NHS Resolution

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22 January 2026

REF: SHA/26764

APPEAL AGAINST LANCASHIRE AND SOUTH CUMBRIA ICB DECISION TO REFUSE AN APPLICATION BY SERIVA LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT 117-121 BOND STREET, BLACKPOOL, FY4 1EY 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 representing Seriva Ltd
PCSE, on behalf of Lancashire and South Cumbria ICB
Community Pharmacy Lancashire and South Cumbria

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1 The Application

By application dated 15 June 2025, Seriva Ltd ("the Applicant") applied to Lancashire and South Cumbria ICB ("the Commissioner") for inclusion in the pharmaceutical list at 117 – 121 Bond Street, Blackpool, FY4 1EY 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

1.2 "Drug Tariff part IX*

1.3 *EXCEPT items that require measuring or fitting."

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

1.5 "Not applicable as no other pharmacy in same or adjacent premises."

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

1.7 "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."

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

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

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

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

1.9 “SEE ATTACHED INFORMATION.”

1.10 [Appendix A for Committee – SOPs for Seriva Ltd] [NOTE Appendix C supersedes Appendix A]

2 Applicant’s ‘14 day comments’ to the Commissioner

The 14 day comments dated 18 August 2025 received by the Commissioner were not circulated to parties prior to it considering the application. NHS Resolution used it discretion to circulate these comments along with the appeal.

2.1 “Thank you for your letter of 18 August 2025. I act for Seriva Ltd in the above application and have been instructed by my client to submit the following reply to the consultation comments received.

2.2 Interested parties ask that the ICB applies the correct legal test when determining the application and my client has provided their SOPs to show that the test will be met in full.

2.3 Lytham Road Pharmacy

2.4 Lytham Road pharmacy’s comments amount to an objection to the existence of regulation 25 rather than any specific comment on my client’s application and we therefore do not respond further to the comments made as they will not be relevant to the ICB’s decision making process.

2.5 LPC Comments

2.6 The LPC lists a number of points which appear to be general commentary on DSPs and the LPC’s dislike of those pharmacies, which is of course of no relevance to the legal test.

2.7 Comments about other existing DSPs and breaches of Regulations should be raised with the ICB specifically in relation to the contractor that is alleged to be in breach of their Terms of Service and are not relevant to my client’s application.

2.8 Dealing with some of the bullet points listed in the LPC letter we reply as follows.

2.9 The LPC should be aware that the superintendent pharmacist is not annotated on the GPhC until after they submit a nomination of superintendent form which is sent at the same time as the premises registration form. This will occur after NHS approval.

2.10 The location of other pharmacies is irrelevant.

2.11 Almost all pharmacy contractors purchase 3rd party SOPs including the pharmacies that the LPC represents. It is not clear from the LPC comment if they are criticising all pharmacies that they represent, or only my client.

2.12 Comments on opening hours are irrelevant to the legal test.

2.13 Premises security is a matter that the GPhC assesses. The GPhC will not register premises if they are not secure and the NHS will not include the pharmacy on the pharmaceutical list without the GPhC premises registration being approved.

2.14 Re NMS – the premises and contractor will not be accredited until after the pharmacy opens and the LPC should really be aware of this. In no way does this undermine my client's ability to provide services safely and effectively and it is unfortunate for the LPC to make such a claim.

2.15 As already noted above, criticism of other pharmacies is of no relevance to my client's application.

2.16 **Regulatory Changes and NMS**

2.17 As a result of the changes made to the Regulations on 23 June 2025, the Committee will no longer consider only the safe and effective provision of essential services and will instead consider the provision all NHS pharmaceutical services provided to patients.

2.18 My client has updated their SOPs to reflect the new legal test and the SOP for NMS has been added and is attached to this reply for the consideration of the Committee.

2.19 The information already provided demonstrates how the legal test will be met in full and the application should therefore be approved.

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

2.21 [Enclosure SOP entitled The New Medicine Services ("NMS"). – Appendix B for Committee]

2.22 [NOTE Appendix C supersedes Appendix B.]

3 **The Decision**

The Commissioner considered and decided to refuse the application. The decision letter dated 21 October 2025 states:

3.1 "Lancashire and South Cumbria 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 Lancashire and South Cumbria 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."

