16 February 2026

REF: SHA/ 26781

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

Tel: 020 3928 2000
Email: nhsr.appeals@nhs.net

APPEAL AGAINST NORTH WEST LONDON ICB DECISION TO REFUSE AN APPLICATION BY PHARMUNITY LIMITED FOR INCLUSION IN THE PHARMACEUTICAL LIST AT OFFICE F19, SILVERBOX HOUSE, 56 MAGNET ROAD, EAST LANE BUSINESS PARK, HA9 7FP 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:

Pharmunity Ltd
PCSE for the Commissioner
Boots UK Ltd

NHS Resolution

REF: SHA/ 26781

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

Tel: 020 3928 2000
Email: nhsr.appeals@nhs.net

APPEAL AGAINST NORTH WEST LONDON ICB DECISION TO REFUSE AN APPLICATION BY PHARMUNITY LIMITED FOR INCLUSION IN THE PHARMACEUTICAL LIST AT OFFICE F19, SILVERBOX HOUSE, 56 MAGNET ROAD, EAST LANE BUSINESS PARK, HA9 7FP UNDER REGULATION 25

1 The Application

By application dated 19 June 2025, Pharmunity Limited ("the Applicant") applied to North West London ICB ("the Commissioner") for inclusion in the pharmaceutical list at Office F19, Silverbox House, 56 Magnet Road, East Lane Business Park, HA9 7FP 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 is in the 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."

1.8 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.

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

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.

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.

1.9 "PLEASE SEE ATTACHED DOCUMENTS."

1.10 [SOPs provided with application – Appendix A for Committee]. Note these SOPs are superseded by SOPS with appeal at Appendix B.

2 The Decision

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

2.1 "North West London 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.

2.2 You have a right of appeal to the Secretary of State against North West London 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:

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

London Pharmaceutical Services Regulations Committee minutes 15 October 2025

2.4 "CAS Reference number: CAS-370518-P6P5T8

2.5 Name of applicant: Pharmunity Limited

2.6 Fitness to practice: Cleared for inclusion

2.7 Address of proposed premises: Office F19, Silverbox House, 56 Magnet Road, East Lane Business Park, HA9 7FP

2.8 Status of location: Non controlled locality

2.9 Relevant regulations and guidance:

2.9.1 Regulations 25 – distance selling premises.

2.9.2 Regulation 31 – refusal: same or adjacent premises.

2.9.3 DH market entry guidance chapter 11.

2.10 Additional information

2.11 PSRC have determined that there is enough information to deal with this application without holding an oral hearing.

2.12 Boots comments

2.13 Boots UK Ltd would like to respectfully request that members of the deciding committee are satisfied that this application fully meets the criteria set out in Regulation 25 and the conditions set out in Regulation 64 when determining this application.

2.14 Rushton Pharmacy

2.15 After reviewing the Pharmaceutical Needs Assessment (PNA), it is evident that there are no current needs in the area. Therefore, I strongly urge the NHS Market Entry to reject this application.

2.16 Please include us in any future correspondence so we can provide further input if needed.

2.17 Applicant's Further comments

2.18 Boots UK representation simply requests that the deciding committee is satisfied that our application fully meets the requirements of Regulation 25 and the conditions set out in Regulation 64 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013. We welcome this and confirm that Pharmunity Limited has ensured full compliance with all conditions set out in the Regulations, including the arrangements necessary for providing NHS pharmaceutical services safely, effectively, and without restricting access on geographical grounds. We are confident the committee will find these conditions satisfied.

2.19 Rushton Pharmacy's representation refers to the Brent Pharmaceutical Needs Assessment (PNA) and suggests that there are no current needs in the area, urging the NHS to reject the application.

2.20 However, this reasoning is not applicable. Our therefore [sic], on was submitted prior to 23 June 2025 and therefore falls under the Distance Selling Premises (DSP) exemption. As such, it is not subject to the Pharmaceutical Needs Assessment test or the standard market entry criteria.

2.21 Pharmunity Limited Distance Selling Premises will provide NHS pharmaceutical services to patients across England, ensuring accessibility, equity, and convenience.

2.22 This model particularly benefits patients who are housebound, those with mobility challenges, and those in rural or underserved areas. In line with NHS priorities around digital access and reducing inequalities, our service will complement the existing community pharmacy network while meeting all requirements of Regulations 25 and 64.

2.23 We respectfully request that the committee determine the application on that basis and confirm the decision of the ICB in due course.

2.24 With regard to Regulation 31 (Refusal: same or adjacent premises) and to the provisions of Schedule 2 to the Regulations: "Applications seeking the listing of premises that are already, or are in close proximity to, listed chemist premises.

2.24.1 The proposed pharmacy is not on the same site or adjacent to any other pharmacy, therefore this regulation is not engaged.

2.25 Distance Selling premises applications

2.26 Regulation 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

2.27 *(2) The ICB must refuse an application to which paragraph (1) applies—*

2.28 *(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*

2.28.1 (a) The premises in respect of which the application is made are not on the same site or in the same building as the premises of a provider of primary medical services with a patient list.

2.29 *b) unless the ICB 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."

2.29.1 (b) The applicant provided information via their application. The application and associated papers have been reviewed, to ensure that the application complies with the regulations.

2.29.2 The applicant has not provided information on *Paragraph 8(15) of Schedule 4.*

2.30 The SOP for NMS states:

"4. Intervention and follow up.

The intervention and follow up stages can be face to face meetings carried out in the consultation room but can also be carried out over the phone as long as the phone call is confidential. Phone conversations must be with the patient, not an intermediary."

2.31 The regulations have recently changed, and DSPs can no longer provide advanced and enhanced services face to face, with 2 exceptions for pharmacies open on 1 Oct 2025, but these would only apply until March 2026. However, the exceptions would not apply to this application as this did not cover the services being offered and they were not open at the beginning of October 2025.

2.32 It may be concluded that the PSRC is not satisfied that pharmacy procedures for the pharmacy are likely to secure the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services.

2.33 It may also be concluded that the applicant is likely to not satisfy the criteria as set out in the Terms of Service of Pharmacists for the safe and effective provision of all essential services without face to face contact.

2.33.1 Therefore, PSRC is not satisfied that the pharmacy procedures for the pharmacy premises are likely to secure the safe and effective provision of essential services without face to face contact between any person receiving the services, whether on their own or on someone else's behalf, and the applicant or the applicant's staff.

2.34 Decision

2.35 Regulation 31.

2.36 There are no current pharmacies listed at the proposed premises or adjacent to the proposed premises. Therefore regulation 31 does not apply for this application.

2.37 Regulation 25(2)(1)(a)

2.38 The proposed site 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. Therefore, this regulation does not apply for this application.

2.39 Regulation 25(2)(1)(b)(i)

2.40 The PSRC is not satisfied that pharmacy procedures for the pharmacy are likely to secure the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services.

2.41 Regulation 25(2)(1)(b)(ii)

2.42 The PSRC is not satisfied that the applicant is likely to satisfy the criteria as set out in the Terms of Service of Pharmacists for the provision of all essential services without face to face contact.

2.43 The PSRC is not satisfied that the pharmacy procedures for the pharmacy premises are likely to secure 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. Therefore, the application has been refused.

2.44 Determination made by London PSRC on behalf of NHS West London ICB.

2.45 Conditions of approval for a Distance Selling Pharmacy

2.46 As this application is in respect of distance selling premises, by virtue of regulation 64(3) of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended, if the applicant is subsequently included in the pharmaceutical list for the area of Brent Health and Wellbeing board in respect of the premises included in the application, that inclusion will be subject to the following conditions:

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

2.46.2 The means by which the applicant provides pharmaceutical services must be such that any person receiving those services does so otherwise than at the proposed premises.

2.46.3 The proposed premises must not be on the same site or in the same building as the premises of a provider of primary medical services with a patient list.

