least one approved community engagement exercise in relation to the promotion of health living each financial year.*

3.74.5 *Patients will be directed to the learning resources via email, text and other non face-to-face communication so that they are aware of the campaign."*

3.75 It was noted an engagement exercise is in the terms of service and they are obligated to do it. This is mentioned in the SOPs but there is little information on how they will achieve that.

3.76 The SW Committee was NOT satisfied that suitable arrangements are in place to provide public health campaigns without face to face contact.

3.77 Paragraph 19 and 20 – Signposting

3.78 On page 100 of the Sop's the process is described with an objective stating:

3.78.1 *"Support for Self-Care, Signposting and Health Promotion*

3.78.2 *Scope*

3.78.3 *The scope of this SOP will include guidance for the provision of self-care to patients and their families, including signposting to appropriate supporting organisations and promotion of a healthy lifestyle including health campaigns.*

3.78.4 *Objective*

3.78.5 *Implementing this SOP will ensure:*

3.78.5.1 *Ensure Services are provided without face to face contact between pharmacy staff and the patient or their representative.*

3.78.5.2 *Enhanced access and choice for patients who want to care for themselves and their families.*

3.78.5.3 *Provision of appropriate advice to people including carers to help them to self-manage a self-limiting or long term condition.*

3.78.5.4 *Provision of information and advice to people who require assistance of appropriate health and social care providers or support organisations.*

3.78.5.5 *Increased patient and public knowledge and understanding of key healthy lifestyle and public health messages.*

3.78.5.6 *Opportunistic provision of health promotion advice to encourage patients to take action to improve their health.*

3.78.5.7 *Patients manage their condition by being more knowledgeable about treatment options*

3.78.5.8 *Patients contact and access further care and support.*

3.78.5.9 *Reduction in inappropriate use of health and social care services.*

3.78.5.10 *To ensure compliance with the Pharmaceutical Services Regulations."*

3.79 The SW Committee was satisfied that suitable arrangements are in place to provide signposting services without face to face contact.

3.80 Paragraph 21 and 22 (self-care)

3.81 See above.

3.82 The SW Committee was satisfied that suitable arrangements are in place to provide self-care services without face to face contact.

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

3.84 On page 102 of the SOP's its [sic] states:

3.84.1 *"Health promotion zone on our website*

3.84.2 *The website allows patients to access pharmaceutical services via our interactive page.*

3.84.3 *Explaining the Interactive Page to Patients*

3.84.4 *The interactive page is promoted on the website so that when a patient first visits the website they are signposted to a range of up to date materials that promote healthy lifestyles.*

3.84.5 *The Superintendent Pharmacist is responsible for ensuring that a reasonable range of materials are accessible via the interactive page and that they address a reasonable range of health issues.*

3.84.6 *The health promotion zone may also includes details of current health campaigns and other information to promote healthy lifestyle choices as well as providing access to the Lifestyle Questionnaire that is used to target health information to patients."*

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

3.86 Other observations

3.87 It was noted the applicant owns Staplegrove Pharmacy which is close to the proposed new DSP premises. There is no mention of how they will manage patient expectation on accessing one site in person and the other not and the SW Committee was concerned about how that would be managed.

3.88 The SW Committee determined that the application should be REFUSED because:

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

3.88.2 The SW Committee is satisfied that the premises of the applicant are not on the same site or in the same building as the premises of a provider of primary medical services with a patient list.

3.88.3 The SW Committee is NOT satisfied that all essential services were likely to be secured without interruption during the opening hours.

3.88.4 The SW Committee is NOT satisfied that all essential services were likely to be secured for persons anywhere in England.

3.88.5 The SW Committee is NOT satisfied that all essential services were likely to be secured without face to face contact

3.88.6 The SW Committee is NOT satisfied that all essential services were likely to be secured in a safe and effective manner because it had insufficient information to be satisfied that the procedures adopted by the applicant would be likely to secure the safe and effective provision of essential services. There was virtually no information included in the application and even if the SW Committee took account of the SOPs (which was significant new information submitted after the 45 day notification period) there were areas where the SW Committee was not satisfied it had sufficient information to be sure services would be provided safely to patients anywhere in England without face to face contact.

3.89 Appeal Rights

3.90 As the application is refused, the applicant will have appeal rights."

4 The Appeal

In a letter dated 23 December 2025, the Applicant, through its representative Rushport Advisory LLP, appealed against the Commissioner's decision. The grounds of appeal are:

4.1 "I act for John Ware Limited and am instructed to submit this appeal against the decision of the Commissioner to refuse the above listed application.

4.2 As the Committee will note from the decision report, due to an error at my client's office the SOPs to support the application were not submitted along with the rest of the application.

4.3 When this error was noted, my client provided their SOPs to the Commissioner, however the Commissioner did not consider the additional information and therefore refused the application.

4.4 I have attached my client's SOPs with this appeal for the Committee's consideration and these contain a number of updates from the previous version provided. The SOPs have been approved by my client's superintendent pharmacist for use at this distance selling pharmacy.

4.5 In addition my client has provided a floorplan for the proposed premises. The premises will operate using a controlled entry system with no access available to the public.

4.6 I look forward to hearing from you in due course."

4.7 [Floor plan and updated SOPs at Appendices C and D for Committee]

5 Summary of Representations

This is a summary of representations received on the appeal.

5.1 Proheal Pharma

Covering email

5.1.1 “We write further to the application for the proposed distance selling pharmacy (DSP) and submit the following consolidated objections.

5.1.2 As a provider of NHS pharmaceutical services in this locality, we respectfully submit that the application fails to meet the requirements of the NHS (Pharmaceutical Services and Local Pharmaceutical Services) Regulations 2013 and should therefore be refused.

5.1.3 No Identified Need or Regulatory Benefit (Regulations 17 and 18)

5.1.4 There is no evidence within the local Pharmaceutical Needs Assessment (PNA) of any current or foreseeable unmet need for additional pharmaceutical services in this area. Our pharmacy already provides the full range of essential NHS services, and the applicant has not demonstrated any unforeseen benefit, necessary provision, or public interest justification as required under Regulations 17 or 18. Approval would therefore result in unnecessary duplication rather than improved access.

5.1.5 Failure to Address Committee Concerns (Decision Report, Point 51)

5.1.6 The Committee previously raised express concerns regarding patient confusion arising from the operation of Staplegrove Pharmacy, which provides face-to-face services, in close proximity to the proposed DSP, which does not. These concerns are recorded in the decision report.

5.1.7 The revised SOPs fail to address how patients will be proactively informed of the functional differences between the two sites, how confusion or misdirection will be prevented, or how patient expectations will be managed in practice. Reliance on verbal explanations alone is inefficient and creates a foreseeable risk of delay where patients attend the DSP expecting face-to-face care.

5.1.8 The SOPs contain no provision for clear website guidance, written patient communications, or site-specific signage to distinguish between premises operating under different service models. This omission represents a failure to respond to a material concern raised by the Committee and increases the risk of attendance contrary to Regulations 25(b)(ii) and 64(3)(d)(ii).

5.1.9 Immediate Proximity and Operational Risk (Regulations 25(b)(ii) and 31)

5.1.10 The proposed DSP premises at Unit 26, Frobisher Way and our pharmacy at Unit 27, Frobisher Way are numerically adjacent and separated only by a grass verge. Although not physically attached, the premises are immediately proximate and reasonably capable of being regarded as adjacent in operational terms.

5.1.11 This proximity creates foreseeable risks relating to courier confusion, misdirected collections, incorrect handovers, and delivery delays. The applicant's SOPs address courier activity only in generic terms and contain no site-specific controls to manage another pharmacy operating in immediate proximity. SOPs designed for a standalone DSP environment are insufficient in this context, and the applicant has not demonstrated that delivery arrangements can operate safely and effectively at this location.

5.1.12 Patient Confidentiality and SOP Non-Compliance (Regulation 25(b)(ii))

5.1.13 The SOPs require telephone consultations to be conducted in a separate consultation room where there is a risk of being overheard. However, the submitted floor plan shows only one consultation room, and the SOPs provide no contingency arrangements for situations where that room is already in use. This creates an inherent conflict between the SOPs and the physical layout of the premises and prevents the applicant from demonstrating that patient confidentiality can be reliably maintained.

5.1.14 Impact on Continuity and Stability of Care

5.1.15 While commercial impact is not determinative, the proposal presents a foreseeable risk to the continuity, safety, and stability of pharmaceutical service provision relied upon by patients in the area. Fragmentation of care, patient confusion, and operational inefficiencies would not deliver improved outcomes and risk undermining existing NHS service provision.

5.1.16 Conclusion

5.1.17 In summary, the applicant has failed to demonstrate a regulatory need or benefit, has not addressed concerns expressly raised by the Committee, has not mitigated foreseeable operational and patient safety risks arising from immediate proximity to existing provision, and cannot demonstrate compliance with Regulations 25(b)(ii) and 64(3)(d)(ii).

5.1.18 For these reasons, we respectfully invite the Committee to refuse the application."

Enclosed letter

5.1.19 "I write to formally submit representations regarding the above application and to request that the Committee consider the following outstanding concerns, which we submit remain unresolved and materially relevant to your determination.

5.1.20 Failure to Address Committee Concerns (Decision Report, Point 51)

5.1.21 The Committee expressly raised concerns regarding the applicant's operation of Staplegrove Pharmacy, Unit 1 Livingstone Way, Staplegrove, Taunton, Somerset, TA2 6BD, which is located approximately 0.1 miles from the proposed DSP premises (based on NHS Find a Pharmacy data). In particular, the Committee identified concerns regarding how patient expectations would be managed where one site provides face-to-face pharmaceutical services and the proposed DSP does not.

5.1.22 These concerns are clearly recorded in the decision report. We submit that the revised SOPs fail to address how patients will be informed of the functional differences between the two sites, how confusion or misdirection will be prevented, or how patient expectations will be managed in practice.

5.1.23 While the SOPs include provisions for verbally managing patient enquiries, this approach is inherently inefficient, and risks delays for patients seeking essential healthcare services — particularly where patients may attend the DSP premises expecting face-to-face care. The absence of proactive measures within the SOPs - such as clear website guidance and other patient-facing communications - creates a foreseeable risk of confusion and misdirection, undermining the safe and effective delivery of services.

5.1.24 Further, the SOPs make no provision for site-specific signage or other public-facing controls to distinguish between the applicant's nearby pharmacy premises operating under a different service model. Where multiple pharmacy premises operate in immediate proximity and one does not offer face-to-face access, clear signage is a fundamental safeguard for managing patient expectations and ensuring regulatory compliance.

5.1.25 The absence of clear patient guidance increases the foreseeable risk that patients will attend the DSP premises in person, be misdirected, experience delays to healthcare, or seek face-to-face services contrary to Regulation 25(b)(ii) and 64(3)(d)(ii).

5.1.26 This omission represents a failure to respond to a material concern expressly raised by the Committee and indicates that the identified risks remain unaddressed. We therefore respectfully urge the Committee to reject the application on this basis.

5.1.27 Operational Risks Based on Proximity to Existing Provision

5.1.28 The Committee previously concluded that the proposed premises were not "adjacent" to existing listed chemist premises for the purposes of Regulation 31, appearing to adopt a narrow interpretation based on physical attachment.

5.1.29 Judicial authority establishes that "adjacent" is a contextual concept and may include premises that are very near to or immediately proximate,

even where separated by minor physical features (Corbett v Cornwall Council [2022] EWCA Civ 1069; McGaw v Welsh Ministers [2021] EWCA Civ 976; English Clays Lovering Pochin & Co Ltd v Plymouth Corporation [1973] 1 WLR 1346).

5.1.30 The proposed DSP premises at Unit 26, Frobisher Way, Taunton, TA2 6BB and our pharmacy at Unit 27, Frobisher Way, Taunton, TA2 6BB are numerically adjacent. Although not physically attached, and notwithstanding the applicant's reliance on misleading mapping imagery to suggest greater separation, the parking areas are divided only by a grass verge with no physical barrier. On this basis, the premises can reasonably be considered adjacent, and Regulation 31(2)(i) is satisfied.

5.1.31 While we recognize that both limbs of Regulation 31 must be met for refusal under that provision, this proximity is directly relevant to operational risk assessment.

5.1.32 The immediate proximity of the proposed DSP premises to an existing distance selling pharmacy creates a foreseeable and material risk of courier confusion, logistical errors, and delivery delays. The applicant's SOPs address courier activity only in generic terms and contain no site-specific procedures to manage the presence of another DSP operating in immediate proximity. There is no defined process for handling misdirected collections, incorrect handovers, or courier-related delays.

5.1.33 The lack of signage and public guidance further increases the likelihood of courier confusion. Given the reliance on third-party delivery services, the absence of documented, site-specific safeguards represents a material control gap. SOPs written for a standalone DSP environment are insufficient in this context.

5.1.34 Accordingly, the applicant has failed to demonstrate that delivery and logistics arrangements can operate safely and effectively at this specific location. This further supports the submission that Regulation 25(b)(ii) is not satisfied.

5.1.35 Distance Map (26, John Ware Ltd – TA2 6BB & 27, Proheal Pharma – TA2 6BB)

5.1.36 [Map and photographs provided]

5.1.37 Patient Confidentiality

5.1.38 Paragraph 35.8 of the applicant's SOPs (Data Protection) states:

5.1.39 "When collecting health data from a customer over the telephone, you should be aware that you may be overheard and, if necessary, take additional steps to protect the customer's privacy, by taking the conversation into a separate consultation room."

5.1.40 Based on the submitted floor plan, the premises contain only one consultation room. This creates an inherent conflict between the written

procedure and the physical layout. The SOP expressly requires use of a separate consultation room where there is a risk of being overheard and does not provide for alternative compliant arrangements.

5.1.41 The SOPs contain no contingency instruction for situations where the consultation room is already in use — a foreseeable and routine scenario. They do not limit the requirement to specific areas nor provide alternative procedural safeguards.