Determination – Pharmaceutical Services Group Wednesday 15 October 2025

3.4 “Seriva Ltd (CAS-370130-P8H8P4) – Distance Selling Premises Application for 117-121 Bond Street, Blackpool, FY4 1EY.

3.5 The application is for distance-selling with no patient access to essential services face-to-face and gives assurances that:

3.5.1 the premises listed in the application are not on the same site or in the same building as a GP practice.

3.5.2 the applicant is not seeking to restrict the provision of essential services in any way.

3.5.3 there will be uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services.

3.5.4 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.

3.6 Using the NHS website, there are 9 other pharmacy contractors within 1 mile of the proposed premises. There is 5 GP practice currently listed within 1 mile of the proposed premises.

3.7 Using google maps, the proposed premises appears to be a former retail unit in an area predominantly made up of retail/commercial buildings on a junction of a main road in the town centre. Access to the proposed premises is at street level.

3.8 It is not on the same site or in the same building as a provider of primary medical services with a patient list.

3.9 In representations, concerns raised included about the layout and security of the premises, cold chain and waste procedures and face to face interactions.

3.10 The Applicant has provided evidence to maintain that granting of the application will support the provision of services and that they will be provided and accessible to patients. The Applicant supported this by providing the information regarding how it intends to carry on the provision of services.

3.11 All representations were considered, including from the Applicant.

3.12 Within the 45-days consultation period, representations were received from:

3.12.1 Boots.

3.12.2 Community Pharmacy Lancashire and South Cumbria (CPLSC).

3.12.3 Lytham Road Pharmacy.

3.13 Outline of Representations.

3.14 **Boots** trusts that the determining committee will consider all aspects of the relevant Regulations but make no material observations for or against the application.

3.15 **CPLSC** opposes the application, questioning whether the services will be carried out in a professional way (e.g., dispensary layout and access/security) according to the 'generic' set of procedures submitted and whether there is a benefit of another pharmacy in the area, particularly when not opening on weekends.

3.16 **CPLSC** notes that:

3.16.1 The named Superintendent is not listed as such on the GPhC register (ICB confirmed OK 09/09/25).

3.16.2 Queries the suitability to provide the New Medicines Service (NMS).

3.16.3 Provides and accompanying report from 2023 DSPs and contractual obligations.

3.17 In summary, **CPLSC** can see no benefit for patients and this application would be detrimental to current pharmaceutical care provision at a time when the system is under major financial constraints. The application lacks sufficient detail on how essential services will be delivered uninterruptedly and safely without face-to-face contact, as required under Regulation 25(2)(b).

3.18 **Lytham Road Pharmacy** recommends rejecting the application and that it would jeopardise the viability of the existing pharmacies in the area, particularly noting the effect of another DSP in the area.

3.19 In response to the representations from interested parties, the **Applicant** refutes the comments and asserts that it has provided evidence that shows that the legal tests will be met in full. Additionally, SOPs for the future provision of NMS have been provided.

3.20 **ICB Professional Advisor** – following assessment of the Application, the Professional Advisor has noted:

3.20.1 The ICB does not approve or authorise SOPs for any contractor.

3.20.2 It is observed that the SOPs provided are 'generic'.

3.20.3 No specific premises assurances. No way to assess access as described. Previous applications have indicated similar and upon presentation of a floor plan did not meet requirements.

3.20.4 No assurances for cold chain. Applicant assures having several to hand, but unable to specify one in the document.

3.20.5 SOPs appear to cover waste and DSP-ready interactions.

3.20.6 In any contractual or controlled drugs visit undertaken by the ICB, we will consider the observed pharmaceutical practices in line with the prevailing or most current SOPs available.

3.20.7 Overall, advise that the specific assertions are not adequate to assure the Group fully.

3.21 Regulation 31

3.22 The Group noted that Regulation 31 does not apply, as the applicant is not undertaking to provide pharmaceutical services from the same or adjacent premises to existing services they provide.

3.23 The Group therefore considered the application under Regulation 25, set out below, and took into account all information provided by the applicant and interested parties. The Group determined the following:

3.24 *"Distance selling premises applications*

25.— (1) Section 129(2A) of the 2006 Act(c) (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 also in respect of premises other than those already listed in relation to that person, in respect of pharmacy premises that are distance selling premises.