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

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

2.46.4.2 the safe and effective provision of pharmaceutical services without face to face contact at the proposed 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; and

2.46.5 Nothing in the applicant's practice leaflet, in the applicant's publicity material in respect of the proposed premises, in material published on behalf of the applicant publicising services provided at or from the proposed premises or in any communication (written or oral) from the applicant or the applicant's staff to any person seeking the provision of essential services from the applicant must represent, either expressly or impliedly, that:

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

2.46.5.2 the applicant is likely to refuse, for reasons other than those provided for in the applicant's terms of service, to provide drugs or appliances ordered on prescription forms or repeatable prescription forms which are presented by particular categories of patients (eg because the availability of essential services from the applicant is limited to other categories of patients)."

3 The Appeal

In a letter dated 12 November 2025, the Applicant appealed against the Commissioner's decision. The grounds of appeal are:

3.1 "I respectfully appeal against the decision of the London PSRC dated 21st October 2025 (CAS-370518-P6P5T8) refusing PHARMUNITY Limited's application for inclusion in the pharmaceutical list for Distance Selling Premises at Office F19, Silver box House, HA9 7FP.

3.2 The refusal was based on the Committee's view that:

3.2.1 The application did not evidence procedures to secure the uninterrupted provision of essential services to persons anywhere in England.

3.2.2 The application did not sufficiently demonstrate the safe and effective provision of essential services without face-to-face contact.

3.2.3 Information was not provided regarding Paragraph 8(15) of Schedule 4, concerning the provision of medicines in suitable containers.

3.3 I respectfully submit that these issues arose due to omissions and wording errors in the documentation originally submitted rather than any deficiency in PHARMUNITY's operating model. The pharmacy has always been designed and intended to operate entirely remotely, in full compliance with the DSP requirements under Regulation 25 and Schedule 4 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as well as providing uninterrupted essential services to any patients in England.

3.4 Following the PSRC determination, all documentation has been fully reviewed and corrected. The appeal is supported by comprehensive revised Standard Operating Procedures and evidence which directly address every cited deficiency:

3.5 1. **Business Continuity and Uninterrupted Essential Services (Reg. 25(2)(b)(i))**

3.6 A fully revised Business Continuity SOP has been produced. It details telecom and EPS fail-over systems, 4G router back up, locum cover arrangements, courier contingencies, power failure protocols, and scheduled quarterly testing. These procedures now demonstrate the pharmacy's ability to provide

uninterrupted essential services to patients anywhere in England during all opening hours.

3.7 The SOPs have been made more comprehensive and detail every aspect and contingency put in place to ensure uninterrupted provision of essential services to ALL patients in England.

3.8 2. **Safe and Effective Provision Without Face-to-Face Contact (Reg. 25(2)(b)(ii))**

3.9 All references implying in-person interaction have been removed.

3.10 The NMS SOP has been rewritten to state that all consultations are delivered remotely (telephone or video) with no patient access to the premises.

3.11 The DMS and related clinical SOPs have been updated accordingly.

3.12 A Patient Visit / Walk-In Protocol SOP has been updated, describing how any patient attending in error is managed entirely via intercom, safely redirected, and logged as a governance incident.

3.13 Premises design, signage, and access control prevent any public entry.

3.14 These measures provide clear evidence that PharmUnity will operate exclusively as a remote-service DSP.

3.15 3. **Paragraph 8(15) of Schedule 4 - Suitable Containers**

3.16 Supply of Medicines in Suitable Containers SOP: sets out procedures to ensure every medicine is supplied in a container suitable for its formulation and patient needs, compliant with the Human Medicines Regulations 2012, Misuse of Drugs Regulations 2001, and relevant British Standards. It includes detailed repackaging procedures using plain white pharmacy cartons of various sizes, with batch number and expiry date clearly marked, tamper-evident sealing, inclusion of manufacturer PILs, and patient-friendly easy-open design.

3.17 An additional SOP was also added to clarify direct access to advise [sic] from a pharmacist:

3.18 Access to Pharmacist Advice SOP: describes the system by which patients anywhere in England can obtain confidential advice directly from the pharmacist by telephone, secure email, or video link during all opening hours, with automatic diversion to a company-owned mobile in case of telephone line failure, and full audit logging.

3.19 **Summary**

3.20 The issues identified by the PSRC arose from documentation oversights rather than any operational or regulatory deficiency. PHARMUNITY's model has always been, and remains, a fully remote, non-face-to-face Distance Selling Pharmacy, operating in full compliance with all relevant NHS and GPhC regulations.

3.21 A complete plan of the premises layout, together with photographs of the DSP setup, has been submitted to demonstrate the secure, non-public-access design.

3.22 PHARMUNITY now has all systems, infrastructure, and Standard Operating Procedures in place to begin providing safe, effective, and uninterrupted NHS pharmaceutical services to patients anywhere in England, delivering the highest standard of care.

3.23 I trust that the information provided is comprehensive and addresses all points raised in the PSRC decision. Should any further clarification be required, please do not hesitate to be in contact. I would be pleased to provide any additional information necessary.

3.24 The corrected and expanded SOPs now provide complete assurance that:

3.24.1 Essential services will be provided safely and effectively without face-to-face contact.

3.24.2 Service continuity is fully secured.

3.24.3 All medicines are supplied in suitable containers with full traceability and patient accessibility.

3.25 For these reasons, PHARMUNITY Limited respectfully requests that NHS Resolution allow this appeal and direct NHS England to grant the application.

3.26 **Supporting Information Submitted**

3.27 Updated Section 7 Response

3.28 Updated NMS SOP

3.29 Updated Business Continuity SOP

3.30 Updated Access to Pharmacist Advice SOP

3.31 Updated Supply of Medicines in Suitable Containers SOP

3.32 Updated Provision of Essential Services without face-to-face contact SOP

3.33 Comprehensive list of SOPs detailing the pharmacy intended operation.

3.34 Layout of Pharmacy Plan

3.35 Pictures of the DSP

3.36 Original DSP Application

3.37 Decision letter and full report”

3.38 [SOPs provided with appeal – Appendix B for Committee].

4 Summary of Representations

This is a summary of representations received on the appeal.

4.1 BOOTS UK LTD

4.1.1 “Thank you for your letter dated 21st November 2025 informing us of the above appeal.

4.1.2 Boots UK Ltd have no further comments to make but respectfully ask that NHS Resolution inform us of the decision in due course.”

4.2 THE COMMISSIONER

4.2.1 “I am writing in response to the above appeal.

4.2.2 The original application was refused due to some missing information within what was received. It was not clear if an NMS consultation was being provided remotely or on site.

4.2.3 The additional information received appears to clarify this although the SOP does refer to “MUR” rather than to “NMS” as part of the accreditation, we presume that this is a typographical error.

4.2.4 Had this information been provided with the original application, this would have been granted. We therefore do not have any further comments to make and have no objections to this application being granted.”

5 Summary of Observations

This is summary of observations received.

5.1 THE APPLICANT

5.1.1 “Thank you for providing the comments in relation to the appeal.

5.1.2 I confirm that the reference to “MUR” within the SOP was a typographical error, and I note NHS England’s confirmation that the additional information provided clarifies that the New Medicine Service is delivered remotely.

5.1.3 I also note NHS England’s confirmation that, had this clarification been provided with the original application, the application would have been granted, and that there are no objections to the application being approved.

5.1.4 I have no further comments to add.”

6 Consideration

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

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

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

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

Regulation 31

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

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

(2) This paragraph applies where -

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

6.6 The Committee noted that, in Part 5 of the application form (pertaining to Regulation 31), the Applicant indicated: *"Not applicable as no other pharmacy is 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

6.7 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."

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

Additional information to be included with excepted applications

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

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

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

Nature of details to be supplied

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

Regulation 25(1)

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

Regulation 25(2)(a)

6.10 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)

6.11 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.

6.12 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.

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

6.14 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.

6.15 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.