5.1.42 Reliance on informal workarounds cannot cure this defect where such measures are not defined within the SOP framework. The applicant therefore cannot demonstrate that patient confidentiality can be reliably maintained when delivering essential services. We submit that Regulation 25(b)(ii) is not met on this ground.

5.1.43 Conclusion

5.1.44 In summary, the applicant has failed to address concerns expressly raised by the Committee, has not mitigated foreseeable risks arising from operating a distance selling pharmacy in immediate proximity to other pharmacy provision, and cannot demonstrate consistent compliance with its own SOPs regarding patient confidentiality.

5.1.45 While we acknowledge that commercial impact is not a determining factor, the proposal presents a risk to the stability, continuity, and safety of pharmaceutical service provision relied upon by patients in the area.

5.1.46 For these reasons, we respectfully submit that the Committee cannot be satisfied that the requirements of Regulation 25(b)(ii) and 64(3)(d)(ii) are met and invite the Committee to reject the application accordingly."

5.2 Healthcare Plus Consulting Ltd, on behalf of Vitastock Ltd

5.2.1 "Thank you for your letter dated 20th January 2026. We write on behalf of Vitastock Ltd, please find a letter of authorisation attached.

5.2.2 We continue to submit that the present purported application must be refused.

5.2.3 **The Purported Application and Appeal Rights**

5.2.4 We note that given the initial purported application failed entirely to explain how it complied with Regulation 25 as required by the regulations, it failed to be an application within the meaning of the regulations, meaning there are not appeal rights.

5.2.5 **Regulation 31**

5.2.6 Furthermore, we continue to have concerns over Regulation 31. Though the representative from Rushport Advisory states; *"My client has no idea what Vitastock is referring to"*, we note that we merely quoted a statement from the purported application as filled out by the client or Rushport Advisory:

5.2.7 [Screenshot of section 5 of the application form which states: "*Not applicable as the nearest pharmacy provides different services and is a member of he* [sic] *same body corporate.*"]

5.2.8 We conclude from this that, as they state, the nearest pharmacy, which appears to be in the same estate as the proposed pharmacy and may share a boundary with the proposed site, is indeed of the same body corporate. While providing different services is not relevant to Regulation 31, we note that being a member of the same body corporate has generally been found to be sufficient to render a pharmacy in breach of Regulation 31(b).

5.2.9 We also continue to submit that the proposed pharmacy does not comply with Regulations 25 and 64. We list a few concerns below.

5.2.10 We note that all referenced page numbers from the SOPs correspond to the page numbers in the PDF appeal document as received.

5.2.11 <u>Hazardous Items</u>

5.2.12 We are concerned that the packaging and delivery SOPs lack any consideration for hazardous material. For example, some drugs and appliances are classed as Flammable, Oxidisers, Corrosives and Pressure Vessels. There appears no consideration of these issues in packing and delivery of medication.

5.2.13 This is generally not an issue for a normal pharmacy which would not need to use delivery services but, for a DSP, a large number of such items must be delivered by couriers. This may lead to a breach of transit regulations or courier terms of service. It may also lead to dangerous issues.

5.2.14 We note that the only consideration of a hazardous material is in respect of collection of unwanted medicines by the pharmacy's drivers. There is no consideration of hazards such Oxidisers, Corrosives, Carcinogens and Pressure Vessels at any point in the packing and delivery of items to be sent.

5.2.15 <u>Disposal of Unwanted Medication</u>

5.2.16 At 25.6, page 106 the SOPs instruct:

5.2.16.1 *"Advise patient of their other options to dispose of unwanted or expired medication if none of these options is suitable for them (signposting to local pharmacies)."*

5.2.17 Additionally, at 25.9, page 109 it is stated that:

5.2.17.1 *"If items are not suitable for return by Royal Mail (eg clinical or contaminated waste) then provide the patient with details of their local procedures for disposal."*

5.2.18 We believe that these quotes indicate that in some situations the DSP does not offer any suitable option for provision of the essential service of disposal of unwanted medications to all persons who request it across England in all cases. Instead, the DSP proposes, in some cases, to shift the burden to other pharmacies or local services. This is a clear breach of the regulations. We emphasise that the first quote shows this includes unwanted or expired drugs and not just other forms of waste.

5.2.19 Signposting for Appliances

5.2.20 The applicant has stated that they will offer all appliances in Part IX of the drug tariff except those that require measuring and fitting. This means that in some cases they are required to refer to a suitable pharmacist or appliance contractor.

5.2.21 We note that the relevant regulation is Schedule 4, Paragraph 20(2):

> *"20 (2) Where, on presentation of a prescription form or repeatable prescription, P is unable to provide an appliance or stoma appliance customisation because the provision of the appliance or customisation is not within P's normal course of business, P must—*
>
> > ***(a)if the patient consents, refer the prescription form or repeatable prescription to another NHS pharmacist or to an NHS appliance contractor; and***
> >
> > *(b)if the patient does not consent to a referral, provide the patient with contact details of at least 2 people who are NHS pharmacists or NHS appliance contractors who are able to provide the appliance or stoma appliance customisation (as the case may be), if these details are known to P."* [Healthcare Plus Consulting Ltd's emphasis]

5.2.22 We note that, when the patient consents, the DSP is required to provide a direct referral of the prescription or repeatable prescription to an NHS pharmacist or appliance contractor. It is only where the patient does not consent that the DSP is allowed to instead merely provide details of two suitable contractors. We note that the section on signposting for appliances requiring measuring and fitting states:

5.2.22.1 *"26.14 Items Requiring Measuring and Fitting*

5.2.22.2 *Where a prescription is received for an appliance or stoma appliance customisation or any item that requires measuring or fitting the patient must be contacted and informed that these items are not available from this pharmacy as we do not provide a measuring and fitting service. Patients must be signposted to at least two other providers of the service in their area. (see signposting SOP)"* (page 115)

5.2.23 We note that none of the options include directly referring the prescription or repeatable prescription when the patient has given consent. We also note that the parenthetical *"see signposting SOP"*

offers no correction as this is the signposting SOP meaning this paragraph refers to itself.

5.2.24 Specified Appliances

5.2.25 We note again that the DSP proposes to offer all appliances in Part IX of the drug tariff except those requiring measuring and fitting. This includes a number of what are defined in the regulations as *"specified appliances."*

5.2.26 Regulation 2 of the 2013 Regulations states:

"specified appliance" means—

(a) any of the following appliances listed in Part IXA of the Drug Tariff—

(i) a catheter appliance (including a catheter accessory and maintenance solution),

(ii) a laryngectomy or tracheostomy appliance,

(iii) an anal irrigation system,

(iv) a vacuum pump or constrictor ring for erectile dysfunction, or

(v) a drainage wound pouch;

(b) an incontinence appliance listed in Part IXB of the Drug Tariff; or

(c) a stoma appliance listed in Part IXC of the Drug Tariff;"

5.2.27 We note that while some of these appliances do require measuring and fitting, a large number may be self-applied or replaced by the patient.

5.2.28 To give but one example, incontinence bags are replaced by the patient themselves after a small amount of training and do not require measuring or fitting. Patients generally replace their own leg bags and night bags regularly, ranging from every week for leg bags to every night for night bags. It is therefore clear that this is not an appliance requiring measuring or fitting.

5.2.29 (see https://www.northerncarealliance.nhs.uk/patient-information/patientleaflets/urology-cathetercare-community?q=%2Fpatient-information%2Fpatient-leaflets%2Furology-catheter-carecommunity).

5.2.30 The proposed DSP has therefore committed to offer this appliance.

5.2.31 We also note that many incontinence bags are included in Part IXB of the Drug Tariff, e.g. A1 Pharmaceuticals Drainable night drainage bags and Bard Ltd Sterile leg bags. For the avoidance of doubt, Part IXB is a subset of Part IX. It is therefore clear that these appliances are a

"specified appliance" within the meaning of the regulations as they are incontinence appliances within Part IXB.

5.2.32 The DSP therefore does propose to supply certain specified appliances. The regulations apply specific rules in Schedule 4, paragraph 12. We note in particular the following requirements:

5.2.32.112(2)(d) *"the manner of delivery of the package and any supplementary items required by sub-paragraph (3) must not convey the type of appliance being delivered."*

5.2.32.212(3) *"In any case where a specified appliance is provided (whether by home delivery or otherwise), P must provide a reasonable supply of appropriate supplementary items (such as disposable wipes and disposal bags) and –…"*

5.2.33 These requirements are not met by the applicant. We note that these additional requirements in respect of specified appliances are an essential service within Schedule 4 and so failure to include this in their procedures is in breach of Regulation 25.

5.2.34 <u>Prescriptions Requiring Supervised Consumption</u>

5.2.35 The SOPs provided do not address what will be done if a patient submits a prescription which specifies Supervised Consumption as a condition. This could lead to a dangerous situation where medication is provided without supervision or a breach of terms of the regulations with supervision provided on site.

5.2.36 <u>Tamper Proof Seals</u>

5.2.37 At 22.9, page 99 of the SOPs staff are required to *"Break the tamper-evident seal to confirm that the contents of the package are as described if a whole pack is to be supplied."* The SOPS never specify that the seal is re-applied, meaning medication would be sent out with an already broken seal.

5.2.38 <u>Urgent Supply</u>

5.2.39 One of the conditions for Urgent Supply outlined by the SOPs at 16.7, page 78 is that:

5.2.39.1*"The Prescriber agrees to provide a **written** prescription within 72 hours."* [Healthcare Plus Consulting Ltd's emphasis]

5.2.40 We note that the regulations clearly also include the option of an electronic prescription being transmitted via EPS within 72 hours.

5.2.41 *Schedule 4, Paragraph 6 (2)*

"(b)in the case of a request for a drug or an appliance, the prescriber undertakes to—

(i) give P a non-electronic prescription form or non-electronic repeatable prescription in respect of the drug or appliance within 72 hours of the request being made, or

*(ii) transmit an electronic prescription to the **Electronic Prescription Service** within 72 hours of the request being made."* [Healthcare Plus Consulting Ltd's emphasis]

5.2.42 Since the SOPs omit the option for prescriber to use EPS, they do not fully provide this essential service.

5.2.43 Pharmacy First

5.2.44 The applicant does not propose to carry out Pharmacy First but Pharmacy First is included in their SOPs. This calls into question whether all elements of the SOPs will be put into practice when the DSP operates.

5.2.45 New Medicine Service

5.2.46 The applicant proposes to offer NMS but also states that they are not accredited to offer the service and that the premises is not accredited. This is contrary to Schedule 2 Paragraph 1(8)(b). This may also lead to the unsafe provision of the service without appropriate accreditation.

5.2.47 Nominating Alternative Dispensing Contractors

5.2.48 It is not clear that the proposed DSP will comply with Schedule 4 Paragraph 11(2).

5.2.49 Schedule 4 Paragraph 11(2) states

"(2) P must, if requested to do so by any person, enter in that person's PDS patient details—

(a)where the person does not have a nominated dispensing contractor, [F5a nominated dispensing contractor]; or

(b)where the person does have a nominated dispensing contractor—

(i) a replacement dispensing contractor, or

(ii) a further dispensing contractor,

chosen by that person."

5.2.50 The DSP, itself, is clearly required to nominate new DACs when requested. There is no provision for this essential service in the SOPs and information provided by the applicant and their representative.

5.2.51 At 12.8, page 66, the SOPs state:

5.2.52 "*Nomination forms are available on the website. If a patient requests information about nominating a dispenser or the EPS service in general give them the following information: …*

5.2.52.1 *patients can change their nominated dispensing contractor at their GP practice or any dispensing contractor at any time. This includes when they are part way through a repeat dispensing cycle, any prescriptions which have not been downloaded before the change of contractor will be accessed by the new nominated contractor.*"

5.2.53 This appears to be the only reference to changing or adding DAC nominations. There is no reference to the DSP changing or adding DAC nomination on request as required by the regulations as an essential service.

5.2.54 **Conclusion**

5.2.55 The reasons outlined above represent only a few examples of SOP breaches and are not exhaustive. We submit that such a large number of issues were identified from only a cursory reading calls into question the SOPs as a whole and make it unlikely that the proposed DSP will comply with Regulation 25.

5.2.56 We note that this is the final occasion on which interested parties can ordinarily offer their views and so we object to further information being provided.

5.2.57 For all these reasons we submit that the application must be rejected."

5.3 The Commissioner

5.3.1 "Thank you for your letter, received 21 January 2026, addressed to Mr [S] at Primary Care Support England (PCSE) enclosing a copy of the above appeal. The South West Pharmaceutical Services Regulations Committee (SW Committee) wishes to make the following comments on the appeal.

5.3.2 The SW Committee notes the applicant has submitted updated SOPs as part of the appeal. As noted in the decision report, the SW Committee had received an earlier version of the applicant's SOP's, after the application had been circulated. It determined little weight could, therefore, be placed on them as it was significant additional information, which had not been circulated to interested parties.

5.3.3 The SW Committee considered the application and determined it was not satisfied that all essential services were likely to be secured in a safe and effective manner, because it had insufficient information to be satisfied that the procedures adopted by the applicant would be likely to secure the safe and effective provision of essential services. There was virtually no information included in the application and even if the SW Committee took account of the SOPs, there were areas where the SW Committee was not satisfied it had sufficient information to be sure

services would be provided safely to patients anywhere in England without face to face contact.

5.3.4 The SW Committee looks forward to receiving the Primary Care Appeals' decision in due course."

6 Unsolicited comments

6.1 Proheal Pharma

6.1.1 "Further to our earlier representation letter, please treat this correspondence as a formal subsequent representation pursuant to Schedule 3 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 ("the 2013 Regulations").