3.25 The application has been checked, and all relevant information is provided and meets the criteria of the Regulations, including Fitness to Practise. From the evidence provided in the application it is felt that the ICB can confirm that the applicant meets this element of the regulations.

3.26 *(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

3.27 The premises listed in the application are not on the same site or in the same building as a provider of primary medical services with a patient list. From the evidence provided in the application it is felt that the ICB can confirm that the applicant meets this element of the regulations.

3.28 *(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

3.29 The applicant has stated the services and hours that will be provided at the new site, supported by procedures to maintain uninterrupted provision of

services. From the evidence provided in the application it is felt that the ICB can confirm that the applicant meets this element of the regulations.

> *(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."*

3.30 Specific assertions/procedures are not adequate to assure the Group fully that safe and effective provision of essential services will be maintained, e.g., security of premises, cold chain. From the evidence provided in the application it is felt that the ICB cannot confirm that the applicant meets this element of the regulations.

3.31 **Decision – REFUSED.**

3.32 Appeal Rights to the Applicant."

4 The Appeal

In a letter dated 21 October 2025, Rushport Advisory LLP representing the Applicant appealed against the Commissioner's decision. The grounds of appeal are:

4.1 "I act for Seriva Limited and have been instructed by my client to submit this appeal against the attached decision of the Commissioner to refuse the above application.

4.2 As the Committee will note, the Commissioner's reason for refusing the application is stated at page 4 as follows.

4.3 *Specific assertions/procedures are not adequate to assure the Group fully that safe and effective provision of essential services will be maintained, e.g., security of premises, cold chain. From the evidence provided in the application it is felt that the ICB cannot confirm that the applicant meets this element of the regulations.*

4.4 It is not entirely clear what the Commissioner means. Security of premises is a matter for the GPhC. The GPhC must inspect and approve any pharmacy premises and an Applicant must provide their GPhC premises registration number when they submit their Notice of Commencement form to the Commissioner.

4.5 In respect of "cold chain" my client's SOPs describe at length how this would be maintained for all deliveries.

4.6 Since my client submitted their application they have prepared a floor plan and for the sake of completeness it is attached along with this appeal.

4.7 In addition, my client has instructed me to submit the attached SOPs that have been approved by my client for use at the proposed pharmacy and we trust that these provide the Committee with sufficient detail to allow the appeal. These SOPs include a number of small changes compared to the SOPs that my client

submitted with their original application and the previous version of the SOPs should now be disregarded.

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

4.9 [Enclosures:

4.9.1 Floor plan

4.9.2 SOPs for Servia Ltd.] [Appendix C for Committee]

5 Summary of Representations including amendments to Regulation 25

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

5.1 No representations were received by NHS Resolution in response to the circulation of the appeal.

6 Late Representations

6.1 COMMUNITY PHARMACY LANCASHIRE AND SOUTH CUMBRIA

6.1.1 "Servia Ltd Application for inclusion in a pharmaceutical list in respect of distance selling premises 1t 117-121 Bond Street, Blackpool, FY4 1EY.

6.1.2 On behalf of Community Pharmacy Lancashire and South Cumbria we enclose a copy of our original letter arguing against the granting of this contract and ask that it is considered as part of the appeal."

Letter to the Commissioner dated 12 July 2025

6.1.3 "Thank you for informing Community Pharmacy Lancashire and South Cumbria (CPLSC) the name adopted by Lancashire and South Cumbria Local Pharmaceutical Committee, of the above application.

6.1.4 We note that this is a Distance Selling Application, and we would be willing to attend an oral hearing if it were to be deemed necessary.

6.1.5 Community Pharmacy Lancashire and South Cumbria have had the opportunity to consider the application and with input from the whole committee CPLSC would like to make the following comments;

6.1.6 The 2023 CCA Report on the Impact of "pseudo" distance selling pharmacies Concluded with evidence that the majority of DSP (Distance Selling Pharmacies) are operating in breach of their NHS Contracts putting brick and mortar pharmacies and therefore local care at risk.

6.1.7 “Failure to regulate rogue businesses is leading to pharmacy closures.”

6.1.8 Public data shows that there were 372 active DSP Contracts in England at the end of 2022. The prescriptions by each were analysed to determine which GP Surgery prescribed them.

6.1.9 268 (72%) are not following their NHS DSP contractual requirements. More than 50% of their prescriptions come from GP’s in a single postcode area that is located within 10 miles of the pharmacy.