6.16 The Committee first considered how the Applicant would provide essential services without interruption. Page 3 of the SOPs under the heading '7.1 (a) Uninterrupted Provision of Essential Services Across England' states:

"*We interpret "Uninterrupted Provision" to mean the ability to receive, clinically check, dispense, dispatch, and deliver medicines consistently, securely, and safely throughout all published opening hours, to persons anywhere in England, and without face-to-face contact. This includes having access to a telephone line where a patient can call and receive advice from a pharmacist throughout the pharmacies opening hours.*

PHARMUNITY would ensure full coverage during operational hours by having:

A GPhC-registered Responsible Pharmacist always on site. …..

Rota planning incorporates buffer staffing and on-call escalation (with locum cover arrangements in place)."

6.17 The Committee noted on page 203, Standard Operating Procedure for Operating in the Absence of a Responsible Pharmacist states:

"*As a Distance Selling pharmacy, we are required to offer continuous service during our operating hours. Therefore, the Responsible Pharmacist (RP) must always remain on the premises during working hours.*

The Pharmacy will have a second pharmacist available during core hours. If the RP needs to leave the premises or take a break on an ad-hoc basis or planned, the second pharmacist must sign in as the RP. ….

Make sure that the RP tells staff well in advance that they are going to leave the premises. Make sure that the RP has already signed the Pharmacy Record. …. Ensure the second pharmacist is aware of your leaving and the length of time you will be absent for. ….

The Responsible Pharmacist should ensure that they remain contactable e.g. leaving their phone number. Monitor the time that the RP has been absent. The second pharmacist must assume the role.

The return of the RP.

Make sure the RP signs into the pharmacy record noting the duration of absence and reason."

6.18 With regard to essential services being available to persons anywhere in England, the Committee noted the following information on page 188 of 'Standard Operating Procedure for Operating for Business Continuity' which states:

"*PharmUnity is a distance selling pharmacy providing NHS and private services remotely to patients across England*."

6.19 On page 355 of 'Overarching Standard Operating Procedure for Distance Selling Pharmacies' it states:

"*Pharmacy has a business continuity plan to ensure that the Applicant delivers essential services safely, effectively, remotely, and without interruption to individuals across England who seek these services during the operational hours of the premises*."

6.20 Page 366 of 'Standard Operating Procedure for Provision of Essential Services without face to face contact' states:

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

6.21 With regard to pharmaceutical services being provided without face to face contact, the Committee noted the following information on page 479 'Standard Operating Procedure for Provision of Essential Services without face-to-face contact' which states:

"*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.*

Provision of NHS Essential Services without face-to-face contact within premises will be achieved by using:

Telephone, including text messaging where appropriate

Live Video Call

Website inbox (through contact us)

Email

Electronic Prescription Service (EPS)

Royal Mail postal service

Courier service

Specialised cold chain courier services e.g. DHL COLDCHAIN."

6.22 Page 425 'Standard Operating Procedure for Patient Walk-In Protocol' states:

"*1. Premises Security and Access Control*

No public signage or collection point is displayed.

Entry is restricted by intercom and coded FOBs.

CCTV continuously records all entry points.

No access to any member of the public as per protocol.

2. Immediate Response

When a patient arrives:

Communicate only via the intercom.

Do not open the door under any circumstance.

State clearly and courteously:

"PharmUnity is a Distance Selling Pharmacy and does not provide services in person."

Identify the reason for attendance to determine appropriate redirection.

3. Redirection and Signposting

Use NHS Service Finder to locate at least two nearby NHS providers.

Relay details by intercom and, if appropriate, confirm via SMS or email.

For urgent issues (e.g. palliative-care medication), contact NHS 111 or advise attendance at an Urgent Treatment Centre.

Record the interaction per the Remote Signposting SOP."

6.23 Further, the Committee was mindful of the regulatory changes as of 1 October 2025, that distance selling pharmacies can no longer provide Directed services (Advanced, National Enhanced and Enhanced Services, with the exception of Covid-19 and Flu vaccination 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 at its premises.

6.24 Page 3 of the SOPs under the heading '7.1 (a) Uninterrupted Provision of Essential Services Across England' states:

"*The pharmacy would operate under a fully SOP-governed framework, supported by secure digital infrastructure and comprehensive clinical governance systems. Our model meets the statutory requirements outlined in the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2025 (SI 2025/636), …..*

… specifically Schedule 4, including DSP exemption rules and delivery obligations."

6.25 Page 175 under the heading '7.3 Provision of Advanced Services Without Providing Any Element of Essential Services' states:

"*PharmUnity confirms its intention to provide one advanced service: The New Medicine Service (NMS). This service will be delivered in accordance with all*

applicable legal and regulatory frameworks, specifically ensuring that it is provided remotely….

These consultations are conducted exclusively by phone or video, depending on the patient's preference. There is no contact with patients at the premises. All communications, documentation, consent, and referrals are completely remotely and audit logged."

6.26 In the 'Standard Operating Procedure for New Medicine Service' at page 370, it states:

"*All pharmacies carrying out the NMS must have a consultation area (to ensure no remote consultation is overheard in the dispensary)……*

To ensure the service is delivered entirely remotely (e.g. by telephone or video consultation) in line with the legal requirements for Distance Selling Pharmacies under Regulations 25 and 64 of the NHS Pharmaceutical Services Regulations 2013."

6.27 The Committee noted the Applicant in its observations confirms "*that the reference to "MUR" within the SOP was a typographical error, and I note NHS England's confirmation that the additional information provided clarifies that the New Medicine Service is delivered remotely*." There is no dispute in this regard.

6.28 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.

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

6.30 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

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

6.32 On p23 of 'Standard Operating Procedure for Checking NHS Exemptions Ensuring No Patient Contact' it makes reference to:

"*1.* ***Receiving Hardcopy FP10 NHS prescriptions***

NHS prescription may arrive at the pharmacy in either an electronic form (via EPS) or in hardcopy form via an FP10 (green prescription) through post or delivery driver."

6.33 On page 37 ‘Standard Operating Procedure for Dispensing of Prescriptions’ it states:

“*1.* ***Receipt of prescription***

Prescriptions will be received by EPS, post and email or where practicable, with the patient's informed consent, collected from a surgery or picked up by the delivery driver.”

6.34 On page 57 of ‘Standard Operating Procedure for The Delivery of Medicines’ it states:

“***Collection of prescriptions from surgeries***

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

6.35 In relation to how products will be provided to patients, the Committee noted page 51 of ‘Standard Operating Procedure for The Delivery of Medicines’ it states:

6.36 “*This SOP encompasses all medicines which are delivered from a pharmacy including those sent via the pharmacy’s own delivery driver or third-party postal/courier services (Royal Mail). However, for Controlled Drugs (CDs), please consult the CD Delivery SOP.”*

6.37 Page 61 ‘Standard Operating Procedure for Delivering Controlled Drugs’ states:

“This SOP covers the procedure for delivering dispensed controlled drug medications to a patient.

It applies to all Controlled Drugs (Schedules 2–5) delivered either by the pharmacy’s own driver/s or by an approved secure medical courier such as DHL Medical Healthcare. Royal Mail Tracked 24 / Tracked 48 Signed For may only be used for Schedule 4 and 5 Controlled Drugs.”

6.38 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

6.39 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.

6.40 The Committee had regard to the 'Standard Operating Procedure for Emergency Supply at the Request of a Patient' and 'Part II - Supply of emergency medication at the request of a prescriber' which describes how the Applicant will process such a request. The Committee noted that the SOPs refer to communication which "*may not be by way of face-to-face contact and must be by other means, e.g. telephone, video call*." Further "*When a prescriber ….. makes a request for medication without a valid prescription by phone, then the pharmacist should speak to the prescriber*."

6.41 Page 313 of the SOPs states:

"*Considering the urgency of such requests, the Pharmacy will give priority to delivering the medication to the patient. For local deliveries, the driver will be explicitly notified that the items are "URGENT," and for courier deliveries, the courier will be instructed to deliver the items as soon as possible via the quickest route available. The Pharmacy will not impose additional fees on the patient, even if incurred during the delivery process. Apart from acknowledging the urgent nature of the delivery, standard delivery procedures will be followed*."