6.1.2 Proheal Pharma operates as a listed chemist at 27, Frobisher Way, Taunton and is directly affected by the proposed premises at 26, Frobisher Way. Proheal Pharma also operates as a distance selling pharmacy. Accordingly, this objection is not based on opposition to distance selling status as a matter of principle.

6.1.3 These further submissions address the following matters:

6.1.3.1 Regulation 31 (adjacent premises and same site considerations).

6.1.3.2 Regulation 25(2)(b) (distance selling requirements); and

6.1.3.3 Additional issues concerning the accuracy, completeness, and integrity of the application.

6.1.4 Regulation 31 – Adjacent Premises

6.1.5 (A) The Legal Test

6.1.6 Regulation 31(1) provides:

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

6.1.8 Regulation 31(2) applies where:

(a) a person on the pharmaceutical list (which may or may not be the applicant) is providing pharmaceutical services at or 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 should be treated as the same site).

6.1.9 (B) The Premises Are Adjacent as a Matter of Fact

6.1.10 The proposed premises at Lea House, 26 Frobisher Way are immediately behind and physically contiguous with Proheal Pharma at 27 Frobisher Way.

6.1.11 They:

6.1.11.1From [sic] part of the same commercial estate.

6.1.11.2Share the same estate access routes.

6.1.11.3Operate under the same postcode and road name.

6.1.11.4Are within the same tightly confined trading cluster.

6.1.12 This is not mere proximity within the same town. It is direct physical adjacency within the same operational site environment.

6.1.13 (C) Corporate Separation Is Legally Irrelevant

6.1.14 The Appellant asserts that Regulation 31 does not apply because there is no shared ownership, director, or shareholder. That submission is legally misconceived.

6.1.15 Regulation 31(2)(a) expressly states:

6.1.16 “a person on the pharmaceutical list (which may or may not be the applicant)”

6.1.17 Corporate connection is irrelevant. The Regulation is concerned with site integrity and functional reality, not ownership structure.

6.1.18 (D) The “Same Service” Test – Substance Over Form

6.1.19 The Appellant proposes to provide:

6.1.19.1Essential services under Schedule 4.

6.1.19.2Drug Tariff Part IX appliances (excluding measuring/fitting);

6.1.19.3NMS (remotely).

6.1.20 These are standard pharmaceutical services identical in nature to those already provided by Proheal Pharma.

6.1.21 The proposed premises are:

6.1.21.1Physically adjacent.

6.1.21.2Within the same trading estate.

6.1.21.3Competing for the same patient population.

6.1.21.4 Operationally indistinguishable in-service scope.

6.1.22 It would be artificial to treat these as separate sites.

6.1.23 Regulation 31 exists precisely to prevent fragmentation of a single site into multiple pharmacy listings through formalistic distinctions. Accordingly, Regulation 31(1) is engaged and mandates refusal.

6.1.24 REGULATION 25(2)(b) – DISTANCE SELLING REQUIREMENTS

6.1.25 Even if Regulation 31 were not determinative (which it is), the appeal must fail under Regulation 25(2)(b). NHS England must refuse the application unless satisfied that pharmacy procedures are likely to secure:

6.1.25.1 The uninterrupted provision of essential services to persons anywhere in England; and

6.1.25.2 The safe and effective provision of pharmaceutical services without face-to-face contact at the pharmacy premises.

6.1.26 (A) Late Submission of SOPs

6.1.27 The original application was materially incomplete because SOPs were not submitted.

6.1.28 That omission goes to the heart of Regulation 25. The decision-maker cannot be satisfied of “likely” uninterrupted and safe provision without reviewing the procedures said to secure that outcome. An applicant must satisfy the statutory test at the time of determination. The attempt to remedy the defect retrospectively on appeal does not erase the original non-compliance nor the regulatory concern it raises. An appeal is not an opportunity to reconstruct a defective application.

6.1.29 (B) Physical Configuration and Co-Location Risk

6.1.30 It is acknowledged that Proheal Pharma also operates as a distance selling pharmacy. The objection is therefore not to distance selling status itself.

6.1.31 The concern arises from the immediate physical co-location of two independent distance selling pharmacies operating within the same confined site environment.

6.1.32 The proposed premises:

6.1.32.1 Are situated immediately behind 27 Frobisher Way.

6.1.32.2 Form part of the same estate footprint.

6.1.32.3 Operate under the same postcode and road name.

6.1.32.4 Use sequential unit numbering.

6.1.32.5 Share the same estate access and delivery routes.

6.1.33 Regulation 25(2)(b) requires NHS England to be positively satisfied that the procedures will secure safe and effective provision without face-to-face contact at the premises.

6.1.34 The statutory question is practical and evidence based.

6.1.35 Where two distance selling pharmacies operate in immediate physical proximity:

6.1.35.1 There is a heightened risk of patient misdirection.

6.1.35.2 There is foreseeable confusion, particularly among elderly or vulnerable patients.

6.1.35.3 There is an increased likelihood of attempted attendance at the wrong premises.

6.1.35.4 The operational distinction between the two contractors becomes blurred.

6.1.36 Patients, including the elderly, are highly likely to become confused by two pharmacies operating under the same postcode and road name, with sequential door numbers.

6.1.37 Distance selling status does not eliminate the need for clear spatial separation. On the contrary, where two independent contractors operate side-by-side within the same site cluster, the regulatory risk increases.

6.1.38 The Regulations do not contemplate multiple distance selling pharmacies functioning as immediate neighbours within what is effectively the same operational site. Accordingly, the physical configuration materially undermines confidence that the Regulation 25(2)(b) test is satisfied.

6.1.39 (C) Consultation Area Inconsistencies

6.1.40 The application originally stated:

6.1.41 “Floor plan will be submitted once shop fitters have agreed layout.”

6.1.42 This confirms that:

6.1.42.1 The premises were not fully designed at the time of application.

6.1.42.2 Consultation arrangements were not finalised.

6.1.42.3 Operational safeguards were speculative.

6.1.43 Regulation 25 requires satisfaction as to likely compliance. Speculation about future layout does not meet a mandatory statutory threshold.

6.1.44 Misleading and Deceptive Site Information

6.1.45 The integrity of the pharmaceutical list regime depends upon full and accurate disclosure.

6.1.46 In the present case, the Appellant:

6.1.46.1 Failed to identify the immediately adjacent pharmacy at 27 Frobisher Way.

6.1.46.2 Marked Section 5 of the application as “Not applicable”.

6.1.46.3 Subsequently admitted that it was “not aware” of the location of the existing pharmacy.

6.1.46.4 Submitted incomplete supporting documentation at first instance.

6.1.46.5 Provided a site map which materially misrepresents the true physical relationship between the premises.

6.1.47 Of particular concern is the plan/map submitted in support of the application. The map does not accurately depict the true physical positioning of the proposed premises in relation to Proheal Pharma. It creates the impression of separation and distance, when in reality the proposed unit is situated directly behind and in immediate physical proximity to 27 Frobisher Way.

6.1.48 The proposed pharmacy is not merely “nearby.” It is directly behind Proheal Pharma within the same estate footprint. The visual presentation of the site is therefore misleading and has the effect - whether deliberate or negligent - of downplaying the degree of adjacency and operational co-location.

6.1.49 In a regulatory context where physical proximity is central to the application of Regulation 31, accurate site depiction is critical.

6.1.50 An applicant seeking inclusion in the pharmaceutical list must exercise proper due diligence and ensure that plans and maps are clear, accurate, and not capable of misleading the decision-maker.

6.1.51 The combination of:

6.1.51.1 Incorrect responses within the application form,

6.1.51.2 Failure to identify the adjacent pharmacy,

6.1.51.3 Subsequent admission of lack of awareness,

6.1.51.4 And submission of a misleading site map.

6.1.52 collectively raises serious concerns regarding the reliability and care exercised in preparing this application.

6.1.53 Public Interest and Regulatory Purpose

6.1.54 The pharmaceutical list framework exists to:

6.1.54.1 Prevent duplication at the same site.

6.1.54.2 Preserve orderly and transparent provision of services.

6.1.54.3 Protect the integrity of the distance selling exception.

6.1.54.4 Maintain public confidence in regulatory decision-making.

6.1.55 Allowing this appeal would:

6.1.55.1 Circumvent Regulation 31.

6.1.55.2 Permit functional co-location of two pharmacies within the same site environment.

6.1.55.3 Undermine the structured control mechanisms within the 2013 Regulations.

6.1.56 Conclusion

6.1.57 For the reasons set out above, we respectfully submit that:

6.1.57.1 Regulation 31 applies and supports refusal of the application.

6.1.57.2 The requirements of Regulation 25(2)(b) are not satisfied.

6.1.57.3 The original application contained material deficiencies.

6.1.57.4 Inaccuracies in the application raise concerns regarding reliability.

6.1.57.5 The physical configuration indicates functional same-site operation.

6.1.58 On this basis, we respectfully consider that the Commissioner's decision was correct and in accordance with the law, and we invite the Committee to dismiss the appeal in its entirety."

7 Summary of Observations

This is summary of observations received.

7.1 Rushport Advisory LLP, on behalf of the Applicant

7.1.1 "I act for John Ware Limited and am instructed to submit this reply to comments received on my client's appeal from interested parties.

7.1.2 **Proheal Pharma**

7.1.3 It is acknowledged that Proheal Pharma operates an existing DSP from an adjoining unit at Frobisher Way under the body corporate name of 3D Healthcare Ltd. My client was not aware of the existence of this pharmacy when they made their application and therefore incorrectly stated that there was no other pharmacy in the same or adjacent premises. We apologise for this error.

7.1.4 Notwithstanding the above, regulation 31 still does not apply in this case. Regulation 31 states; [quotes Regulation 31]

7.1.5 Contrary to the submission from Proheal, the High Court has considered Regulation 31(2)(b) and determined that there must be some connection between the two pharmacies (other than physical) for the regulation to apply (*R (Pharmacy Care Plus) v FHSAU [2013] EWHC 824 (Admin*)).

7.1.6 The Regulation 31 Guidance Note issued by Primary Care Appeals details how the test should be applied and we do not repeat the guidance here except to note paragraph 29 of the Guidance Note which states;

7.1.6.1 *In light of that Judgment, the Committee has previously considered the following factors:*

• whether the same company would be operating both sets of premises;

• whether the two providers are separate legal entities;

• whether there is any shared ownership or control and, if so, what its impact might be;

• whether any employees would work for both enterprises; and

• any other matters which appear to the Committee to be relevant.

7.1.7 There is no connection of any sort between my client and Proheal Pharma. This is perfectly clear from the fact that Proheal Pharma is an objector to this application. As there is no connection whatsoever between Pro Heal and my client regulation 31(b) does not apply.

7.1.8 The remainder of the points raised by Pro Heal are addressed below.

7.1.9 No Identified Need

7.1.10 There is no requirement for the PNA to identify a need for this pharmacy.

7.1.11 Patient Confusion

7.1.12 No patients will attend my clients premises and there is no reason for there to be any confusion.

7.1.13 Immediate Proximity

7.1.14 Addressed above in relation to regulation 31.

7.1.15 Patient Confidentiality

7.1.16 My client will have a consultation room for all telephone and video consultations with patients.

7.1.17 **Vitastock Limited ("Vitastock")**

7.1.18 Vitastock's representative raises a number of points that we deal with in turn below.

7.1.19 **Regulation 31**

7.1.20 It is unclear why Vitastock's representative continues to suggest that my client John Ware Ltd and Pro Heal Pharma (3D Healthcare Ltd) are the same corporate body. Not only is there no evidence to support the suggestion, but there is clear evidence that the suggestion is false.

7.1.21 **Hazardous Items**

7.1.22 Vitastock's representative claims that the packaging and delivery SOPs contain no consideration for hazardous materials. This is factually incorrect. The Choice of Packaging section makes clear that the nature of items being delivered must determine the appropriate level of protection. There is no requirement to list all types of medicines with individual packaging requirements.

7.1.23 SOP 18.7 states "*Choice of packaging will depend on the nature of the items being delivered and the appropriate level of protection must be used to ensure that the item can withstand the normal rigours of the delivery process*."

7.1.24 SOP 25 identifies hazardous waste as requiring separate handling and disposal procedures due to the fact that these items may have been opened by patients and may not be in their original packaging or containers.

7.1.25 **Disposal of Unwanted Medicine**

7.1.26 Vitastock's representative states;

7.1.26.1 *We believe that these quotes indicate that in some situations the DSP does not offer any suitable option for provision of the essential service of disposal of unwanted medications to all persons who request it across England in all cases. Instead, the DSP proposes, in some cases, to shift the burden to other pharmacies or local services. This is a clear breach of the regulations. We emphasise that the first quote shows this includes unwanted or expired drugs and not just other forms of waste.*

7.1.27 Nothing in this statement is correct.

7.1.28 All NHS pharmacies in England are required to accept medicines for disposal from all patients, irrespective of whether that patients received the medicine from the pharmacy they wish to return it to. If a patient does not wish to use any of the options available to them for returning medicine to my client's pharmacy, or insists that they wish to return medicines in person to a pharmacy (a service that my client cannot offer), then my client will signpost the patients to a service or pharmacy that can accept the waste medicines. This is entirely appropriate and correct.

7.1.29 **Signposting for Appliances**

7.1.30 It is accepted that the signposting instructions for patients who require a measuring or fitting service for appliances do not repeat the entirety of the Terms of Service and refer to providing details of 2 alternate providers but not to referring the prescription to an alternate provider. My client would of course be happy to refer any such prescription to another provider and the point made is a minor drafting error at best and does not in any way mean that the SOP is unsafe or ineffective.