6.1.10 28 (72%) are not following their NHS DSP requirements. More than 50% of their prescriptions come from GP’s in a single postcode area. However more than 50% of their prescriptions come from more than 10 miles from the pharmacy.

6.1.11 15 (4%) receive up to 50% of their prescriptions come from GP’s in a single postcode area. However fewer than 50% of their prescriptions come from more than 10 miles from the pharmacy.

6.1.12 Only 63 (16%) receive prescriptions from across the country and provide the service expected of DSP’s.

6.1.12.1 Ayesha Ahmed is named as the Pharmacy Superintendant but today 12/07/2025 she is not named as a Superintendant on the GPhC register.

6.1.12.2 There are eight other pharmacies within 1 mile of the pharmacy (using NHS Pharmacy Finder website).

6.1.12.3 We note the provision of a wholly generic standard set of SOP’s from Rushport.

6.1.12.4 We note the minimum 40 hours of pharmacy coverage (wholly during the daytime when other pharmacies are open) and ask what benefit that brings to the local or national population.

6.1.12.5 We note the absence of a floorplan and would ask that consideration to adequate security is looked at, an issue that has been a problem in pharmacies previously in Lancashire and South Cumbria.

6.1.13 We would ask that it is noted, that this application will in no way cause any loss of pharmaceutical cover.

6.1.14 In summary, there is evidence that the majority of DSP (Distance Selling Pharmacies) are operating in breach of their NHS Contracts putting brick and mortar pharmacies and therefore local care at risk and we urge the ICS to ensure that if this pharmacy is approved that it is audited to ensure its does not operate in breach of its contract.”

7 Consideration

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

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

7.3 The Committee acknowledged the LPC's late representations concerning distance selling pharmacies in general. However, it recognised that these comments could not be considered in relation to this specific application.

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

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

Regulation 31

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

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

(2) This paragraph applies where -

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

7.7 The Committee noted that, in Part 5 of the application form (pertaining to Regulation 31), the Applicant indicated: *"Not applicable as no other pharmacy in same or adjacent premises."* Additionally, the Committee noted that the Commissioner's decision letter stated: *"Regulation 31 does not apply."* This information was not challenged during the appeal process. Consequently, the Committee concluded that there were no grounds to refuse the application under Regulation 31.

Regulation 25

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

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

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

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

in respect of pharmacy premises that are distance selling premises.

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

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

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

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

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

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

Additional information to be included with excepted applications

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

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

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

Nature of details to be supplied

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

Regulation 25(1)

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

Regulation 25(2)(a)

7.11 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)

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

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

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

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

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

7.17 The Committee noted in the SOPs provided by the Applicant that SOP 1 'Introduction and Background to SOPs' point 1.3 states that the pharmacy must provide: *"The uninterrupted provision of pharmaceutical services, during the opening hours of the premises, to persons anywhere in England who request those services."* Also; *"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."*

7.18 Further, SOP 3 'Procedures for NHS Pharmaceutical Services' states: "*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*."

7.19 In its SOP 34 'The Responsible Pharmacist' point 34.9, the Applicant states: "*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*." [emphasis in SOPs].

7.20 SOP 34 goes on to state: "*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*."

7.21 Based on the information before it, including the new suite of SOPs, the Committee was satisfied that the provision of essential services would be available to persons anywhere in England and without interruption.

7.22 The Committee went on to consider whether pharmaceutical services would be without face to face contact.

7.23 The Commissioner was not satisfied that the Applicant would provide pharmaceutical services as it was not assured that the premises had adequate security. As commented on by the Applicant in its appeal, physical security of premises is a matter for the General Pharmaceutical Council.

7.24 The Committee noted that throughout the SOPs the Applicant states that pharmaceutical services will be provided without face to face contact between any patient and the pharmacy staff. SOP 1 'Introduction and Background to SOPs' point 1.3 states:

"*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."

7.25 The Committee noted, as per SOP 3 'Procedures for NHS Pharmaceutical Services', that patients would be able to utilise multiple methods to contact the pharmacy that did not result in face to face communication. The SOP, under the heading 'Communication Channels' point 3.1 states:

"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.