6.42 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

6.43 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.

6.44 The Committee noted 'Standard Operating Procedure for Checking NHS Exemptions Ensuring No Patient Contact' at page 238 states:

"*NHS prescriptions that are received by the pharmacy in hardcopy via the post or softcopy via EPS. …..*

NHS prescription may arrive at the pharmacy in either an electronic form (via EPS) or in hardcopy form via an FP10 (green prescription) through post or delivery driver. …..

If the patient declares a specific exemption (listed below), they will [sic] *eligible to receive free NHS prescriptions from our pharmacy. Alongside the RTEC functionality to check whether the claim may be fraudulent, our system intelligently applies a second check, using a logic gate of NHS stipulations against specific patient criteria, any instances which are contrary to this logic are flagged to the Responsible Pharmacist calls the patient either by telephone or video chat. …..*

Where appropriate (ie 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). The pharmacy can record that the evidence provided was not in the original format. It is the pharmacist in charge who determines if the evidence is satisfactory; if not, they should check the 'Evidence not Seen' box. Exemptions sent to the pharmacy by post will

have postage paid by the pharmacy, and the exemption will be returned to the patient free of charge."

6.45 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.

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

6.47 The Committee noted 'Standard Operating Procedure for Taking an NHS Prescription Charge' at page 242 which states:

"*This SOP covers all NHS prescription charges taken from the patient for NHS prescriptions. …..*

In every instance an NHS charge is taken from a patient for NHS prescription items, this is conducted by our secure payments system. This can either be performed bank transfer or through payment link or for local deliveries via handheld mobile card machine or over the phone manually using the "Customer not present" functionality of our card processing provider.

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."

6.48 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

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

6.50 The Committee noted 'Standard Operating Procedure for the Delivery of Medicines' on page 278 states:

"*This SOP encompasses all medicines which are delivered from a pharmacy, including those sent via the pharmacy's own delivery driver or third-party postal/courier services (e.g. Royal Mail). However, for Controlled Drugs (CDs), please consult the CD Delivery SOP. ……*

4. Record the delivery.

Write the number of bags for each person in the delivery record book and branch record sheet. For Royal Mail deliveries, record tracking numbers, date/time of dispatch, and the courier's collection signature on the Delivery Log Sheet.

5. Driver arrival

a. In house delivery service).

During delivery, the driver must confirm with patient/representative for their name and address, check the label on the bag against the prescription, branch record sheet and book. File prescriptions. Cold chain medications will be separated from local delivery and to be done via courier. Check and tick against the branch record sheet label when transferring items to the delivery driver. The driver signs and dates the branch record sheet at this stage to confirm the pickup. Ask the patient or representative to sign their details on the delivery sheet.

b. Deliveries via Royal Mail (non-CD / non-cold chain)

All deliveries will be sent via Royal Mail Tracked 24 or Tracked 48 delivery service, requiring a signature on receipt. The Pharmacist should contact patients before delivery to confirm dispatch and provide any necessary counselling. Ensure that the RP is available to oversee the handover of all items for delivery. Print and securely attach the appropriate Royal Mail Tracked 24 / 48 Signed For delivery labels using the pharmacy's Royal Mail business account to the outer packaging. Clearly print a return address on the outer packaging. Verify the details of all prescriptions to be delivered. Record all tracking numbers for prescriptions being delivered via Royal Mail on the Delivery Log Sheet.

Ensure the Royal Mail driver signs the Delivery Log Sheet for all prescriptions accepted for delivery. Retain the Delivery Log Sheet for at least 3 months from the dispatch date. Email patients with dispatch confirmation and their tracking number once the prescriptions have left the premises. All deliveries will require a patient signature to confirm receipt of their prescription.

6. Controlled drugs delivery.

If a CD is included, call the patient by telephone beforehand to confirm they are in. The driver should sign the blue box on the back of the script and write 'delivery' to complete the audit trail.

The driver's name and 'delivery' is written in the CD register as the person collecting the medication. If delivery is unsuccessful, the CD is returned to the pharmacy, booked back into the CD register and signed out again on retry of delivery.

7. Driver departure.

Ensure that the driver takes the delivery record book with them. The branch record sheet stays in the pharmacy as a record of which items have been taken by driver. On delivery at the appropriate address, the driver should give the patient every opportunity to answer the door. The delivery driver must not enter the patient or representative's home unless with consent. Medicines must be kept out of sight and secured at all times.

If the patient is in:

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

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

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

4. The driver should not offer medical advice unless qualified to do so. If the patient has a query about their delivered medication, the driver can provide the telephone number of the pharmacy (which is printed on all medication labels) and ask the patient to phone the pharmacy for advice.

If the driver is asked to give written advice to a patient in the form of a note or letter from the pharmacy, then the pharmacy should phone the patient after delivery to ensure the note has been received and understood. Medicines should be kept securely in the vehicle, and doors and windows are always closed/locked. The medication should be kept out of sight, e.g. in the boot.

For courier deliveries, the patient's electronic or written signature (captured by Royal Mail or courier system) constitutes proof of receipt.

If the patient is out:

1. In the event of an unsuccessful delivery, the driver will leave a failed delivery card at the delivery address specifying the date and time of the attempted delivery and providing clear instructions and contact details for the patient to contact the pharmacy and reschedule the delivery.

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

For Royal Mail or courier deliveries, a 'Sorry We Missed You' or equivalent notice will be left by the courier. The patient can collect their medication from the designated postal depot or reschedule delivery. Returned items must be logged, checked for integrity, and stored securely upon return.

DO NOT leave the delivery items:

unattended in porches or on doorsteps

with children

with neighbours (unless written and signed authorisation from the patient or carer is held on file)

To ensure the safe and appropriate delivery of medicines, local deliveries (apart from cold chain deliveries) will be handled by pharmacy own delivery driver. Nationwide deliveries will be sent via Royal Mail Tracked 24 or Tracked 48

Signed for service (as clinically appropriate), requiring a signature from the patient, their notified carer, or an authorised representative.

Patients will receive a tracking number to monitor their delivery status online and will be informed about their delivery through a text messaging system. Medicines will be packed, transported, and delivered to preserve their integrity, quality, and effectiveness. All postal or courier deliveries must use secure, tamper-evident, and discreet packaging with no indication of contents. The pharmacy's return address must be clearly printed on the outer packaging. The delivery process will provide a verifiable audit trail from the initial request to final delivery or return to the pharmacy in case of delivery failure. Post delivery items will not be put through letter boxes or left unattended in porches on doorsteps, with children or with neighbours, unless arrangements have been made by patient/carer. This request would be obtained in writing from the patient/carer with a signature authorising delivery to another address. A signature is always required from the recipient to indicate safe receipt. For postal/courier items, at a minimum, use padded envelopes for non-fragile items to protect the manufacturer's packaging. For most items, use bubble wrap and, if necessary, polystyrene filler inside a reinforced cardboard box. The patient, carer, or authorised representative must always sign and date a receipt to confirm safe receipt of the medicines. If the patient is not at home during the delivery attempt, they will be notified with a non-delivery notice, and an alternative delivery date will be arranged.

Cold-chain (fridge) items will be delivered only via a validated, temperature-controlled courier service such as DHL ColdChain (or equivalent). This will ensure the integrity of the cold chain and the maximum stability of temperature-sensitive drugs by packing, transporting, and delivering them in a manner that preserves their integrity, quality, and effectiveness. This is a dedicated, fully monitored, and temperature-controlled delivery service. In the event of an unsuccessful delivery, DHL ColdChain (or equivalent) will leave a 'Missed Delivery' card, stating the date and time of the attempted delivery. The patient can then rearrange delivery for a convenient time by telephone or Internet. DHL COLDCHAIN will keep the cold chain intact until successful delivery. …….