7.1.31 **Specified Appliances**

7.1.32 There is a category of appliances known as "specified appliances". The Applicant's representative lists some examples of specified appliances and then states;

7.1.32.1 *The DSP therefore does propose to supply certain specified appliances. The regulations apply specific rules in Schedule 4, paragraph 12. We note in particular the following requirements:*

7.1.32.2 *12(2)(d) "the manner of delivery of the package and any supplementary items required by sub-paragraph (3) must not convey the type of appliance being delivered."*

7.1.32.3 *12(3) "In any case where a specified appliance is provided (whether by home delivery or otherwise), P must provide a reasonable supply of appropriate supplementary items (such as disposable wipes and disposal bags) and –…"*

7.1.32.4 *These requirements are not met by the applicant. We note that these additional requirements in respect of specified appliances are an essential service within Schedule 4 and so failure to include this in their procedures is in breach of Regulation 25.*

7.1.33 In respect of 12(2)(d) this is dealt with at SOP 18.6 which states;

7.1.33.1 *Mark the package with the words 'Urgent Medical supplies' but do not describe exactly the contents of the package.*

7.1.33.2 Place a 'Private & Confidential' label on the package.

7.1.34 In respect of 12(3) - Some, but not all specified appliances require additional products to be provided as part of the normal dispensing process and any pharmacy dispensing such products provides items such as disposable wipes as part of any order. My client will also operate in this manner. This is no different from any other normal supply of medicine where a pharmacist may include additional support items or information for patients.

7.1.35 There is no requirement for the SOPs to repeat all parts of the Terms of Service in relation to every service provided. SOPs are operating procedures rather than a repetition of the pharmacy's obligations.

7.1.36 **Prescriptions Requiring Supervised Consumption**

7.1.37 The submission on this point is misconceived. My client's pharmacy is not permitted to provide a supervised consumption service and has not applied to offer the service. No DSP can provide this service. Any prescription containing a medicine for supervised consumption would not be dispensed and the patient would be signposted to alternate providers.

7.1.38 **Tamper Proof Seals**

7.1.39 SOP 22.9 directs the pharmacist to confirm that the content of the package are as described. A tamper proof seal cannot be "re-applied" as suggested by Vitastock's representative. A patient would be counselled that the seal was broken by pharmacy staff as part of the dispensing process to ensure that the contents was correct.

7.1.40 When these medicines are being packaged for dispatch then SOP 18.7 is followed which states;

7.1.40.1 *All packaging must have the tamper proof seals provided in the pharmacy attached to the packaging so that any tampering with the packaging will be evident.*

7.1.41 It will therefore be clear that the content of the package has been prepared by the pharmacy and the tamper proof seal on the external packaging provides the required confirmation that the contents has not been interfered with since the package left the pharmacy premises.

7.1.42 **Urgent Supply**

7.1.43 It is correct that the pharmacy can receive a written or electronic prescription after an urgent supply of medicine. The omission of the words "or electronic" is a minor drafting point and in no way makes the process either unsafe or ineffective. The additional words will be added for clarity.

7.1.44 **Pharmacy First**

7.1.45 The SOP makes it clear that the SOP is included for completeness but will only be relevant if the service is subsequently applied for and commissioned from my client.

7.1.46 **NMS**

7.1.47 There is no requirement to be accredited for the NMS service in order to apply for it.

7.1.48 **Nominating Alternative Dispensing Contractors**

7.1.49 The submission from Vitastock's representative on this point is misconceived. As previously stated, SOPs are not supposed to repeat the wording of the Terms of Service as they are operating procedures rather than a repetition of obligations. In this case the Committee will note that there is a separate procedure (SOP 12.10) that deals with changing nomination and 12.13 confirms this must be actioned within 1 working day.

7.1.50 **Summary**

7.1.51 The legal test requires the Committee to be satisfied that the pharmacy procedures must be likely to secure 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 someone else's behalf) and the applicant or the applicant's staff.

7.1.52 Whilst Vitstock's representative has correctly highlighted minor drafting points, these in no way render the procedures either unsafe or ineffective and the appeal should be allowed as my client's application meets the legal test.

7.1.53 I look forward to hearing from you in due course."

7.2 Proheal Pharma

7.2.1 "We write further to our previous correspondence and now submit this consolidated and formal objection pursuant to Schedule 3 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 ("the 2013 Regulations").

7.2.2 Proheal Pharma operates as a listed chemist and distance selling pharmacy from 27 Frobisher Way, Taunton TA2 6BB. The proposed premises at Unit 26, Frobisher Way TA2 6BB directly and materially affect us. Our objection is not to the principle of distance selling pharmacies; rather, it concerns the statutory compliance, regulatory integrity, and operational safety issues arising from this specific application and its physical configuration.

7.2.3 For the reasons set out below, we respectfully submit that the appeal must be dismissed.

7.2.4 Regulation 31 – Adjacent Premises and Same Site Considerations

7.2.5 (a) The Legal Framework

7.2.6 Regulation 31(1) mandates refusal of a routine application where Regulation 31(2) applies.

7.2.7 Regulation 31(2) applies where:

7.2.7.1 A person on the pharmaceutical list (which may or may not be the applicant) is providing pharmaceutical services at or from the premises to which the application relates, or adjacent premises; and

7.2.7.2 It is reasonable to treat the services proposed as part of the same service such that the premises should be treated as the same site.

7.2.8 Corporate separation is expressly irrelevant. The Regulation concerns site integrity and functional reality, not ownership structure.

7.2.9 (b) The Premises Are Adjacent as a Matter of Fact

7.2.10 The proposed premises at Unit 26 and Proheal Pharma at Unit 27:

7.2.10.1 Are numerically adjacent.

7.2.10.2 Share the same road name (Frobisher way) and postcode (TA2 6BB).

7.2.10.3 Form part of the same confined commercial estate.

7.2.10.4 Share access routes and delivery infrastructure.

7.2.10.5 Are physically contiguous within the same trading cluster.

7.2.11 The applicant's mapping imagery materially underrepresents this physical proximity. In reality, Unit 26 sits immediately behind and within the same estate footprint as Unit 27.

7.2.12 Judicial authority confirms that "adjacent" is a contextual concept and may include premises that are immediately proximate, even if not physically attached. The degree of proximity here plainly satisfies that test.

7.2.13 [Photographs provided]

7.2.14 (c) The "Same Service" Test – Substance Over Form

7.2.15 The applicant proposes to provide:

7.2.15.1 Essential services under Schedule 4;

7.2.15.2 Drug Tariff Part IX appliances (excluding measuring/fitting);

7.2.15.3NMS (remotely).

7.2.16 These are identical in nature and scope to the pharmaceutical services already provided from 27 Frobisher Way.

7.2.17 Given:

7.2.17.1Immediate physical proximity.

7.2.17.2Overlapping service scope.

7.2.17.3Competition for the same patient population.

7.2.17.4Operational indistinguishability in service type,

7.2.18 it would be artificial to treat these as distinct sites for regulatory purposes. Regulation 31 exists to prevent fragmentation of what is functionally the same site into multiple listings. On the facts, Regulation 31(1) is engaged and mandates refusal.

7.2.19 Regulation 25(2)(b) – Distance Selling Requirements

7.2.20 Even if Regulation 31 were not determinative, the application fails under Regulation 25(2)(b).

7.2.21 NHS England must be positively satisfied that the applicants' procedures are likely to secure:

7.2.21.1The uninterrupted provision of essential services to persons anywhere in England; and

7.2.21.2The safe and effective provision of services without face-to-face contact at the premises.

7.2.22 The applicant has not discharged that burden.

7.2.23 (a) Failure to Address Committee Concerns

7.2.24 The Committee previously raised explicit concerns (Decision Report, Point 51) regarding management of patient expectations, given the applicant's nearby pharmacy at Staplegrove and the proposed DSP model at Frobisher Way.

7.2.25 The revised SOPs:

7.2.25.1Do not contain proactive patient-facing safeguards.

7.2.25.2Rely primarily on verbal management of enquiries.

7.2.25.3Do not set out robust website guidance.

7.2.25.4Contain no clear site-specific signage strategy.

7.2.26 In circumstances where a DSP operates immediate proximity to other pharmacies, clear and proactive differentiation is a fundamental safeguard. The absence of such measures creates foreseeable risk of patient confusion, misdirection, and delay in care. This is directly relevant to Regulations 25(b)(ii) and 64(3)(d)(ii).

7.2.27 (b) Co-Location Risk – Two DSPs in Immediate Proximity

7.2.28 The Regulations do not contemplate multiple independent-distance-selling pharmacies operating side-by-side within the same tightly confined site cluster. The proposed configuration creates foreseeable risks, including:

7.2.28.1 Courier misdirection and incorrect collections.

7.2.28.2 Delivery delays.

7.2.28.3 Blurring of operational boundaries.

7.2.28.4 Patient confusion, particularly among elderly or vulnerable persons.

7.2.28.5 Attempted attendance at the wrong premises.

7.2.29 The applicant's SOPs are generic and contain no site-specific procedures to manage:

7.2.29.1 Misdirected deliveries.

7.2.29.2 Courier confusion.

7.2.29.3 Cross-site logistical errors.

7.2.30 SOPs written for a standalone DSP are insufficient where another DSP operates immediately adjacent.

7.2.31 On that basis, the statutory requirement that services be "likely" to be provided safely and effectively is not satisfied.

7.2.32 (c) Consultation Room and Confidentiality Conflict

7.2.33 Paragraph 35.8 of the applicant's SOPs requires telephone conversations involving health data to be moved to a separate consultation room where there is risk of being overheard.

7.2.34 The submitted floor plan identifies only one consultation room.

7.2.35 The SOP:

7.2.35.1 Does not provide for circumstances where the consultation room is already occupied.

7.2.35.2 Does not define alternative compliant safeguards.

7.2.35.3 Creates an operational inconsistency between written procedure and physical layout.

7.2.36 Regulation 25 requires confidence in reliable and repeatable compliance. Reliance on informal workarounds outside the written SOP framework is insufficient. Accordingly, patient confidentiality safeguards are not demonstrably secured.

7.2.37 Material Deficiencies and Misleading Site Information

7.2.38 The integrity of the pharmaceutical list system depends upon accurate and complete disclosure.

7.2.39 In this case:

7.2.39.1 The original application omitted SOPs.

7.2.39.2 Section 5 was marked “Not applicable.”

7.2.39.3 The immediately adjacent pharmacy at 27 Frobisher Way was not identified.

7.2.39.4 The applicant subsequently stated it was unaware of its location.

7.2.39.5 The submitted site map materially underrepresents the true physical proximity.

7.2.40 Accurate depiction of physical location is central to the Regulation 31 analysis. A site map that conveys an impression of separation, where immediate adjacency exists, is materially misleading.

7.2.41 The cumulative effect of:

7.2.41.1 Incorrect form responses.

7.2.41.2 Failure to identify adjacent provision.

7.2.41.3 Late submission of key documentation.

7.2.41.4 Misleading site imagery,

7.2.42 raises serious concerns regarding the reliability and care exercised in preparation of the application.

7.2.43 An appeal process does not cure foundational defects in the original application.

7.2.44 Public Interest and Regulatory Purpose

7.2.45 The 2013 Regulations are designed to:

7.2.45.1 Prevent duplication at the same site.

7.2.45.2 Preserve orderly service provision.

7.2.45.3 Protect the integrity of the distance selling exception.

7.2.45.4 Maintain public confidence in regulatory decision-making.

7.2.46 Allowing this appeal would:

7.2.46.1 Circumvent Regulation 31.

7.2.46.2 Permit functional co-location of multiple DSPs within the same operational site.

7.2.46.3 Undermine the structured safeguards built into the statutory scheme.

7.2.47 Conclusion

7.2.48 For the reasons set out above:

7.2.48.1 Regulation 31 applies and supports mandatory refusal.

7.2.48.2 The requirements of Regulation 25(2)(b) are not satisfied.

7.2.48.3 The original application was materially deficient.

7.2.48.4 The submission of inaccurate and misleading site information undermines reliability.

7.2.48.5 The physical configuration creates operational and patient safety risks inconsistent with the statutory framework.

7.2.49 Accordingly, we respectfully submit that the Commissioner's original decision was correct in law and invite the Committee to dismiss the appeal in its entirety."

8 Further comments

8.1 Healthcare Plus Consulting Ltd, on behalf of Vitastock Ltd

8.1.1 "Thank you for your letter dated 11th March 2026. We unfortunately feel compelled to correct the record on certain matters in the applicant's observations.

8.1.2 <u>Hazardous Items</u>

8.1.3 The Applicant's representative misunderstands our position and states that our representations were 'factually incorrect'. We stand by our claim that *"the packaging and delivery SOPs lack any consideration for hazardous material."* We stated ourselves that the only consideration of hazardous material is in respect of collection of unwanted medicines by the pharmacy's drivers.

8.1.4 The quote the Applicant's representative presents from SOP 18.7 offers no consideration of hazardous materials in respect of packaging. It is apparently not disputed by the Applicant's representative that hazardous materials are not considered in respect of delivery.

8.1.5 We do not believe that a DSP can operate safely and effectively without consideration of hazardous materials in packaging and delivery.

8.1.6 Disposal of Unwanted Medication

8.1.7 We reiterate that per the Applicant's SOPs at 25.9 (page 109 of the appeal) it is stated that:

8.1.7.1 *"If items are not suitable for return by Royal Mail (eg clinical or contaminated waste) then provide the patient with details of their local procedures for disposal."*

8.1.8 This makes it clear that there are occasions where the Royal Mail cannot collect unwanted medication. In these situations, the Applicant proposes only to signpost to other contractors. It is therefore highly misleading at best for the Applicant's representative to suggest that the use of signposting is only for cases where "*a patient does not wish to use*" available options. The reality is that there are cases where the pharmacy offers no safe and effective option for disposal of unwanted medication and so relies on the services of other contractors.

8.1.9 Specified Appliances

8.1.10 The Applicant's representative does not dispute that they will provide specified appliances.

8.1.11 While SOPs need not be structured around the Terms of Service, we submit that given the Applicant's reliance on the SOPs, all services should be addressed in their entirety by the SOPs.