7.26 *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."*

7.27 The Committee considered the information provided in the SOPs was sufficient to provide assurance that the Applicant, if granted, would be offering pharmaceutical services without face to face contact.

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

7.29 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 safe and effective provision of pharmaceutical services was likely to be secured.

7.30 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

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

7.32 From the information contained in the SOPs provided by the Applicant, SOP 3 'Procedures for NHS Pharmaceutical Services' in the first paragraph states:

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

7.33 SOP 6 ‘Online Order Receipt & Exemption Checking’, point 6.2 under the heading ‘Scope’ states:

“… *Requests to collect and dispense NHS Prescriptions*.”

7.34 The Committee had regard to SOP 20 ‘Order Delivery’ which under the heading ‘Choice of Delivery Method’ at point 20.6 states:

*“For items **other than** 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 should 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.”*

7.35 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.

7.36 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 (3) of Schedule 4.

Urgent supply without a prescription

7.37 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.

7.38 The Committee had regard to SOP 17 “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 methods 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.

7.39 SOP 17 under the heading ‘Delivery of Urgent and Emergency Supply Items’ at point 17.11 also states:

“Given the nature of a request of this type, the Pharmacy should prioritise delivery of the medication to the patient. For local deliveries the driver should be specially informed of the fact that the items are “URGENT” and for any items delivered by courier, the company must be informed that items must be delivered ASAP by the quickest route possible. The Pharmacy must not charge additional fees to the patient even if these are incurred in the delivery process.”

7.40 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

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

7.42 The Committee noted SOP 6 "Online Order Receipt & Exemption Checking" under the heading 'Exempt NHS Prescriptions' point 6.8 states:

"… Where no satisfactory evidence of exemption has been provided patients should be informed that checks to prevent and detect fraud are routinely undertaken by the NHS. …

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, …) 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."

7.43 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.

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

7.45 The Committee noted SOP 6 under the heading at point 6.11 'Paid NHS Prescription' states:

"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."

7.46 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

7.47 The Committee considered whether the Applicant had explained how drugs/appliances will be provided to the patient (including to ensure that (i) the

'cold chain' is maintained, where relevant, and (ii) that the requirements of the Misuse of Drugs Regulations 2001 and, in particular, Regulations 14 and 16, are met). The Committee noted that the Commissioner had refused the application on 'cold chain' but had not articulated why.

7.48 The Committee noted that SOP 20 'Order Delivery' under the heading 'Transfer to the Delivery Driver' at point 20.10 states:

"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."

7.49 At SOP 20, point 20.11 '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."

7.50 At SOP 20, point 20.12 ‘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.”

7.51 At SOP 20, point 20.13 ‘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.”

7.52 Further, SOP 20 at point 20.14, under the heading ‘Delivery of a prescription via Royal Mail (Not for cold chain or CDs) states:

“Follow preparation for delivery process. The pharmacist should 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. Store Delivery Log sheet for a minimum of 3 months from dispatch date.

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."

7.53 The Committee noted that the SOP then, under the heading 'Cold chain delivery via courier', at point 20.16 states:

"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. ….

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.

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

Ensure courier signs Delivery Log sheet for all prescriptions being accepted for delivery.

Remove items from the DELIVERY FRIDGE and match against the delivery log and place a copy of the barcode sticker on the packaging.

At hand-over to courier scan the aggregated FMD code [NOTE THAT A NEW FMD PROCESS HAS YET TO BE AGREED POST BREXIT] (the system will disaggregate the unique identifiers and forward them to the NMVS for decommissioning)

Give all fridge line deliveries to the courier.

Contact the patient and dispatch confirmation with their Tracking number when the prescriptions have left the premises. Live tracking with estimated ETA is available via the courier website.

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

7.54 The Committee noted SOP 20.17 under the heading 'Unsuccessful cold chain delivery via courier' states*:*

"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."

7.55 The Committee noted SOP 20.18 under the heading 'Breach of Integrity of Cold Chain' states:

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

7.56 *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."

7.57 The Committee noted that SOP 24 'Controlled Drugs: Delivery' under the heading 'Delivery of Schedule 2 & 3 CDs' at point 24.5 states:

"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."

7.58 The Committee noted SOP 24.6 under the heading 'Successful Schedule 2 & 3 Delivery' states:

"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 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."

7.59 The Committee noted SOP 24.7 under the heading 'Unsuccessful Schedule 2 & 3 Delivery via pharmacy driver' states:

"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."