Delivery of prescription via Royal Mail (Not for Cold Chain or CDs)

All postal deliveries will be made via Royal Mail Tracked 24 or Tracked 48 Signed For services, as appropriate, ensuring a full audit trail and requiring a signature on receipt.

The pharmacist should contact patients before delivery to confirm dispatch and provide any necessary counselling.

> *Ensure that the RP is available to oversee the handover of all items for delivery.*
>
> *Print and securely attach the appropriate Royal Mail racked 24 / 48 Signed For delivery labels using the Royal Mail online business account to the outer packaging.*
>
> *Clearly print a return address on the outer packaging. Verify the details of all prescriptions to be delivered.*

Record all tracking numbers for prescriptions being delivered via Royal Mail on the Delivery Log sheet.

Ensure the Royal Mail driver signs the Delivery Log sheet for all prescriptions accepted for delivery.

Retain the Delivery Log sheet for at least 3 months from the dispatch date.

Email patients with dispatch confirmation and their tracking number once the prescriptions have left the premises.

All deliveries will require a patient signature to confirm receipt of their prescription. …..

Controlled Drugs (Schedule 2 and 3) will not be sent via Royal Mail or standard courier. These will only be delivered via an approved secure medical courier or by the pharmacy's trained driver, maintaining full chain of custody and audit trail.

Unsuccessful Delivery via Royal Mail

If a delivery attempt is unsuccessful, Royal Mail will leave a 'Sorry We Missed You' card, indicating the date and time of the attempt. The patient can then either choose to collect and sign for their medication at their local post office or reschedule the delivery for a convenient time by phone or email. If items are returned to the pharmacy, the medicines must be logged, checked for integrity, and stored securely. Cold chain items must be quarantined and disposed of if temperature integrity cannot be verified."

6.51 Page 286 'Standard Operating Procedure for Delivering Controlled Drugs' states:

"*This SOP covers the procedure for delivering dispensed controlled drug medications to a patient.*

It applies to all Controlled Drugs (Schedules 2–5) delivered either by the pharmacy's own driver/s or by an approved secure medical courier such as DHL Medical Healthcare. Royal Mail Tracked 24 / Tracked 48 Signed For may only be used for Schedule 4 and 5 Controlled Drugs. …..

Controlled drugs should be given extra caution when delivering extra care and record-keeping is required. Figure out which drugs need to be delivered and signed for. Make sure when dispensing CD's the SOP for Dispensing Controlled Drugs is followed. …..

2. Dispatch the item.

Give the correctly labelled and bagged item to the driver along with the delivery sheet. Make sure that the driver understands that this is not a regular delivery and needs to be signed for.

Make sure that the deliverer understands that 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 and will be left unattended.

When a courier such as DHL Medical Healthcare is used, the Responsible Pharmacist must supervise handover and record the courier representative's signature, name, and time of collection in the Delivery Log.

3. Driver delivers the item.

The person who is delivering the controlled drug should double-check the address to be delivered to and ask the person who is present for identification if necessary. A signature should be obtained from the patient who receives their item. Where the recipient is not the patient, their full name should be recorded on the delivery record form, along with their signature. If the patient has a carer and is incapable of signing then the delivery driver is effectively the patient's nominated representative authorised to collect the CD on their behalf. As such the driver should sign the 'collected by' section on the reverse of the prescription. 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. Electronic proof of delivery or signature confirmation provided by the courier must be reviewed by the pharmacy team to verify completion.

4. Report back to the pharmacist. …..

… the driver must confirm the patient details and ensure the delivery record form is signed by the recipient. Once delivered, the driver must return the signed delivery note to the pharmacy. File the delivery record form as evidence of successful delivery of the controlled drug. The forms should be stored for a minimum of six months in case the delivery is later queried. Electronic or courier tracking confirmations must also be retained securely for at least six months as part of the audit trail.

5. Entry into the CD register

This should be exclusively performed by the Responsible Pharmacist. This is a legal requirement for specific controlled drugs.

Entries must clearly state whether the item was delivered by driver, or dispatched via secure courier, with the relevant tracking or delivery reference recorded.

6. Failure to Deliver

If the patient is not home during the agreed delivery slot, the CD must be returned to the pharmacy on the same day and at the earliest opportunity.

Do NOT push the medicines through the letterbox.

Do NOT leave the medicines outside the door.

Inform the authorised pharmacy staff upon return to the pharmacy.

The CD register entry for failed CD deliveries should be annotated by marginal note or footnote to state that the delivery was not made and the CD entry is not accurate.

If the pharmacist is satisfied that the product has been stored correctly and is suitable to be issued to the patient at a later date the item should be re-entered in the supplied section of the CD register.

Where delivery is by secure courier and same-day return is not possible, the courier must store the Controlled Drug securely in accordance with Home Office safe-custody requirements and return it to the pharmacy at the earliest opportunity. …….

8. CD delivery with Courier

Delivery of controlled drugs in local area will be managed by pharmacy delivery driver, otherwise will be handled by DHL, which has pharma-grade specialist facilities meeting specific quality and validation requirements for healthcare products, including Home Office-licensed controlled drug stores. …….

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.

All courier and Royal Mail tracking data must be reconciled daily by the pharmacy team to ensure no discrepancies exist between dispatch and receipt records."

6.52 In the 'Standard Operating Procedure for Cold Chain' on page 304, it states:

"Product dispatch

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 should 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. Patients will be contacted to inform and arrange for cold chain deliveries. All cold chain deliveries should be booked on courier specific portal. The cold chain medication should be kept in the fridge until the courier arrives to accept the delivery. Pharmacy staff verify with the courier that the delivery will be kept within the specified temperature range.

Details of all prescriptions scheduled for delivery will be confirmed with courier driver. The courier must scan a barcode sticker for each item, with the pharmacy retaining a copy of the barcode, which also serves as the tracking number. Ensure the on-duty pharmacist is available to oversee the handover of all items for delivery and match against the delivery log and prescription. ……

Patient will be contacted with 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. Delivery log is stored for a minimum of 3 months from dispatch date.

Using courier service

All cold chain deliveries must be done via a specialist cold chain courier service. Provisions such as DHL COLDCHAIN (or a similar specialist cold chain courier service) will ensure the integrity of the cold chain and the maximum stability of temperature-sensitive drugs by packing, transporting, and delivering them in a manner that preserves their integrity, quality, and effectiveness. This is a dedicated, fully monitored, and temperature-controlled delivery service.

They utilise real-time monitoring devices to continuously monitor temperature, humidity and other environmental conditions with GPS tacking. DHL vehicles have built-in refrigeration systems to maintain the required temperature during road transportation. Any cold chain breach will be reported to the driver, and any impacted delivery will be cancelled, with the pharmacy promptly informed of the breach. Medications are stored in warehouses with temperature controlled storage facilities for interim or failed delivery storage. 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.

6. Unsuccessful cold chain delivery via courier

If a delivery attempt is unsuccessful, the specialist cold chain courier, DHL COLDCHAIN, will leave a 'Missed Delivery' card. This card will indicate the date and time of the attempted delivery and provide instructions for contacting the courier to arrange a redelivery. Patients can reschedule the delivery at a convenient time via telephone or online.

DHL COLDCHAIN will maintain the cold chain throughout the process, with a maximum 48-hour window for cold chain deliveries. If delivery is not successful within 48 hours, the items will be returned to the pharmacy. The pharmacy will then contact the patient to arrange a new delivery.

7. Breach of Integrity of Cold Chain

DHL vehicles are equipped with built-in refrigeration systems to ensure the required temperature is maintained during road transportation. The system automatically alerts the delivery driver that the cold chain has been breached and affected deliveries will be cancelled.

The patient and pharmacy will be promptly informed of the breach, or the patient will receive a 'Missed Delivery' card.

The pharmacy must arrange for an immediate re-delivery of the items via courier and ensure the return of undelivered items to the pharmacy. Items compromised by a cold chain breach are not reused and must be segregated from the pharmacy stock upon their return. If the breach of the cold chain is

discovered after the medication has been given to the patient, then the Incident Reporting Policy should be followed. The patient must be referred to the responsible pharmacist for review."