8.1.12 The Applicant suggests that the SOPs are sufficient to deal with the specific requirements of specified appliances. We are doubtful that the Applicant will ensure accessories will be available and provided free of charge since the SOPs offer its users no guidance on this matter.

8.1.13 Prescriptions Requiring Supervised Consumption

8.1.14 We note that Applicant's SOPs offer staff no procedures to follow when prescriptions requiring supervised consumption are received. We also note that simply signposting a patient to a different contractor may be insufficient to allow that contractor to access the prescription.

8.1.15 New Medicine Service

8.1.16 The Applicant's representative has stated that no accreditation is needed to apply to offer NMS. However, in their application they stated "N" (No), rather than "NA" (Not Applicable).

8.1.17 The NMS service specification states:

8.1.17.1 *"Consultations undertaken as part of this service must only be carried out by pharmacists who have the necessary knowledge and skills to do so, with them assessing and declaring their competence by completing the NMS self-assessment form"*

8.1.17.2 (https://www.england.nhs.uk/long-read/community-pharmacy-advanced-servicespecification-nhs-new-medicine-service/)

8.1.18 Given that the Applicant denies they have accreditation, we doubt that the service can be provided safely.

8.1.19 Nominating Alternative Dispensing Contractors

8.1.20 SOP 12.10 which the Applicant's representative references only refers to changing pharmacy nomination rather than DACs.

8.1.21 Time Estimates

8.1.22 We note that Schedule 4, Paragraph 7(1) states:

"7(1) If a person specified in sub-paragraph (2) [a person presenting a non-electronic or EPS prescription] *asks an NHS pharmacist (P) to do so—*

(a) P must give an estimate of the time when the drugs or appliances will be ready; and

(b) if they are not ready by then, P must give a revised estimate of the time when they will be ready (until they are ready)."

8.1.23 It is clear that the DSP is required to offer time estimates when asked by the patient and must update this estimate if it is missed.

8.1.24 The Applicant's SOPs do include provision for giving time estimates on demand and their updating in respect of PTPs. However, in respect of ordinary prescriptions, an estimate is only given when items are dispatched. There appears to be no provision for patients to request an estimate on demand, nor any provision for these estimates to be updated if missed in respect of normal non-electronic and EPS prescriptions."

9 Response to further comments

9.1 Rushport Advisory LLP, on behalf of the Applicant

9.1.1 "I act for John Ware Limited and am instructed to submit this reply to comments received on my client's appeal from interested parties. We note that Healthcare Plus Consulting has continued to submit comments even though they had no right to do so.

9.1.2 Below I address the points raised by Healthcare Plus Consulting ("HCP") so as there is no confusion about my client's position.

9.1.3 **Hazardous Materials**

9.1.4 HCP States;

9.1.4.1 *It is apparently not disputed by the Applicant's representative that hazardous materials are not considered in respect of delivery*

9.1.5 A professional advisor should not make a comment like this when the point in issue has been specifically disputed and denied.

9.1.6 The Choice of Packaging section makes clear that the nature of items being delivered must determine the appropriate level of protection. There is no requirement to list all types of medicines with individual packaging requirements.

9.1.7 SOP18.7 states "*Choice of packaging will depend on the nature of the items being delivered and the appropriate level of protection must be used to ensure that the item can withstand the normal rigours of the delivery process*."

9.1.1 SOP 25 identifies hazardous waste as requiring separate handling and disposal procedures due to the fact that these items may have been opened by patients and may not be in their original packaging or containers.

9.1.2 **Disposal of Unwanted Medicine**

9.1.3 HCP describes my client's position on the Disposal of Unwanted Medicines as "highly misleading". This is an unprofessional comment which should not have been made. The SOP is absolutely clear about how medicines can be disposed of using various routes.

9.1.4 **Signposting for Appliances**

9.1.5 HCP continues to question how additional items supplied with specified appliances will be delivered to patients despite the fact that this is a perfectly normal part of dispensing. The other items referred to by HCP such as bags or wipes are simply added to the dispensed products.

9.1.6 SOP 19.6 states;

9.1.6.1 *Pack the prescription bag **and any other items for delivery** securely in the appropriate outer packing. Ensure that all relevant paperwork and any notes from the pharmacist are included.*[emphasis added].

9.1.7 **Prescriptions Requiring Supervised Consumption**

9.1.8 The submission on this point is misconceived. My client's pharmacy is not permitted to provide a supervised consumption service and has not applied to offer the service. No DSP can provide this service. Any prescription containing a medicine for supervised consumption would not be dispensed and the patient would be signposted to alternate providers.

9.1.9 **NMS**

9.1.10 HCP's submission on the NMS service has become even more misconceived. If an Applicant does not have accreditation to provide NMS at the time that they submit their application then they should write "N" for "No" in the relevant box.

9.1.11 The service cannot be commenced until the Applicant receives accreditation at a later date.

9.1.12 **Nominating Alternative Dispensing Contractors**

9.1.13 The submission from Vitastock's representative on this point is still misconceived. SOP12.10 is not limited to changing the pharmacy nomination and refers to nominations in general.

9.1.14 **Time Estimates**

9.1.15 We note that HCP is now introducing a new ground into their submissions despite their time for doing so having long passed. Whilst the ground is entirely without merit it is another example of the behaviour that HCP engages in.

9.1.16 In fact the provision of time estimates to patients for delivery of medication (including updating these times) is dealt with at;

9.1.16.1 Page 26 – 6.7 Delivery estimate for special items

9.1.16.2 Page 44 – point 15 delivery times for Pharmacy First

9.1.16.3 Page 48 – point 39 for Pharmacy First

9.1.16.4 Page 69 - SOP 14.5 for Prescription Owings

9.1.16.5 Page 76 – 16.11 for Urgent Items

9.1.16.6 Page 77 – 17.5 for PtP

9.1.16.7 Page 82 – 19.8 for Delivery Process

9.1.16.8 Page 83 – 19.13 para 3 – updated delivery time following unsuccessful delivery

9.1.16.9 Page 85 18.6 part 15 courier live updates on delivery time.

9.1.17 I look forward to hearing from you in due course."

10 **Consideration**

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

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

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

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

Regulation 31

10.5 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") at or 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).

10.6 The Committee noted that on its application form the Applicant had stated "*Not applicable as the nearest pharmacy provides different services and is a member of he* [sic] *same body corporate.*" In the determination, the Commissioner stated:

10.6.1 "*The SW Committee noted there is another DSP in premises very near to the proposed premises and in considering Part 2 a) and b) of Regulation 31 noted part a) may be met, however, the DSP already operating nearby is a different company with different directors therefore it is not reasonable to treat the services as the same services so part b) is not met. The SW Committee agreed it ought not to matter if both providers are providing services nationally to patients.* ***The SW Committee was satisfied it is not required to refuse the application by virtue of Regulation 31.***"

10.7 The Committee had regard to Proheal Pharma's representations which state:

10.7.1 "*The proposed DSP premises at Unit 26, Frobisher Way and our pharmacy at Unit 27, Frobisher Way are numerically adjacent and separated only by a grass verge. Although not physically attached, the premises are immediately proximate and reasonably capable of being regarded as adjacent in operational terms.*"

10.8 The Committee noted that Rushport Advisory, on behalf of the Applicant, respond as follows:

10.8.1 "*It is acknowledged that Proheal Pharma operates an existing DSP from an adjoining unit at Frobisher Way under the body corporate name of 3D Healthcare Ltd. My client was not aware of the existence of this pharmacy when they made their application and therefore incorrectly stated that there was no other pharmacy in the same or adjacent premises. We apologise for this error.*"

10.9 The Committee noted there is no dispute that the proposed premises are adjacent to those of Proheal Pharma at Unit 27, Frobisher Way and therefore Regulation 31(2)(a) is satisfied.

10.10 With regard to Regulation 31(2)(b), the Committee considered whether it is reasonable to treat the services that the Applicant proposes to provide as part of the same service as the existing services.

10.11 The Committee noted Proheal Pharma's comment that "*Corporate separation is expressly irrelevant. The Regulation concerns site integrity and functional reality, not ownership structure.*" Proheal Pharma also contend that the services proposed by the Applicant are "identical in nature and scope" to those Proheal Pharma already provide at the adjacent premises.

10.12 The Committee also noted Healthcare Plus Consulting Ltd's comments:

10.12.1"*…the nearest pharmacy, which appears to be in the same estate as the proposed pharmacy and may share a boundary with the proposed site, is indeed of the same body corporate. While providing different services is not relevant to Regulation 31, we note that being a member of the same body corporate has generally been found to be sufficient to render a pharmacy in breach of Regulation 31(b).*"

10.13 In response Rushport Advisory states that:

10.13.1"*Contrary to the submission from Proheal, the High Court has considered Regulation 31(2)(b) and determined that there must be some connection between the two pharmacies (other than physical) for the regulation to apply (R (Pharmacy Care Plus) v FHSAU [2013] EWHC 824 (Admin)). …*

10.13.2*There is no connection of any sort between my client and Proheal Pharma. This is perfectly clear from the fact that Proheal Pharma is an objector to this application. As there is no connection whatsoever between Pro Heal and my client regulation 31(b) does not apply. …*

10.13.3 *It is unclear why Vitastock's representative continues to suggest that my client John Ware Ltd and Pro Heal Pharma (3D Healthcare Ltd) are the same corporate body. Not only is there no evidence to support the suggestion, but there is clear evidence that the suggestion is false.*"

10.14 Whilst noting that confusion had been caused by the statement in the application form, the Committee was satisfied, based on the information subsequently provided, that there is no connection between the Applicant and Proheal Pharma. Proheal Pharma does not seek to argue that it has any connection with the Applicant, and the Committee noted that Healthcare Plus Consulting Ltd did not comment further on the matter after having received a copy of Rushport Advisory's representations. The Committee was also mindful that the Commissioner was satisfied that "*the DSP already operating nearby is a different company with different directors therefore it is not reasonable to treat the services as the same services so part b) is not met.*"

10.15 The Committee was therefore not required to refuse the application under the provisions of Regulation 31.

Regulation 25

10.16 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."

10.17 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)

10.18 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)

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

Regulation 25(2)(b)

10.20 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.

10.21 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.

10.22 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.

10.23 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 updated SOPs which the Applicant has prepared or commissioned.

10.24 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 updated SOPs in order to satisfy itself that it is appropriate to grant the application, the absence of which would require it to reject it.

10.25 The Committee first considered how the Applicant would provide essential services without interruption and noted the following information in the Applicant's SOPs:

10.26 SOP 1: "Introduction and Background to SOPs"

10.26.1"*1.3 Overriding Provisions Applicable to All SOPs*

> *The uninterrupted provision of pharmaceutical services, during the opening hours of the premises, to persons anywhere in England who request those services.*
>
> *The safe and effective provision of pharmaceutical services without face-to-face contact between any person receiving the services, whether on their own or on someone else's behalf, and the owner of this pharmacy or any member of staff either on or in the vicinity of the premises.*"

10.27 SOP 33: "The Responsible Pharmacist"

10.27.1"*33.9 Absence of the RP*

As a Distance Selling pharmacy, we must provide uninterrupted service throughout the opening hours of the pharmacy. Whilst the GPhC permits the absence of the RP from the pharmacy in particular situations, the NHS Terms of Service still require a pharmacist to be present so that services are not interrupted. [Applicant's emphasis]

If, for any reason, the RP wishes to leave the premises or wishes to take a break then the second pharmacist must sign in as the RP and arrangements must be made for this prior to one RP leaving the premises and another RP signing in."

10.28 With regard to services being available to persons anywhere in England, the Committee noted the following information in the Applicant's SOPs:

10.29 SOP 1: "Introduction and Background to SOPs"

10.29.1"*1.3 Overriding Provisions Applicable to All SOPs*

In order to comply with our terms of service, this pharmacy will provide… to persons anywhere in England who request those services."

10.30 SOP 3: "Procedures for NHS Pharmaceutical Services"

10.30.1"*NHS Pharmaceutical Services will be provided to any patient living in England who requests such services, this is made clear on the website and in the Practice leaflet.*"

10.31 The Committee next considered how the Applicant would provide pharmaceutical services without face to face contact. The Committee noted the Commissioner was not satisfied that all essential services were likely to be secured without face to face contact. The Committee also had regard to comments from Proheal Pharma regarding potential confusion for patients arising from the location of Staplegrove Pharmacy which provides face-to-face services in close proximity to the proposed premises.

10.32 The Committee considered the following information in the Applicant's SOPs:

10.33 SOP 1: "Introduction and Background to SOPs"

10.33.1"*1.3 Overriding Provisions Applicable to All SOPs*

In order to comply with our terms of service, this pharmacy will provide;…

The safe and effective provision of pharmaceutical services without face-to-face contact between any person receiving the services, whether on their own or on someone else's behalf, and the owner of this pharmacy or any member of staff either on or in the vicinity of the premises…

… All staff must be made aware that face to face contact between patients (or their representatives) is prohibited in respect of any and all NHS services either on or in the vicinity of the premises.

Any reference to 'contact' with or 'contacting' a patient in relation to these SOPs means contact other than face-to-face contact either on or in the vicinity of the premises."

10.34 SOP 3: "Procedures for NHS Pharmaceutical Services"

10.34.1"*3.1 Communication Channels*

All communication regarding NHS Pharmaceutical Services should be carried out using the most suitable non face to face method for the patient and the service being provided with particular consideration to maintaining confidentiality. This may be telephone, email, video-conferencing or other types of non face to face communications such as text messages.

The pharmacy has provision for both live audio and live video communication with patients and this must always be carried out in the specified confidential area of the pharmacy premises."

10.34.2"*3.2 Request for face-to-face service provision*

OUR PHARMACY OPERATES FROM SELF-CONTAINED PREMISES THAT USE A CONTROLLED ACCESS SYSTEM. MEMBERS OF THE PUBLIC ARE NOT ABLE TO ATTEND THE PREMISES TO RECEIVE ANY NHS SERVICES [Applicant's emphasis]

If any member of staff receives a query from any member of the public, or patient or their carers that requests the provision of any pharmaceutical service face to face on or in the vicinity of the premises then they must;

Inform the person that, we cannot provide any face to face NHS services

Refer the person to the Responsible Pharmacist if they require any further explanation."