7.60 The Committee noted SOP 24.8 under the heading 'Unsuccessful Schedule 2 & 3 Delivery via courier' states:

"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. …

7.61 The Committee noted SOP 24.9 under the heading 'Note re Use of Couriers for Controlled Drug Deliveries' states

"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."

7.62 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.

7.63 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.

7.64 The Committee noted that on its application form, the Applicant had stated that it intended to provide appliances: *"Drug Tariff Part IX (except items that require measuring or fitting)".*

7.65 The Committee noted SOP 27 'Support for Self-Care, Signposting and Health Promotion' under the heading 'Items Requiring Measuring and Fitting' at point 27.14 states:

"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)."

7.66 In the event that the application is granted, the Applicant would not therefore, be able to provide to patients any appliances that require measuring or fitting.

7.67 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.

7.68 The Committee next considered whether the Applicant had explained what containers would be suitable for posted/delivered items.

7.69 The Committee noted that SOP 19 'Bagging Up' under the heading 'Choice of Packaging' at point 19.7 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.

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 [sic] 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****." [Emphasis added by the Applicant.]*

7.70 Based on the information placed 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

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

7.72 The Committee noted that SOP 35 'Repeat Dispensing' states under the heading 'Pharmaceutical & Legal Assessment' at point 35.11:

"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."

7.73 The Committee further noted SOP 35 under the heading 'Prescription Reception' at point 35.10 states:

"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.

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.

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.

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."

7.74 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

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

7.76 The Committee noted SOP 35 'Repeat Dispensing' under the heading 'Prescription Reception' at point 35.10 states:

"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."

7.77 Further, the Committee noted SOP 35 goes on under 'Pharmaceutical and Legal Assessment' at point 35.11 to states:

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

7.78 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

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

7.80 For the return of controlled drugs, the Committee noted that in SOP 25 'Controlled Drugs: Collection and Disposal of Patient Returns', particularly under the heading 'Patient Returned Medication', at point 25.5 states:

*"This service is available to **all** [Applicants emphasis] patients living in England.*

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

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 should 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…"

7.81 The Committee noted that SOP 25 goes on under the heading 'Return by Royal Mail' to state at point 25.7:

"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 to other pharmacies where the patient prefers to dispose of unwanted medicines locally."

7.82 The Committee noted that SOP 25 under the heading 'Handling Patient-Returned CDs from Delivery Driver' states at point 25.8:

"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."

7.83 The Committee noted that SOP 26 'The Safe and Effective Receipt and Disposal of Medicines' under the heading 'Process for Patients to Return Medication' at point 26.6 states:

"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)."

7.84 The Committee noted that SOP 26 goes on under the heading 'Process for accepting patient returns by the Driver' at point 26.7 to state:

"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"

7.85 The Committee noted SOP 26 under 'Disposal of returned medicines' at point 26.10, states:

"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."

7.86 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

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

7.88 The Committee noted that SOP 28 'Promotion of Healthy Living, Lifestyles & Health Campaigns' under the heading 'Health Campaigns and Community Engagement Exercise' states at point 28.4:

"Terms of Service require participation in up to 6 campaigns per financial year, but you should agree to take part in all campaigns where practicable.

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 [sic] specifies—

> *a clinical audit carried out in a manner which is compatible with the NHSCB's [sic] arrangements for the receiving and processing of data from the audit, or*
>
> *a policy based audit (to support the development of the commissioning policies of the NHSCB) [sic] carried out in a manner which is compatible with the NHSCB's [sic] 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."

7.89 Further, in SOP 28, under the heading 'Identification of patients for promotion of Healthy lifestyles' states at point 28.3:

"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."

7.90 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

7.91 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.

7.92 The Committee noted SOP 28 'Promotion of Healthy Living, Lifestyle & Health Campaigns' at point 28.3 under the heading 'Identification of patients for promotion of Healthy Lifestyles' states:

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

***Active patients** [Applicants emphasis] 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** [Applicants emphasis] 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) [Applicants emphasis] 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."

7.93 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

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

7.95 The Committee noted that in SOP 28 'Promotion of Healthy Living, Lifestyle & Health Campaigns' under the heading 'Health Campaigns & Community Engagement Exercise', at point 28.4 states:

"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 [sic] 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. …..