6.53 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.

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

6.55 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*."

6.56 The Committee noted 'Standard Operating Procedure for Remote Appliance Fitting and Dispensing Appliances' on page 387 states:

"*1. Receiving a Repeat Appliance Prescription*

In the event that a prescription for an appliance which needs fitting is received from a patient, before ordering the medicine, pharmacy staff will check the patient's PMR history as to whether they have had the appliance before and as such confirm with the patient that there is no change to the size that is needed.

2. Receiving a New Appliance Prescription

If a new prescription for an appliance requires fitting, and the pharmacy cannot provide or customise the appliance or stoma appliance because it is outside the pharmacy's regular services, the pharmacist will:

> *(a) With the patient's consent, refer the prescription to another NHS pharmacist or NHS appliance contractor; and*
>
> *(b) If the patient does not consent to a referral, give the patient contact details of at least two NHS pharmacists or NHS appliance contractors who can provide the required appliance or customisation, if the pharmacist knows these details.*

The pharmacist will also keep and maintain a record of any information given or referrals made to ensure proper auditing and follow-up care when appropriate."

6.57 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.

6.58 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.

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

6.60 The Committee noted that the ‘Standard Operating Procedure for Dispensing of Prescriptions’, on page 272 states:

“*9. 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. If needed plain brown paper can be used to stuff the box to ensure the medicines is protected during transport. 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. For postal/courier items, at a minimum, use padded envelopes for non-fragile items to protect the manufacturer's packaging. For most items, use bubble wrap and, if necessary, polystyrene filler inside a reinforced cardboard box. Large or any fragile medicines should be packed into cardboard boxes with bubble packaging and filling materials to protect from damage.

Small flat parcels - Small square cartons (Kite Packaging)

Medium and large flat parcels – medium and large Defender boxes

Small parcels - CD1 boxes

Medium parcels – Medium carton (7x5x5) (Kite Packaging)

Large parcels – C1 boxes.”

6.61 Further ‘Standard Operating Procedure or the Supply of Medicines in Suitable Containers’ on page 484 states:

“*1. Container Types and Specifications*

PharmUnity uses the following approved container types, all of which comply with BS and MHRA standards:

Solid dosage forms (e.g. tablets, capsules): Type I or II amber plastic bottles (HDPE or PET), child-resistant caps unless clinically inappropriate.

Liquids and oral suspensions: Food-grade amber glass or plastic bottles with tamper-evident caps and seal liners.

External preparations (creams, ointments, lotions): Opaque or amber jars/tubes with appropriate closure to prevent contamination or leakage.

Controlled drugs: Original manufacturer’s tamper-evident packaging or amber glass containers with serialized security labels.

Cytotoxic, cytostatic, or hazardous medicines: Original packaging only; no repackaging unless absolutely necessary and performed under containment.

Blister packs / original packs: Supplied intact unless partial dispensing is required; any cut blister strips must maintain legibility of batch and expiry data.

Fridge lines / temperature-sensitive items: Supplied in original packs inside validated cold-chain containers."

6.62 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

6.63 The Committee asked itself how the Applicant will be satisfied that when dispensing a repeatable prescription other than on the first occasion, that the patient is still using the medication, is not suffering from any side effects, the medicine 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.

6.64 The Committee noted 'Standard Operating Procedure for Repeat Dispensing' on page 307 states:

"*Patients using the service to obtain repeat supplies of NHS prescriptions without the need for their GP practice to issue a prescription each time. This would benefit any patient who has long term but stable medical conditions who require regular medications in respect of that medical condition. Any advice, dispensing or management on repeat dispensing will be provided to patients without face-to-face contact within the premises.*

Once a patient signs up, we will obtain the batch prescription (both the Repeat Authorising Prescription RA and the Repeat Dispensing Prescriptions RD) either from the surgery, electronically or via post.

Either the patient will contact the pharmacy via phone, email, post, website or webcam to dispense the next RD instalment prescription or the pharmacy contacts the patient when they are due their next RD instalment.

Prior to each dispensing episode including those dispensed in dosette boxes as may be required under the Equality Act 2010, the pharmacist will conduct a telephone consultation to verify that the patient is using the prescribed medicines or appliances correctly and is likely to continue. Pharmacist must ensure that the patient is not suffering any side effects from the treatment otherwise which may suggest the need for a review of treatment.

The pharmacist will also assess whether there have been any alterations to the patient's medication regimen or other changes in their health or any recent hospitalisations.

If the pharmacist approves the request, DSP will dispense in accordance with the directions given on the repeatable prescription.

If treatment needs to be reviewed by the prescriber, the patient will be notified by telephone and/or email. We will keep records of dates of dispensing for each individual batch for each patient, to monitor compliance.

Records of interventions made by the pharmacist considered by the pharmacist to be clinically significant will be maintained on the PMR. These actions will ensure a safe and effective service is delivered for patients using the repeat dispensing service."

6.65 Further, in 'Standard Operating Procedure for Dispensing of Prescriptions' on page 267 it states:

"*3. Check for potential interactions.*

Check for contra-indications such as ciclosporin / clarithromycin / erythromycin / itrcinazole / gemfibrozil given with simvastatin. (MHRA safety update, Au 2012). Confer with the prescriber on how to proceed. Check prescription and/PMR drug/disease interactions. This is especially important when new drugs are prescribed, such as macrolide antibiotics are prescribed for a short course but may interact with long term medication such as warfarin, or when omeprazole high dose is prescribed for someone on clopidogrel. Watch for medicines that have a low therapeutic index or interact with many other drugs (e.g. warfarin, lithium, theophylline, methotrexate). Drug/disease interactions require some knowledge of the patient's medical condition. Champix prescribed for smoking cessation should not be given to patients with psychotic illness or depression. Check for interactions with OTC medicines, if known.

4. Check for potential compliance issues.

Assessment of possible side effects and risks of adverse reactions. Assessment of compliance or inappropriate use/misuse. If the prescription is for a new medication or doses after hospital discharge, confirm changes if possible."

6.66 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

6.67 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.

6.68 The Committee noted the 'Standard Operating Procedure for Repeat Dispensing' on page 307 states:

"*Procedure*

Patients using the service to obtain repeat supplies of NHS prescriptions without the need for their GP practice to issue a prescription each time. This would benefit any patient who has long term but stable medical conditions who require regular medications in respect of that medical condition. Any advice,

dispensing or management on repeat dispensing will be provided to patients without face-to-face contact within the premises. …..

Either the patient will contact the pharmacy via phone, email, post, website or webcam to dispense the next RD instalment prescription or the pharmacy contacts the patient when they are due their next RD instalment.

Prior to each dispensing episode including those dispensed in dosette boxes as may be required under the Equality Act 2010, the pharmacist will conduct a telephone consultation to verify that the patient is using the prescribed medicines or appliances correctly and is likely to continue."

6.69 On page 386 of 'Standard Operating Procedure for Remote Patient Assessment of Repeat Dispensing Need' it states:

"*Supply will only be made when medication is required and when no changes have occurred that would require referral back to the GP. Before any issuance of a repeated prescription, all patients are asked the following questions.*

Did you experience any side effects from your last prescription?

Are you experiencing any issues with your last prescription?

Did your last prescription arrive at your delivery address damaged?

Have there been any changes to your health since the issuance of this prescription which would lead to you not requiring it?

If any of the above questions are returned by the patient indicating a need, the Responsible Pharmacist will telephone/video call 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 the 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 will be recorded on the Intervention and Referral Form."

6.70 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

6.71 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.

6.72 For the return of controlled drugs, the Committee noted that in 'Standard Operation Procedure for Return of Unwanted Controlled Drugs to the Pharmacy' at page 322 states:

"*This service is available to ALL patients living in England.*

Patients or their representatives will not return and medicines directly to the pharmacy 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 should always be the pharmacist on duty.