10.35 The Committee was mindful of the regulatory changes as of 1 October 2025 and 31 March 2026, that distance selling pharmacies can no longer provide Directed services (Advanced, National Enhanced and Enhanced Services) face to face with the patient at the pharmacy premises. As a result of this amendment, the Committee noted that the Applicant would not be able to provide any pharmaceutical services to patients present at its premises.

10.36 In its application the Applicant stated that it intended to provide "*NMS (remotely with consent where required)*" where accredited and commissioned. The Committee noted SOP 7 'The New Medicine Service ("NMS")' which states "*The service must be provided remotely by phone or video call.*"

10.37 The Committee was aware that if 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.

10.38 The Committee was satisfied that the provision of essential services would be without interruption, would be available to persons anywhere in England and pharmaceutical services would be provided without face to face contact. The Committee went on to consider whether the safe and effective provision of pharmaceutical services was likely to be secured.

10.39 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.

Dispensing of drugs and appliances

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

10.41 The Committee noted SOP 3 'Procedures for NHS Pharmaceutical Services' states:

10.41.1*"…Patients who wish to send paper prescriptions to the pharmacy by post should be sent stamped addressed envelopes to enable them to do so."*

10.42 SOP 6 'Online Order Receipt & Exemption Checking' states:

10.42.1"6.7 Administration Checks

Check all prescriptions received in the post against printed and written prescription reception forms. Check the corresponding prescription has been received in the post…"

10.43 SOP 19 'Order Delivery' states:

10.43.1"*19.6 Choice of Delivery Method*

For items <u>other than</u> cold chain / "fridge line" items, local deliveries (up to 30 miles radius, but may be extended at the discretion of the RP) the delivery driver should deliver medication. Outside this area Royal Mail should be used unless the prescription is for a controlled drug, in which case the nominated controlled drugs courier must be used (see SOP for Delivery of Controlled Drugs), or the items are fridge lines, in which case the cold chain courier must be used (see below). [Applicant's emphasis]."

10.44 The Committee was therefore satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 5(2) and 5(3) of Schedule 4.

10.45 The Committee was satisfied that the Applicant was proposing to offer the service to all of England, as per the information contained in the SOPs.

Urgent supply without a prescription

10.46 The Committee considered whether the Applicant had explained how it proposes to safely and effectively receive requests from prescribers for urgent supplies of drugs and appliances. In doing so, it had regard to Healthcare Plus Consulting Ltd's comments.

10.47 The Committee noted the information in the Applicant's SOPs under the heading 'Emergency Supply and Urgent Supply' which describes how the Applicant will process such a request. The Committee noted that the SOPs refer to pharmaceutical services being delivered by several means of non-face to face communication including telephone and email, and considered that it was reasonable to infer that these methods would be used to receive requests from prescribers for the urgent supply of drugs.

10.48 The Committee was therefore satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 6 of Schedule 4.

Preliminary matters before providing ordered drugs or appliances

10.49 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.

10.50 The Committee noted SOP 6 'Prescription Receipt & Exemption Checking states:

10.50.1"*6.9 Exempt NHS Prescriptions*

> *Where evidence of exemption is required or provided by the patient it can be sent to the pharmacy for verification via the delivery driver and then returned to the patient. The PMR system should be updated to reflect that necessary check has been carried out and a note of when the next check is required should be entered onto the system. The Regulations require a patient to produce 'satisfactory evidence' to confirm exemption. Where appropriate (i.e., for deliveries made other than by the pharmacy's delivery driver), the patient may scan or fax copies of the evidence to the pharmacy (or use the postal / courier service, but see NOTE below) and the pharmacy can note that the evidence provided was not in original format. It is for the pharmacist in charge to determine if the evidence is satisfactory or not and, if not, then cross the 'Evidence not Seen' box.*"

10.51 The Committee was therefore satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 7(3) of Schedule 4.

10.52 The Committee considered whether the Applicant had explained how charges will be paid.

10.53 The Committee noted SOP 6 'Prescription Receipt & Exemption Checking states:

10.53.1"*6.12 Paid NHS Prescription*

Check the prescription to confirm how many charges are due.

Check to see if any fees have been paid and if so, was the correct amount paid?

Contact the patient to arrange payment using the secure payments system using the "customer not present" option.

If no fees have been paid or there is a discrepancy between fees paid and those due, the patient should be contacted and directed to pay the appropriate fees via the online payment system."

10.54 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 7(5)(b) of Schedule 4.

Providing ordered drugs or appliances

10.55 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).

10.56 The Committee noted SOP 19 'Order Delivery' states:

10.56.1"*19.10 Transfer to the Delivery Driver*

Ensure that the pharmacist on duty is available to supervise the handing over of all items for delivery.

Ensure that any special instructions for the delivery are included with the packaging.

Ask the delivery driver to check the details on the delivery sheet correspond to the deliveries.

Ensure the delivery driver completes all the sections on the delivery sheet including their name and the date.

Ensure the delivery driver is notified of any messages for the patient or representative.

Make and retain a copy of the delivery sheet until the original has been returned by the delivery driver. The original must be returned to the pharmacy on the same day.

Ensure the deliveries are placed in the delivery vehicle and are stored securely and out of sight. The delivery vehicle must be locked at all times when left unattended."

10.56.2"*19.11 Delivery of prescription to patient or representative address*

Ask the patient/representative for their name and address.

Check the patient name and address against the prescription and the bag label. Patient confidentiality should be maintained at all times, especially if delivering to a representative.

Where appropriate ask the patient or representative to complete the reverse of the prescription.

Hand the medication to the patient or representative.

Ask the patient or representative to sign their details on the delivery sheet. If they are unable to sign the delivery sheet the delivery driver should sign on their behalf with their consent and write a note explaining the reason the patient or representative could not sign.

If necessary, collect any medication returns. Always use the Patient Returned Medication Tray that is available in the delivery vehicle. Refer to the Patient Returned Medicines SOP for further guidance."

10.56.3"*19.12 Successful delivery*

Once the deliveries are completed, return the delivery sheets to the pharmacy on the same day. The delivery sheets must be scanned into the pharmacy IT system and kept for a minimum period of 7 years."

10.56.4"*19.13 Unsuccessful Delivery*

If the patient or representative is not able to receive the delivery of their medication, complete the 'attempted delivery' form and post it through the letterbox. The form will have details for arranging re-delivery.

The prescription and medication must be returned to the pharmacy on the same day and the pharmacist informed of the unsuccessful delivery.

The pharmacy must follow up the unsuccessful delivery by contacting the patient to arrange a second delivery time.

DO NOT:

Post the medication through the letter/post box.

Leave the medication in the porch or any other out building.

Leave the medication at an unauthorised address."

10.56.5“*19.14 Delivery of a prescription via Royal Mail (Not for Cold Chain or CDs)*

Follow preparation for delivery process. The pharmacist must contact any patients for whom there are relevant messages or counselling required.

Ensure that the pharmacist on duty is available to supervise the handing over of all items for delivery.

Print and attach relevant Royal Mail Signed For delivery labels using the Royal Mail online business account and attach securely to outer packaging.

Ensure a return address is printed clearly on the outer packaging.

Confirm details of all prescriptions to be delivered.

Make a note of all Tracking numbers for prescriptions being delivered by Royal Mail on Delivery Log sheet.

Ensure Royal Mail driver signs Delivery Log sheet for all prescriptions being accepted for delivery. The delivery sheets must be scanned into the pharmacy IT system and kept for a minimum period of 7 years.

Email patients dispatch confirmation with their Tracking number when the prescriptions have left the premises.

All deliveries will require a signature from the patient to confirm receipt of their prescription.”

10.56.6“*19.15 Unsuccessful Delivery via Royal Mail*

In the event of an unsuccessful delivery, Royal Mail will leave a ‘Sorry We Missed You’ card, stating the date and time of the attempted delivery. The patient can then either choose to collect and sign for their medicines at their local post office, or rearrange delivery for a convenient time by telephone or email.”

10.56.7“*19.16 Cold chain delivery via courier*

All cold chain deliveries must be carried out by couriers with verified and approved cold chain procedures. A list of approved cold chain couriers is available within the Pharmacy and will be updated from time to time. Each approved courier meets stringent criteria to ensure a fully monitored and dedicated cold chain service.

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

Any breach of cold chain conditions will be notified to the driver and any affected delivery will be cancelled with the pharmacy informed of the cold chain breach.

… Ensure any items for cold chain delivery via courier are stored in the fridge and accompanying items are appropriately marked with a fridge line sticker. Accompanying items must include a note to explain that fridge items will be delivered separately to the rest of their items to enable the cold chain to be maintained.

Ensure that the pharmacist on duty is available to supervise the handing over of all items for delivery.

A delivery must be booked using the couriers specified Cold Chain Services (refer to booking procedure with courier in the "cold chain courier" folder),

Select a delivery maintaining 2– 8°C unless the item requires shipping at a different temperature.

The cold chain item must be kept in the fridge until the courier arrives to accept the delivery.

Confirm with the courier that the delivery will be maintained at the booked temperature range.

Confirm details of all prescriptions to be delivered.

The courier must scan a barcode sticker for each item. The pharmacy retains a copy of the barcode which is also the tracking number."

10.56.8"*19.17 Unsuccessful cold chain delivery via courier*

In the event of an unsuccessful delivery, the courier will leave a 'Missed Delivery' card, stating the date and time of the attempted delivery along with details of how to contact the courier to arrange the redelivery. The patient can then rearrange delivery for a convenient time by telephone or Internet.

We operate to a 48 hour maximum window for cold chain deliveries and the courier will keep the cold chain intact until successful delivery for up to 48 hours. After 48 hours the items will be returned to the pharmacy and the pharmacy will contact the patient to rearrange delivery."

10.56.9"*19.18 Breach of Integrity of Cold Chain*

The courier ensures temperature integrity throughout the supply chain, from point of collection & goods-in to pharmaceutical storage to final delivery.

The cold chain service is a dedicated, fully monitored and temperature controlled delivery service. However, in the event of any breach in the

integrity of this service, the system automatically alerts the delivery driver that the cold chain has not been kept intact.

Where such an event occurs, the courier is instructed to leave a 'Missed Delivery' card and also inform the pharmacy that the delivery was unsuccessful due to a breach of the cold chain. The pharmacy must arrange for immediate re-delivery of the items via courier and the return of the items that have failed to be delivered to the pharmacy by the courier. items subject to a cold chain breach may not be re-used and must be segregated from the pharmacy stock."

10.57 SOP 23 'Controlled Drugs: Delivery' states:

10.57.1"*23.5 Delivery of Schedule 2 & 3 CDs*

A robust audit trail is essential when controlled drugs are involved. The delivery can be made to a person who is not the patient (the patient must have given authorisation for a representative to take receipt of CDs on their behalf). A Controlled Drugs Delivery Sheet must also be filled in for CD deliveries in addition to the Delivery Log sheet.

CDs must be in a separate bag to any other medication being delivered and the bags should be attached together.

CDs and any other medicines on that patient's delivery must be stored in the lockable compartment of the delivery van and out of sight.

The delivery van must be kept locked at all times when the driver is not in the vehicle.

The delivery driver/courier must sign the back of the prescription as the representative when accepting the CD for delivery.

The delivery driver/courier must check the identity of the person accepting the delivery to ensure that it is the patient or authorised representative (passport, driving licence or government approved photo ID card are acceptable forms of ID). A delivery cannot be left with anyone who is not the patient or their authorised representative.

All entries in the CD register must be made when the medication leaves the pharmacy premises. The delivery driver/courier must be entered as the 'person collecting'.

The prescription must be retained in the pharmacy until the delivery driver returns the appropriate paperwork signed by the patient or representative to confirm successful delivery or the patient signature is confirmed online if delivered by courier."

10.57.2"*23.7 Successful Schedule 2 & 3 Delivery*

The delivery driver/courier must check the identity of the person accepting the delivery to ensure that it is the patient or authorised

representative. A delivery cannot be left with anyone who is not the patient or their authorised representative.

For all successful deliveries the Controlled Drug delivery sheet signed by the patient or online courier delivery record should be cross-referenced with the prescription and CD register prior to the prescription being processed as part of the end of day procedure."

10.57.3"*23.8 Unsuccessful Schedule 2 & 3 Delivery via pharmacy driver*

Unsuccessful deliveries sent with a pharmacy driver must be returned to the pharmacy on the same day and entered back into the CD register where appropriate with an explanation. These must then be secured in the CD cabinet where appropriate."

10.57.4"*23.9 Unsuccessful Schedule 2 & 3 Delivery via courier*

Unsuccessful deliveries sent with a courier must be returned to the pharmacy on the same day and entered back into the CD register where appropriate with an explanation. These must then be secured in the CD cabinet where appropriate. Where the time of attempted delivery means that the return cannot be made on the same day, the courier will store the drugs at their approved warehouse overnight.

When a failed delivery occurs, the tracking service will notify the pharmacy and the patient of the failed delivery so that delivery can be re-arranged for the patient at the next convenient time or returned to the pharmacy."

10.57.5"*23.10 Note re Use of Couriers for Controlled Drugs Deliveries*

The courier has pharma grade specialist facilities to meet specific quality and validation requirements for healthcare products. This includes Home Office licensed controlled drug stores."

10.58 Based on the information before it, the Committee was satisfied that the Applicant had provided information sufficient to show that there would be compliance with paragraph 8(1) of Schedule 4.

10.59 The Committee considered whether the Applicant had explained the arrangements which ensure that, for appliances which require fitting/ measuring, a registered pharmacist measures/fits them. In doing so, it had regard to Healthcare Plus Consulting Ltd's comments.