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."

7.96 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

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

7.98 The Committee noted that in SOP 27 'Support for Self-Care, Signposting and Health Promotion' under the heading 'Patient Identification' at point 27.13, states:

"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 [sic] 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."

7.99 The Committee noted that in SOP 27 under the heading 'Other Provider Organisations and Support Details' at point 27.10 states:

"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 [sic] be provided to patients via written mailshots, flyers, sent with prescription deliveries, our website and by telephone or email."

7.100 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

7.101 The Committee considered whether the Applicant had explained or otherwise demonstrated how it will provide advice and support for people caring for their families.

7.102 The Committee noted the Applicant's SOP 27, point 27.9 under the heading 'Service outline' states:

"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."

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

Discharge Medicines Service

7.104 The Committee considered whether the Applicant had now 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.

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

7.106 The Committee noted SOP 29 'Discharge Medicines Service' ("DMS") at point 29.3 under the heading 'Process' states:

"Every day the RP must check the pharmacy's NHS mail 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."

7.107 The Committee noted point 29.5 under the heading 'DMS Stages' states:

"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."

7.108 The Committee noted point 29.10 under the heading 'Additional Advice assistance and support' states:

"When the pharmacy either receives a prescription (in whatever form) or has been made aware via a referral to the DMS that a prescription is the first prescription for a medicine that has been made following the patient's discharge from hospital, or where the patient's care has been transferred from another NHS service provider, the following steps must be followed:

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

Arrange a live video call or audio call with the patient (or where appropriate and bearing in mind the duty of confidentiality their carer to; [sic]

Assess the patient / carer understanding of the medicines that the patient should be taking

The patient should have received a copy of the prescribed medication from the hospital which lists the medication you are taking. This must match the discharge prescription when written.

If changes have been made to the patient's medication regimen, clearly explain the changes.

Offer such advice, assistance and support as is appropriate in your clinical judgement in respect of the medicines being taken and the medication regimen overall.

Think about high risk medicines or those where the treatment is more complex and where extra advice and support should be provided – e.g. anticoagulants

Discuss common or expected side effects

Discuss the use of medication apps which can be downloaded and may help the patient stick to their treatment plan.

If injectables have been prescribed and the patient is considered to be able to self-administer these, then have they received appropriate training from their GP practice nurse or hospital?

Inform the patient/carer

The disposal service offered in respect of unwanted drugs (see separate SOP). This is particularly relevant to medicines which may still be in the patient's home but may no longer be prescribed.

Any other pharmaceutical services that the patient or their carer may benefit from following their stay in hospital and / or the transfer of care from another NHS pharmacy.

Follow up

Where you identify any areas of concern then to the extent it is appropriate to do so in your clinical judgement, contact the patient's GP to discuss the concerns and consider any appropriate action plan to deal with the concerns.

In every case it is important to keep and maintain records of the above discussions, concerns and actions taken as part of providing this service and these will also assist in service evaluation processes."

7.109 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

7.110 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.

7.111 The Committee noted SOP 27 'Support for Self-care, signposting and health promotion' states under the heading 'Health Promotion Zone on our website' at point 27.11:

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

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 [sic] 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."

7.112 The Committee also noted further mention of health promotion zones is made in SOP 28 'Promotion of Healthy Living, Lifestyle & Health Campaigns' under the heading 'Identification of patients for promotion of healthy lifestyles' at point 28.3 which states:

"The website, app and email newsletters will also be used to promote healthy lifestyles via the health promotion zone."

7.113 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.

Summary

7.114 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).

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

7.115.1 confirm the Commissioner's decision;

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

7.115.3 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.

7.116 The Committee has reached a different conclusion from the Commissioner regarding the application. In those circumstances the Committee determined that the decision of the Commissioner must be quashed.

7.117 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.

7.118 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.

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

8 Decision

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

8.2 The Committee:

8.2.1 quashes the decision of the Commissioner; and

8.2.2 redetermines the application as follows -

8.2.2.1 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;

8.2.2.2 the Committee was satisfied that all essential services were likely to be secured without interruption during the opening hours;

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

8.2.2.4 the Committee was satisfied that pharmaceutical services were likely to be secured in a safe and effective manner; and

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

8.2.3 The application is granted.

Case Manager
Primary Care Appeals