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 through tracked and signed for delivery. ……

Drivers need to:

> *Be aware that they cannot accept patient returns from patients without prior arrangement. The driver should 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.*

Return by DHL

Pharmacist must send the packaging to the patient along with the instructions for appropriate packing of the goods and inform DHL of the nature of the medication and to be kept in a lockable compartment with tracked next day delivery.

Remind patients not to send on Friday as pharmacy is not open during weekend 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."

6.73 The Committee noted that 'Standard Operating Procedure for Disposal of Unwanted Medicines Returned to the Pharmacy' on page 376 states:

"*1. Return of Unwanted Medicine without face-to-face contact within premises.*

This service is accessible to all patients across the entire country without face-to-face contact.

Patients will be offered various options for disposing of unwanted medicines and out-of-date stock:

> *A specialised waste management company will safely and securely dispose of unwanted medicines by collecting them from patients and residential homes.*
>
> *Patients who wish to return unwanted medicines to the pharmacy can do so via courier, with the cost covered by the pharmacy.*
>
> *Patients in the local area can arrange for pharmacy staff or delivery driver to collect unwanted medicines from their home or workplace by contacting the pharmacy via phone or email.*
>
> *Patients will receive appropriate packaging in advance, and information about the service and how to schedule a collection at patient's place will be available on the Pharmacy website. ……*

Any patients/members of the public attending face to face will be advised to attend a local community pharmacy via the intercom system. Medicinal waste collections from patients/members of the public via the inhouse delivery driver or via royal mail.

Although not obligatory, waste can also be accepted from care homes with nursing, hospices not operated by charities and GP/dental surgeries, after discussion with the local area authority about how the waste will be managed and its disposal paid for.

Before accepting the container or bag of unwanted medicine, ask if it contains:

> *Any sharps.*
>
> *strong painkillers (controlled drugs).*

Poisons or chemicals.

Liquids.

When items are to be returned to the pharmacy by Royal mail the pharmacist must:

Explain the process to the patient/ their representative about the return and identify the items being returned.

Assess the items for suitability for return by Royal Mail

Ensure if items are suitable for return by Royal Mail, then the pharmacy make a note on the PMR and arrange to send the appropriate packaging to the patient for safe return.

Provide details to the patients of their local process for disposal If items are not suitable for return by Royal Mail.

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

Send the packaging to the patient / their representative along with the instructions for appropriate packing of the items to be returned.

Contact the patient/ representative to ensure that the package has been received. ……

The unwanted medicines should be removed to a designated storage area.

If the returned medicines cannot be sorted immediately, they should be clearly labelled as patient returned waste medicine.

Store returned medicines in the quarantine area of the van for transport. Ensure medicines are always not visible in the vehicle.

2. Sorting Unwanted Medicines

Unwanted medicines must be sorted by a trained member of staff according to the accompanying protocol. In order to process waste, the pharmacy needs non-hazardous waste containers (usually large yellow sealable bins) and hazardous waste containers (usually purple topped). A sharps bin is also required for emergency use (obtainable from the waste handler), even if the pharmacy does not deal with sharps (see below). Some waste handlers provide different bins for different types of non-hazardous waste. Appropriate protective clothing (gloves, apron, mask) should be worn. The bag or container should be emptied out into a plastic tray that is only used for waste medicine. Hands should never be placed directly into the bag or container to remove the medication. If sharps are inadvertently accepted in a bag of returns, the pharmacist must contact the waste supplier to obtain a sharps box/discuss disposal with them. If poisons, inflammable materials or chemicals are accepted inadvertently by the pharmacy, phone the waste supplier to confirm that the item can be accepted and discuss a disposal method."

6.74 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

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

6.76 The Committee noted 'Standard Operating Procedure for Remote Promotion of Healthy Lifestyle and Public Health Campaigns' on page 397 stated:

"*Upon consultation, if the pharmacist notices that the patient is suffering from diabetes, is at risk of coronary heart disease, or smokes or is overweight, the Responsible Pharmacist will provide advice without face-to-face contact with the aim of increasing that person's knowledge and understanding of the health issues which are relevant to that person's personal circumstances. This advice could be given verbally over phone or video call, or through written material e.g. leaflets to be delivered to patients' home and by referring the person to other sources of information or advice*. …..

3. Health Campaigns

The Pharmacy will actively engage in national health campaigns to disseminate health messages to our patients throughout England. This will involve distributing leaflets along with prescriptions during targeted campaign periods and offering additional advice and educational materials through the pharmacy website.

Patients will receive guidance on accessing these learning resources via email, text messages, and other forms of non-face-to-face communication to ensure awareness of the campaigns. Additionally, patients will be evaluated for participation in at least one clinical audit and any other audits specified by the NHSCB [sic]. These audits may include clinical audits conducted in accordance with NHSCB [sic] data processing arrangements or policy-based audits designed to support the development of NHSCB commissioning policies, all of which will comply with NHSCB data processing protocols."

6.77 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

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

6.79 The Committee noted 'Standard Operating Procedure for Remote Promotion of Healthy Lifestyle and Public Health Campaigns' on page 397 stated:

6.80 "*Upon consultation, if the pharmacist notices that the patient is suffering from diabetes, is at risk of coronary heart disease, or smokes or is overweight, the Responsible Pharmacist will provide advice without face-to-face contact with the aim of increasing that person's knowledge and understanding of the health issues which are relevant to that person's personal circumstances. This advice could be given verbally over phone or video call, or through written material e.g. leaflets to be delivered to patients' home and by referring the person to other sources of information or advice.*

6.81 In the 'Standard Operating Procedure for Dispensing of Prescriptions' on page 266, it states:

"*Safety and clinical efficacy*

1. Check dosage and form.

Check if dosage form and route of administration is appropriate….

2. Check whether clinically appropriate.

Make sure the length of treatment or number of dosage units is appropriate. Check if drug and dose is appropriate in relation to patients condition- age, gender, pregnancy, breastfeeding, kidney or liver disease, previous treatment e.g. If a patient is known to have developed liver or renal failure, the dose of medication such as statins should be greatly reduced or stopped. If the dose of a medicine has changed dramatically compared to previous records, confirm rationale with the patient/prescriber.

Be especially careful where there is a calculated dose based on patients weight, such as doses for babies and children. …….

3. Check for potential interactions.

Check for contra-indications such as ciclosporin / clarithromycin / erythromycin / itrcinazole / gemfibrozil given with simvastatin. (MHRA safety update, Au 2012). Confer with the prescriber on how to proceed. Check prescription and/PMR drug/disease interactions. This is especially important when new drugs are prescribed, such as macrolide antibiotics are prescribed for a short course but may interact with long term medication such as warfarin, or when omeprazole high dose is prescribed for someone on clopidogrel. Watch for medicines that have a low therapeutic index or interact with many other drugs (e.g. warfarin, lithium, theophylline, methotrexate). Drug/disease interactions require some knowledge of the patient's medical condition. Champix prescribed for cessation should not be given to patients with psychotic illness or depression. Check for interactions with OTC medicines, if known."

6.82 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

6.83 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.

6.84 The Committee noted 'Standard Operating Procedure for Remote Promotion of Healthy Lifestyle and Public Health Campaigns' on page 397 stated:

"If a non-electronic prescription or non-electronic repeatable prescription is presented to the pharmacy by post, the patient will be contacted via telephone/video consult. Upon consultation, if the pharmacist notices that the patient is suffering from diabetes, is at risk of coronary heart disease, or smokes or is overweight, the Responsible Pharmacist will provide advice without face-to-face contact with the aim of increasing that person's knowledge and understanding of the health issues which are relevant to that person's personal circumstances. This advice could be given verbally over phone or video call, or through written material e.g. leaflets to be delivered to patients' home and by referring the person to other sources of information or advice.