10.60 The Committee noted that in the application form, in response to the question as to whether they were undertaking to provide appliances, the Applicant had stated *"Drug Tariff part IX* *EXCEPT items that require measuring or fitting".* The Committee noted the Applicant's SOPs state:

10.61 SOP 9 'Pharmaceutical & Legal Assessment':

10.61.1"*9.9 Items Requiring Measuring and Fitting*

Where a prescription is received for an item that requires measuring or fitting the patient should be contacted and informed that these items are not available from this pharmacy as we do not provide a measuring and fitting service. Patients should be signposted to at least two other providers of the service in their area. (see signposting SOP)"

10.62 SOP 26 'Support for Self-Care, Signposting and Health Promotion':

10.62.1"*26.14 Items Requiring Measuring and Fitting*

Where a prescription is received for an appliance or stoma appliance customisation or any item that requires measuring or fitting the patient must be contacted and informed that these items are not available from this pharmacy as we do not provide a measuring and fitting service. Patients must be signposted to at least two other providers of the service in their area. (see signposting SOP)"

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

10.64 The Committee considered whether the Applicant had explained what containers will be "suitable" for posted/delivered items. In doing so, it had regard to Healthcare Plus Consulting Ltd's comments.

10.65 The Committee noted that SOP 18 'Bagging-Up' states:

10.65.1"*18.7 Choice of Packaging*

Choice of packaging will depend on the nature of the items being delivered and the appropriate level of protection must be used to ensure that the item can withstand the normal rigours of the delivery process.

All packaging must have the tamper proof seals provided in the pharmacy attached to the packaging so that any tampering with the packaging will be evident.

Medicine for local delivery which is not fragile and to be delivered by the delivery driver can be packaged in the using the pharmacy bags supplied for standard prescription items.

DO NOT use normal cardboard boxes. When cardboard boxes are required ALWAYS use the re-enforced boxes that are purchased for delivery purposes.

For postal items, either:

At the very least - padded envelopes even for non-fragile items as this will help to ensure the integrity of the manufacturers packaging.

*For most items - bubble wrap and where necessary, polystyrene filler, placed within a cardboard box. **use the re-enforced cardboard boxes***

Large or any fragile medicines should be packed into the re-enforced cardboard boxes with bubble packaging and filling material to protect from damage.

Coldchain items should be bubble wrapped and placed in Styrofoam filled re-enforced cardboard boxes and kept in the DELIVERIES FRIDGE (rather than the storage fridge) with the "FRAGILE" and "FRIDGE LINE" stickers attached. The courier company will transport the boxes in vans with cold chain sections that protect the integrity of the box ("cold ship" packaging) and are fully monitored – typically at 2 to 8 degrees Celsius range- (see delivery SOP). Pharmacy staff should be aware that some thermolabile products can be damaged by excessive cold as well as heat. Items such as ice packs can cause freezing in medicines which is damaging to them and such items must not be used. [Applicant's emphasis]"

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

Refusal to provide drugs or appliances ordered

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

10.68 The Committee noted SOP 34 'Repeat Dispensing' states:

10.68.1"*34.10 Prescription Reception*

The pharmacy record card must be completed and attached to a RA and an entry made on each occasion a dispensing takes place.

Any amendments to the RD, e.g. items not issued or change to expected interval must be recorded in the comment section of the pharmacy copy of the card."

10.68.2"*34.11 Pharmaceutical & Legal Assessment*

Terms of Service states that a pharmacy must, when providing drugs in accordance with a repeatable prescription the importance of only requesting those items which they need. Patients should be so advised either by phone or through the inclusion of written information with delivered medication.

The pharmacist should telephone and speak with the patient before issuing a repeat and ensure:

They are taking or using, and likely to continue to take or use the medicine or appliances appropriately

Advise the patient that they should only order items that they need

Check that the patient is not suffering any side effects which may suggest they need a review of their medication

Check that the patient's regimen has not been changed since the prescriber authorised the repeatable medication.

Check that there has not been any change to the patient's health since prescription was authorised

Provide advice and encourage patients with long term, stable medical conditions to discuss repeat dispensing of their medicine with their prescriber.

Any interventions, referrals (to the patient's GP or otherwise) or refusal to supply decisions which are deemed to be clinically significant should be recorded on the Intervention and Referral Form which must be shared with the patient's GP.

The prescriber must have signed the RA. The RDs will not be signed but will be numbered as appropriate. The RA will detail the specific number of issues and, if appropriate, the dispensing interval."

10.69 The Committee was therefore satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 9(4) of Schedule 4.

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

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

10.71 The Committee noted SOP 34 'Repeat Dispensing' states:

10.71.1"*34.10 Prescription Reception*

Appropriate advice about the benefits of repeat dispensing must be given to any patient who:

has a long term, stable medical condition (that is, a medical condition that is unlikely to change in the short to medium term); and,

requires regular medicine in respect of that medical condition, including, where appropriate, advice that encourages the patient to discuss repeat dispensing of that medicine with a prescriber at the provider of primary medical services whose patient list the patient is on.

Such advice will be provided by the Pharmacy using its permissible methods of non face-to-face contact with patients.

On receipt of a repeatable prescription from the patient, either in the post or collected from the surgery for the first time, the pharmacy staff should ensure that the patient fully understands the Repeat Dispensing Process and is provided with a patient information leaflet that outlines the benefits of the service.

Check to confirm if the patient has a long term, stable medical condition that requires regular medicine in the short to medium term and ensure relevant patients have the scheme explained to them."

10.71.2"*34.11 Pharmaceutical & Legal Assessment*

The pharmacist should telephone and speak with the patient before issuing a repeat and ensure:

… Provide advice and encourage patients with long term, stable medical conditions to discuss repeat dispensing of their medicine with their prescriber."

10.72 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 10(1) of Schedule 4.

Disposal service in respect of unwanted drugs

10.73 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. In doing so, it had regard to Healthcare Plus Consulting Ltd's comments.

10.74 The Committee noted SOP 24 'Controlled Drugs: Collection and Disposal of Patient Returns' states:

10.74.1"*24.5 Patient Returned Medication*

This service is available to <u>all</u> patients living in England.

Patients or their representatives may not return and medicines directly to the pharmacy and must follow the procedures set out in this SOP. [Applicant's emphasis]

Patients should be referred to the 'Returning unwanted medication' page on the website for information.

To arrange the return of unwanted medicines to the Pharmacy the patient must telephone and speak to a member of the dispensary team. For controlled drugs this must always be the pharmacist on duty.

The process for returning medication must be explained to the patient.

Each return will be made by booking an appointment for the pharmacy's driver to visit the patient's home to collect the returned medication or by sending the appropriate packaging to the patient to arrange for return by Royal Mail – Note the Royal Mail website refers to a prohibition on carrying "controlled drugs" but this refers only to illicit controlled drugs and not those supplied under the direction of a physician."

10.74.2"*24.7 Return by Royal Mail*

The pharmacist must

Speak to the patient about the return and clarify the items being returned.

Assess the items for suitability for return by Royal Mail

If items are suitable for return by Royal Mail then make a note on the PMR and arrange to send the appropriate packaging to the patient for safe return (refer to bagging up SOP for appropriate packaging)

If items are not suitable for return by Royal Mail (eg clinical or contaminated waste) then provide the patient with details of their local procedures for disposal.

Send the packaging to the patient along with the instructions for appropriate packing of the goods

Contact the patient to ensure that the packaging has been received

Provide signposting via phone or email to other pharmacies where the patient prefers to dispose of unwanted medicines locally."

10.74.3"*24.8 Handling Patient-Returned CDs from Delivery Driver*

Drivers need to:

Be aware that they cannot accept patient returns from patients without prior arrangement. The driver must notify the patient to follow the "returning unwanted medication" process as set out on the website.

Ensure that appropriate packaging is within the van prior to starting the journey as the patient may not have requested the correct type or there may be a requirement for additional packaging.

Pharmacy staff need to:

If CDs have been identified, immediately on receipt from the driver, secure them in a bag, clearly marking on 'Patient-returned CDs for destruction' and include the date of return; place the bag in the CD cabinet away from pharmacy stock until they can be destroyed.

As soon as possible, Refer to the 'Returned medicines form' to make the entry in the 'Patient returned CD register', to record the CD that require destruction at a later date."

10.75 SOP 25 'The Safe and Effective Receipt and Disposal of Medicines' states:

10.75.1"*25.6 Process for Patients to Return Medication*

Patient Returned Medication

Patients or their representatives MAY NOT return and medicines directly to the pharmacy and must follow the procedures set out in this SOP.

This service is available to all patients living in England.

Patients can be referred to the 'Returning unwanted medication' page on the website for information.

To arrange sending medication back to the Pharmacy the patient must telephone and speak to a member of the dispensary team.

Patients may

Arrange collection by the Pharmacy driver at an appointed time, or

Send unwanted medication back to the Pharmacy via courier (at the pharmacy's cost), or Royal Mail (subject to risk assessment of contents by the RP in advance) or,

The Pharmacy can arrange for medication to be collected by our specialist waste management contractor.

Advise patient of their other options to dispose of unwanted or expired medication if none of these options is suitable for them (signposting to local pharmacies).

Explaining the Process to Patients

Check which patient or patients the medication belonged to.

Check the relevant PMR to identify any hazardous / dangers drugs or items that have been dispensed and could potentially form part of the return.

Ask the patient to identify the type of medication being returned.

If there is any item considered dangerous, such as a cytotoxic, inform the patient that we will collect items using the specialist waste management contractor and arrange for that collection to take place at a convenient time.

Go through the "unwanted medicines card" (available from the CPE website) over the phone with the patient."

10.75.2"*25.7 Process for accepting patient returns by the Driver*

Confirm that a collection of unwanted medication for disposal has been booked. Returns without a booking should only happen in exceptional circumstances as this increases the chance that the proper process for segregation of medicine has not been followed.

Ensure you are fully equipped with the utensils in your vehicle to accept unwanted medication as patients may have placed unwanted medication into incorrect bags

Wear appropriate protective clothing where there is a requirement to handle any returned waste.

Identify any controlled drugs (check with the pharmacist if necessary); segregate these and place in a labelled clear bag for the pharmacist for denaturing and disposal. For further guidance read SOP Controlled Drugs: Disposal of Patient returned medication'.

Identify any sharps and ask the customer to take these back if it safe to do so, signposting to the most appropriate route of disposal.

Identify any cytotoxic or other hazardous waste (check with the pharmacist where necessary).

Identify any flammable waste and store separately until this can be removed by the waste contractor.

Where large quantities of the same medicine are being returned, then report this to the pharmacist as this could indicate a compliance issue requiring intervention.

Complete the 'Patients Returns Sheet' detailing the patients name and address, also if relevant their representatives name.

Store returned medicines in the quarantine area of the van for transport.

The returnable items can be taken back to the pharmacy for destruction.

Ensure medicines are not visible in the vehicle at all times."

10.75.3"*25.9 Return by Royal Mail*

The pharmacist must

Speak to the patient about the return and clarify the items being returned.

Assess the items for suitability for return by Royal Mail

If items are suitable for return by Royal Mail then make a note on the PMR and arrange to send the appropriate packaging to the patient for safe return (refer to bagging up SOP for appropriate packaging)

If items are not suitable for return by Royal Mail (eg clinical or contaminated waste) then provide the patient with details of their local procedures for disposal.

Send the packaging to the patient along with the instructions for appropriate packing of the goods

Contact the patient to ensure that the packaging has been received

Provide signposting via phone or email to other pharmacies where the patient prefers to dispose of unwanted medicines locally."

10.75.4"*25.10 Disposal of returned medicines*

Use the specialist waste management company to provide safe and secure disposal of unwanted medicines by collection of unwanted medicines from patients and residential homes.

Unwanted medicines collected by the driver must be sorted and placed in disposal units / containers provided by the NHSCB or a waste contractor retained by the NHSCB ready for waste management services to collect."

10.76 Based on all of the information before it, the Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 13 - 15 of Schedule 4.

Promotion of healthy lifestyles

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

10.78 The Committee noted SOP 27 ‘Promotion of Healthy Living, Lifestyle & Health Campaigns’ states:

10.78.1“*27.3 Identification of patients for promotion of Healthy Lifestyles*

Identification can take three forms, namely, passive, active, or as part of the repeat (or normal) dispensing process.

Active patients will be those who have chosen to access the Lifestyle Questionnaires via the website or returned them by post and who are then identified from the results as patients to whom further information should be sent, or who should be called to follow up on the results and offer additional support and information. All patients who have prescriptions dispensed or purchase medicines from the pharmacy will be asked to fill in the Lifestyle Questionnaire which will ask for details such as existing medical conditions, height, weight and also lifestyle questions such as whether a patient is a smoker and how much exercise they normally have on a weekly basis.

Passive patients are those where the identification happens as part of another interaction with the patient, but where the patient does not appear to be actively seeking additional assistance. For example, the dispensing of a prescription which identifies the patient as having high blood pressure / diabetes etc.

As part of repeat dispensing process (or during any other interaction with a patient) staff should record the information provided by patients on the PMR system. Where a patient provides information that indicates that they would benefit from promotion of healthy lifestyles they should be recorded as a ‘target patient’ and the appropriate information that is relevant to them should be provided.

Leaflets will be delivered to patients with their medication. Those identified as having medical conditions such as diabetes, coronary heart disease, COPD, Asthma, high blood pressure, smokers, overweight individuals, etc. or being at risk from them or other conditions will also receive targeted campaigns. The website, app and email newsletters will also be used to promote healthy lifestyles via the health promotion zone.”

10.78.2“*27.4 Health Campaigns & Community Engagement Exercise*

10.78.3*Terms of Service require participation in a maximum of 2 campaigns per financial year, but you should agree to take part in all campaigns where practicable.*

10.78.4*The Pharmacy will take part in national health campaigns to promote public health messages to patients across England. This will be achieved by sending out leaflets with prescriptions during specific targeted campaign periods and providing additional advice and learning resources via the website on the health promotion zone.*

10.78.5… *We will also offer help and support on our website and direct patients to appropriate links for the health campaigns. This will ensure that patients across the UK are able to easily access information about health campaigns at all times.*"

10.79 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 16 – 18 of Schedule 4.

Prescription linked intervention

10.80 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.

10.81 The Committee noted SOP 27 'Promotion of Healthy Living, Lifestyle & Health Campaigns' states:

10.81.1"*27.6 Long Term Conditions*

If it is appropriate to provide advice the pharmacist should provide any advice necessary and within their area of competency. Where advice is provided it should be recorded on an Intervention & Referral form. Any advice given should always aim to include counselling on healthy lifestyle as well as management of the long-term condition.

If it is not appropriate to provide advice the patient should be referred to the appropriate health or social care provider or support organisation (see Signposting SOP). Where advice cannot be provided it should be recorded on an Intervention & Referral form along with the referral organisation.

For specific groups of patients (those with diabetes, at risk of coronary heart disease, especially those with high blood pressure, and patients who smoke or who are overweight) the pharmacists must provide advice without face-to face interaction (eg telephone, Live video, via the website). Such advice should be backed up, as appropriate, by the provision of written material such as leaflets."

10.81.2"*27.7 Identification of patients for Support with Long Term Conditions*

Identification can take three forms, namely, passive, active, or as part of the repeat (or normal) dispensing process.

Active patients will be those who have chosen to access the Lifestyle Questionnaires via the website or returned them by post and who are then identified from the results as patients to whom further information should be sent, or who should be called to follow up on the results and offer additional support and information. All patients who have prescriptions dispensed or purchase medicines from the pharmacy will be asked to fill in the Lifestyle Questionnaire which will ask for details such as existing medical conditions, height, weight and also lifestyle

questions such as whether a patient is a smoker and how much exercise they normally have on a weekly basis.

Passive patients are those where the identification happens as part of another interaction with the patient, but where the patient does not appear to be actively seeking additional assistance. For example, the dispensing of a prescription which identifies the patient as having high blood pressure / diabetes etc.

As part of repeat dispensing process (or during any other interaction with a patient) staff should record the information provided by patients on the PMR system. Where a patient provides information that indicates that they would benefit from promotion of healthy lifestyles they should be recorded as a 'target patient' and the appropriate information that is relevant to them should be provided.

Leaflets will be delivered to patients with their medication. Those identified as having medical conditions such as diabetes, coronary heart disease, COPD, Asthma, high blood pressure, smokers, overweight individuals, etc. or being at risk from them or other conditions will also receive targeted campaigns. The website, app and email newsletters will also be used to promote healthy lifestyles."

10.82 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 17 of Schedule 4.

Health campaigns

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

10.84 The Committee noted SOP 27 'Promotion of Healthy Living, Lifestyle & Health Campaigns' states:

10.84.1"*27.4 Health Campaigns & Community Engagement Exercise*

The Pharmacy will take part in national health campaigns to promote public health messages to patients across England. This will be achieved by sending out leaflets with prescriptions during specific targeted campaign periods and providing additional advice and learning resources via the website on the health promotion zone.

The pharmacy will also take part in at least one approved community engagement exercise in relation to the promotion of health living each financial year.

Patients will be directed to the learning resources via email, text and other non face-to-face communication so that they are aware of the campaign.

Patients should also be assessed for participation in at least one clinical audit and whichever of the following that the NHSCB specifies—

(i) a clinical audit carried out in a manner which is compatible with the NHSCB's arrangements for the receiving and processing of data from the audit, or

(ii) a policy based audit (to support the development of the commissioning policies of the NHSCB) carried out in a manner which is compatible with the NHSCB's arrangements for the receiving and processing of data from the audit.

We will also offer help and support on our website and direct patients to appropriate links for the health campaigns. This will ensure that patients across the UK are able to easily access information about health campaigns at all times.

The Pharmacy will use the opportunity when dispensing prescriptions for patients who have conditions such as diabetes, heart disease, obesity and high blood pressure, to offer health advice over the phone or provide them with leaflets about their conditions. Patients will also be able to speak to the pharmacist regarding information about the campaigns. Advice and help will be available to patients during opening hours of the pharmacy and patients can access information on our pharmacy website at all times. This ensures the uninterrupted provision of the service to patients across England."

10.85 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 18 of Schedule 4.

Signposting

10.86 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.

10.87 The Committee noted SOP 26 'Support for Self-Care, Signposting and Health Promotion' states:

10.87.1"*26.10 Other Provider Organisations and Support Details*

Details of local health and social care providers to whom patients can be referred as well as contact details for local patient and support groups can should be provided to patients via written mailshots, flyers sent with prescription deliveries, our website and by telephone or email."

10.87.2"*26.12 Signposting*

Service Description

To minimise inappropriate use of health and social care services and support services, patients who require further support, advice or treatment which cannot be provided by the pharmacy, on other health and social care providers or support organisations who may be able to assist the person must be given sufficient information to enable them to access those services. Where appropriate, this may take the form of a referral."

10.87.3"*26.13 Patient Identification*

Identification can take place during any interaction that the patient has with the pharmacy staff. In particular, staff should consider the results from the identification of patients for the promotion of healthy lifestyles and those who have filled in the Lifestyle Questionnaire on the website.

Staff should always consider that in order to minimise inappropriate use of health and social care services and of support services and person who:

requires advice, treatment or support that we cannot provide; but

we are aware of another provider of health services who is likely to be able to provide that advice, treatment or support.

We must provide the patient with contact details of that provider and, where appropriate, refer the person to the provider. At least two providers should be identified if this is possible."

10.88 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 19 – 20 of Schedule 4.

Support for self-care

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

10.90 The Committee noted SOP 26 'Support for Self-Care, Signposting and Health Promotion' states:

10.90.1"*26.8 Patient Identification*

As part of repeat dispensing process / medicine sale or during any other interaction with a patient staff should record the information provided by patients on the PMR system. Where a patient provides information that indicates that they would benefit from support for self-care they should be recorded as a 'target patient' and the appropriate information that is relevant to them should be provided and should include:

treatment options, including advice on the selection and use of appropriate drugs which are not prescription only medicines; and

on changes to the patient's lifestyle."

10.90.2"*26.9 Service outline*

Upon receipt of a request for help with the Support for Self-Care, including treatment of minor illness and long-term conditions, pharmacy staff should consider available resources and provide general information and advice on how to manage illness.

If appropriate, access the patient's Summary Care Record / National Care Records Service to see if it assists in delivery of the service.

… The pharmacist should provide advice on the appropriate use of non-prescription medicines which can be used in the self-care of the relevant minor illness and / or long-term conditions."

10.91 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 21 – 22 of Schedule 4.

Discharge medicines service

10.92 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 regiment by the staff of an NHS trust and NHS foundation trust as part of arrangements linked to the transfer of care between different providers of NHS services.

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

10.94 The Committee noted SOP 28 'Discharge Medicines Service (DMS)' states:

10.94.1"*28.3 Process*

Every day the RP must check the pharmacy's NHS.net Connect system, PharmOutcomes and Refer to Pharmacy for referrals to the DMS. Pharmacy contractors must consider any communication in the following form and manner as constituting a referral: "Any written patient information received by a community pharmacy via secure electronic message from an NHS trust or other provider of NHS services concerning a patient's discharge to usual primary care services and their medicines regimen"."

10.94.2"*28.4 Consent*

Obtain and record the informed consent from the patient prior to provision of the service using the consent form. As part of obtaining

consent discuss the requirements for data sharing. Inform the patient that any information discussed as part of the service may be shared with their GP."

10.94.3"*28.5 DMS Stages*

It is expected that all patients referred to the pharmacy will receive all three stages of the service. Note that stages 1, 2 and 3 of the service may occur in parallel and first contact with the patient (as defined in the NHS Discharge Medicines Service toolkit) could happen at any stage in the process."

10.94.4"*28.6 DMS Stage 1 (within 72 hours of referral excluding times when the pharmacy is not open)*

The community pharmacy receives a discharge referral. A clinical review is undertaken by a community pharmacist following receipt of a patient referral. The community pharmacy team may contact the referring NHS trust contact or the PCN pharmacy team to discuss any concerns (eg an important medicine the patient usually takes is omitted on the discharge referral) and to seek clarification about the discharge referral."

10.94.5"*28.7 Considering the appropriateness of any medication changes prior to discharge*

DMS requests will not necessarily all be in the same form.

Summary Care Record / National Care Records Service Access - If appropriate, access the patient's Summary Care Record / National Care Records Service to see if it assists in providing the service

The pharmacist must review the actions requested in the DMS and consider whether the actions requested are, in the pharmacists clinical judgement, appropriate.

For actions that are considered appropriate the pharmacist must;

Use the information in the referral, to compare (as far as possible) the patient's medicines at discharge to those they were taking before admission to hospital.

Check any prescriptions issued to be dispensed to assess whether any changes are appropriate and identify any areas of concern.

Where necessary, discuss changes that may be appropriate or raise any issues of concern identified, to the extent that in accordance with the pharmacist's clinical judgement, it appropriate to do so with—

(i) the staff of the hospital or other provider of NHS services that made the referral, and

(ii) any provider of primary medical services on whose patient list the patient is; and

keep and maintain records of the DMS referrals received and of any actions taken, as appropriate (in particular, to support delivery of stages 2 and 3 of the service).

REQUIRED ACTIONS AS PER NHS GUIDANCE"

10.94.6"*28.8 DMS Stage 2*

The community pharmacy receives the first prescription following discharge. The pharmacist or pharmacy technician will ensure medicines prescribed post-discharge take account of the appropriate changes made during the hospital admission. If there are discrepancies, the pharmacy team will try to resolve them with the general practice, utilising existing communication channels. Alternatively, the community pharmacist may refer the patient to the PCN pharmacy team for a Structured Medication Review or other intervention.

If the pharmacy receives either a written or electronic prescription (or repeatable prescription) or EPS token and the pharmacy as received a request for Stage 2 of the DMS service either from Stage 1 or

Even without a referral to Stage 2, the pharmacy receives such a prescription as described above and the pharmacy is aware as a result of an earlier referral to Stage 2 or Stage 3 that this is the first prescription for a medicinal product following the patient's discharge from hospital, or a transfer of the patient's care from another NHS service provider, AND

The pharmacy is aware that either the patient, or their carer wishes the pharmacy to provide Stage 2 of the DMS service then the pharmacy must provide the following service as part of Stage 2

Then the pharmacist must:

Review / perform a further review of any prescription

Summary Care Record / National Care Records Service Access - If appropriate, access the patient's Summary Care Record / National Care Records Service to see if it assists in providing the service.

Specifically consider if in your clinical judgement appropriate account has been taken to any changes in the medication regimen during the patient's stay in hospital or prior to the transfer of the DMS from another pharmacy.

Where you see areas of concern, raise those issues as appropriate with the patient's GP

Keep and maintain records of the DMS referrals received and of any actions taken, as appropriate (in particular, to support delivery of stage 3 of the service)."

10.94.7"*28.9 DMS Stage 3*

The NHS Discharge Medicines Service should also be used as an opportunity to engage with patients about their medicines on a shared decision-making basis. Whether the patient or their carer makes contact themselves for advice, a referral is received from an NHS trust on discharge or a prescription is received following prescribing changes, the pharmacist or pharmacy technician should take the opportunity to establish the patient's understanding of their condition(s), their associated medications and how each medicine can be best administered to get optimum benefit and reduce unwanted side effects.

The community pharmacy checks the patient's understanding of their medicines regimen. The pharmacist or pharmacy technician will hold a discussion, adopting a shared decision-making approach, with the patient (or the carer if appropriate) to check their understanding of their post-discharge medicines' regimen. The pharmacist or pharmacy technician will identify any adherence, clinical issues, outstanding questions or needs the patient may have regarding their medicines."

10.95 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 22B and 22C of Schedule 4.

Websites and health promotion zones

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

10.97 The Committee noted that SOP 26 'Support for Self-Care, Signposting and Health Promotion' states:

10.97.1"*26.11 Health promotion zone on our website*

The website allows patients to access pharmaceutical services via our interactive page.

Explaining the Interactive Page to Patients

The interactive page is promoted on the website so that when a patient first visits the website they are signposted to a range of up to date materials that promote healthy lifestyles.

The Superintendent Pharmacist is responsible for ensuring that a reasonable range of materials are accessible via the interactive page and that they address a reasonable range of health issues.

The health promotion zone may also includes details of current health campaigns and other information to promote healthy lifestyle choices as well as providing access to the Lifestyle Questionnaire that is used to target health information to patients."

10.98 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 28C of Schedule 4.

Other considerations

10.99 The Committee noted Proheal Pharma's comments in their representations under the heading "*No Identified Need or Regulatory Benefit (Regulations 17 and 18)*" and was of the view that these were not relevant considerations for an application made under Regulation 25.

Summary

10.100 On the information before it, the Committee could be satisfied that there are procedures likely to secure the safe and effective provision of pharmaceutical services as required by Regulation 25(2)(b).

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

10.101.1 confirm the Commissioner's decision;

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

10.101.3 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.

10.102 Given that the Committee had reached a different decision, it determined that the decision of the Commissioner must be quashed.

10.103 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.

10.104 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.

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

11 Decision

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

11.2 The Committee:

11.2.1 quashes the decision of the Commissioner; and

11.2.2 redetermines the application as follows -

11.2.2.1 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;

11.2.2.2 the Committee was satisfied that all essential services were likely to be secured without interruption during the opening hours;

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

11.2.2.4 the Committee was satisfied that pharmaceutical services were likely to be secured in a safe and effective manner; and

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

11.2.3 The application is granted.

Case Manager
Primary Care Appeals