Where advice is provided it should be recorded on the PMR for auditing purpose and follow-up care. The email newsletter and website will also be used to promote a healthy lifestyle. Information about support organisations, the treatment of common illnesses, minor ailments, long term medical conditions and appropriate usage of OTC medications will be available on the website, app and email newsletter.

The pharmacist on duty can be contacted by telephone for more advice and drug interactions. If it is not appropriate for the pharmacist to give advice, then the patient should be signposted to an appropriate health or social care provider. Refer to the SOP on 'Signposting'. An intervention and referral form shall be filled out with information and the referral organisation shall be noted. …..

Patients will receive guidance on accessing these learning resources via email, text messages, and other forms of non-face-to-face communication to ensure awareness of the campaigns. Additionally, patients will be evaluated for participation in at least one clinical audit and any other audits specified by the NHSCB. These audits may include clinical audits conducted in accordance with NHSCB data processing arrangements."

6.85 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

6.86 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.

6.87 The Committee noted that 'Standard Operating Procedure for Remote Signposting' on page 400 states:

"*1. Signposting the patient.*

If a patient requests information or staff recognise that a patient needs services or advice from that cannot be provided by the pharmacy, but aware of other appropriate health and social care providers or support organisations who are likely to be able to provide that advice, treatment or support, pharmacy staff will refer to the signposting booklet and advise the patient of the appropriate organisation and their contact details without face-to-face contact. This can be done through telephone, video calls, website or email. Any help or advice that cannot be accessed on the website and app links will be available by telephoning the pharmacy and asking for advice. The patient will be able to speak with the pharmacist directly.

If a range of healthcare providers are available in one category, e.g. local dentists, then no one provider should be recommended as being better than others by members of staff. Pharmacy staff 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. Occasionally patients/customers need to be referred to other organisations such as medical charities, patient organisations and government helplines to provide financial aid or for medical services."

6.88 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

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

6.90 The Committee noted 'Standard Operating Procedure for Remote Support for Self Care' on page 394 stated:

"*1. Defining Self Care*

There is a wide range of self-care support interventions. These have varying levels of intensity, differences in content, and a range of theoretical underpinnings (from didactic education to the use of behavioural counselling techniques and theories of behaviour change). The goal is to empower individuals with greater understanding of their treatment options and to reduce unnecessary utilisation of health and social care services.

The advice provided encompasses:

(i) Provision of advice to people, including carers, requesting helping with the treatment of minor illness and long-term conditions, including general information and advice on how to manage illness.

(ii) Provision of advice on appropriate use of the wide range of non-prescription medicines which can be used in the self-care of minor illness and long-term conditions.

(iii) Provision of healthy lifestyle interventions when appropriate for promotion of healthy lifestyle service.

(iv) Signpost patients to other health and social care providers when appropriate.

2. Providing Self Care

The organisation will endeavour to provide maximum support from the pharmacy to enable people to care for themselves or their families. There is a range of topics ranging from long-term conditions to minor ailments on the website in the well-being section that aims to provide information and advice in support of patient's conditions. This information is also linked to the NHS Choices website for up-to-date information and support and also if the patient would like more in-depth scientific knowledge. Self-care our pharmacy intends to provide our patients include:

Information-giving

Addressing motivations and barriers to change

Teaching coping strategies.

Designing action plans.

Dealing with emotional sequelae of illness ongoing monitoring/support.

Engaging family and social support.

3. Opportunistic self-care

The pharmacist can appropriately make use of patients Summary Care Records to support patients, if required with patient's consent. The support for self-care will also be provided opportunistically if a patient or carer telephones the pharmacy for advice. A note will be made of any advice given to patients whether online or over the phone if deemed necessary. This service intertwines of course with signposting and public health promotion. A record should be made in the PMR."

6.91 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

6.92 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.

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

6.94 The Committee noted 'Standard Operating Procedure for Remote Discharge Medicine Service' on p390 which stated:

"*1. Preparation for the service.*

All referrals will be received electronically via pharmaoutcomes, this needs to be checked regularly or at least twice daily.

All consultations must be taken over the phone in a private area of the pharmacy to maintain confidentiality.

When providing this service, ALL communications with the patient/ patient's carer or other third parties shall be non-face to face and via telephone or email. Consultations will take place in a private room separate from the dispensary, ensuring patient confidentiality and privacy are maintained throughout the remote delivery of this service. …..

Confirm minimum requirements of information have been provided on the referral and start the DMS Stage 1.

If information missing contact details of referring clinician/hospital department.

3. DMS - Stage 1 (Completed as soon as possible, but within 72hrs on receipt of referral) (*excludes hours of days when pharmacy not open)*

Check referral for clinical information and actions required.

Check all previously ordered prescriptions for the patient (including any awaiting delivery) are still appropriate.

Pay particular attention to electronic repeat dispensing prescriptions as may be pulled down from the NHS spine a while after patient has been discharged.

Compare post discharge list of medicines with those being taken before admission.

If necessary, raise any issues identified with the NHS Trust or Patient's GP, as appropriate.

Record notes as appropriate on the PMR system and/or other appropriate record.

Ensure flag in place on record to alert staff of the need to complete Stages 2 and 3, when the first prescription received, or first contact with patient/carer.

4. DMS - Stage 2 (Completed when 1st Prescription received following discharge, Usually with 1 week to 1 month following discharge)

Check medicines prescribed reflect appropriate changes made during the hospital discharge.

Any discrepancies / issues to be raised with GP practice to try and resolve.

Record notes as appropriate on the PMR system and/or other appropriate record.

DMS - Stage 3 (Confidential discussion with patient/carer on dispensing of this 1st prescription)

Conduct a confidential conversation with the patient / carer to check their understanding of the medicines.

The consultation room must be used to ensure the remote consultation is not overheard in the dispensary to maintain patient confidentiality.

If any information discussed, is considered to be clinically appropriate to support patients' on-going care, it should ideally be shared with patient's general practice/PCN pharmacy team.

Gain patient consent to share and record on notes. Send notes using a secure method

If appropriate, offer to dispose of medicines no longer required by non-face-to-face contact, to avoid any potential confusion.

Record notes as appropriate on the PMR system and/or other appropriate record.

6. All stages of DMR cannot be completed

If the above normal patient journey through the service cannot be completed.

Pharmacist to use professional judgement to determine the appropriate actions to take."

6.95 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

6.96 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.

6.97 The Committee notes 'Standard Operating Procedure for Pharmacies Providing Services via the Internet' on page 347 which states:

"*Procedure*

1. All website information should be checked for any omitted errors.

A list of pharmacy services would be clearly shown and explained on the pharmacy website, so people could make an informed decision. People would be given the right to make decisions about their care and medicines, and the services they want to receive and would be signposted to relevant healthcare professionals if they are not eligible. Checking for any omitted errors must occur before any sales may be completed by an online pharmacy."

6.98 The Committee noted reference to the pharmacy website in relation to several SOPs where patients can obtain advice including how to access appropriate packaging to schedule a collection for returning medication, customers registering an account on the pharmacy website. With reference to self care, the SOPs state "*There is a range of topics ranging from long-term conditions to minor ailments on the website in the well-being section that aims to provide information and advice in support of patient's conditions*." and with regard to Health Campaigns, "*The Pharmacy will actively engage in national health campaigns to disseminate health messages to our patients throughout England. This will involve distributing leaflets along with prescriptions during targeted campaign periods and offering additional advice and educational materials through the pharmacy website*."

6.99 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.

6.100 *Summary*

6.101 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).

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

6.102.1 confirm the Commissioner's decision;

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

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

6.103 The Committee has reached a different conclusion from the Commissioner regarding the application because the Applicant provided an updated suite of

SOPs with its appeal. In those circumstances the Committee determined that the decision of the Commissioner must be quashed.

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

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

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

7 Decision

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

7.2 The Committee:

7.2.1 quashes the decision of the Commissioner; and

7.2.2 redetermines the application as follows -

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

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

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

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

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

7.2.3 The application is granted.

Case Manager
Primary Care Appeals