NHS Resolution

4 March 2025

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10 South Colonnade
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Tel: 020 3928 2000
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REF: SHA/26395

APPEAL AGAINST HERTFORDSHIRE & WEST ESSEX ICB DECISION TO REFUSE AN APPLICATION BY SIGCARE LTD FOR A RELOCATION THAT DOES NOT RESULT IN A SIGNIFICANT CHANGE TO PHARMACEUTICAL SERVICES PROVISION UNDER REGULATION 24 FROM UNIT 1, 1-7 COLONIAL WAY, WATFORD WD24 4YR TO L H HOUSE, BERMER ROAD, OFF IMPERIAL WAY, WATFORD, HERTFORDSHIRE, WD24 4YX

1 Outcome

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

1.2 The Committee determined that the application should be granted.

A copy of this decision is being sent to:

Rushport Advisory LLP on behalf of Sigcare Ltd
PCSE on behalf of Hertfordshire & West Essex ICB

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1 The Application

By application dated 14 June 2024, Sigcare Ltd ("the Applicant") applied to Hertfordshire & West Essex ICB ("the Commissioner") for a relocation that does not result in a significant change to pharmaceutical services provision under Regulation 24 from Unit 1, 1-7 Colonial Way, Watford WD24 4yr to L H House, Bermer Road, off Imperial Way, Watford, Hertfordshire, WD24 4YX. In support of the application it was stated:

1.1 In response to why the application should not be refused pursuant to Regulation 31 the Applicant made no comment.

1.2 "We are Distance selling pharmacy and therefore we do not provide physical access to pharmacy currently for any essential services. We do have one consultation room on current premises [sic] which we use to provide any advance services.

1.3 Move [sic] to new premises is going to enhance the access to our consultation rooms and as a registered DSP we will not be providing physical access to pharmacy for patients requiring an essential service.

1.4 Our new location is less than 5 minutes walk from our current location. We will also have signs displayed on [sic] current location indicating new [sic] location and also we will utilise advertisement facilities near to [sic] new location for directing the patients to our pharmacy.

1.5 Furthermore, our main cohort of customers who receives NHS services are care homes and they receive delivery service.[sic]

1.6 PNA, [sic] published by Hertfordshire County Council in August 2022, identified no gaps in the provision of necessary services for Watford and Three revers [sic] locality.

1.7 We are relocating to a next-door property in order to enhance work space area. We are not changing any of our service provisions at new premises compare what we provide at current location. [sic] Currently there are no bricks and mortar pharmacies near our location. Therefore we believe relocation of the premises would not result in a

significant change to the arrangements that are in place for the provision of local pharmaceutical services and pharmaceutical services.

1.8 We are relocating to a next door property in order to enhance availability of space to our working area. We are not making any changes to any pharmaceutical service provision currently provided by us. We are DSP and offer distance level service to nationwide and our majority of customer cohort is care and residential homes[sic]

1.9 We currently use [sic] delivery driver, royal mail and parcel force couriers to deliver dispensed medications in England.

1.10 We have telephone and email facilities for customers or patient [sic] to contact us on. Our website displays all required information on how to contact us via mail, telephone call or post.

1.11 We also have ability to provide remote consultation via a secure video link (provided by approved IT provider) allowing us to provide Advance services such as Pharmacy First.

1.12 We ensure our service provisions are safe and effective by adhering to our SOPs. We constantly review our processes and incidents to learn from them.

1.13 As visible in our drawings of layout we have kept our consultation rooms separate to our main dispensing unit, this allows member of public to see the clear separation of both services. Furthermore, anyone attends the premises requesting the essential services will be assessed and will be directed to nearby pharmacy where they can be provided with face-to-face essential service. We have a list local pharmacies with their addresses and opening hours.

1.14 Risk assessment of all advance services includes the risk of providing essential services such as selfcare and sale of pharmacy medicines. Any pharmacy staff carrying out advance services will be appropriately trained on how to identify any element of the service they are providing [sic] may be an element of essential service. This will enable service provider to be aware of the possible scenarios and how to deal with them e.g. referring patient to another nearby pharmacy."

1.15 The services to be provide at the new premises are the same and without interruption.

1.16 The pharmaceutical services to be provided at these premises are:

1.16.1 Essential services;

1.16.2 Advanced and Enhanced services:

1.16.2.1 New Medicine Service (NMS)

1.16.2.2 Community Pharmacy Seasonal Influenza Vaccination

1.16.2.3 Community Pharmacist Consultation Service (CPCS)

1.16.2.4 Hypertension Case Finding Service

1.17 The Applicant's core opening hours are:

1.17.1 Mon to Fri – 08.00 to 18.00

1.17.2 Sat - 09.00 to 14.00

1.17.3 Sun Closed

1.18 The Applicant's total opening hours are

1.18.1 As above.

2 **The Decision**

The Commissioner considered and decided to refuse the application. The decision letter dated 8 November 2024 states:

Covering letter

2.1 "Hertfordshire and West Essex 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 Hertfordshire and West Essex ICB's decision. Should you choose to appeal then 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: Primary Care Appeals

2.3 NHS Resolution
8th Floor
10 South Colonnade
Canary Wharf
London
E14 4PU"

Decision report

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

2.4 "**CAS-310139-F7M3M9**

2.5 **New Inclusion Pending No Significant Change Relocation:**

2.6 Sigcare Ltd, L H House, Bermer Road, Off imperial Way, Watford, HERTFORDSHIRE, WD24 4YX

2.7 The Pharmaceutical Services Regulations Committee (hereafter referred to as "the Committee") considers all pharmaceutical services applications for the 6 Integrated Care Boards (ICB) within the East of England footprint. NHS Hertfordshire and West Essex ICB (HWE ICB) hosts the meeting on behalf of the 6 ICBs, in accordance with the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 as amended (hereafter referred to as "the Regulations").

2.8 The Committee considered this application for a no significant change relocation application within the Hertfordshire HWB area under Regulations 24 of the Regulations.

2.9 **The Committee first considered Regulation 31.**

2.10 The Committee noted that there are no persons on the pharmaceutical list providing pharmaceutical services in the same or adjacent premises. The applicant confirmed that the same essential services will continue at the proposed site.

2.11 The Committee agreed it was not required to refuse this application under the provision of Regulation 31.

2.12 **The Committee considered the regulatory requirements of Regulation 24:**

2.13 **Regulation 24(1)(a)**

2.14 The Committee was required to determine whether the patient groups, accustomed to accessing pharmaceutical services at the existing site, would continue to routinely access pharmaceutical services from the applicant if the proposed relocation was granted. Further, whether it could be considered that the evidence indicates that the proposed pharmacy contractor would not be significantly less accessible.

2.15 The Committee noted that the applicant is a Distance Selling Pharmacy (DSP). The proposed location is less than 5 minutes' walk (approximately 0.1 miles from the current premises). A map was provided to the Committee prior to the meeting. The proposed move is to enhance the workspace area.

2.16 The Committee noted the supporting information provided by the applicant and distributed to attendees prior to the meeting.

2.17 The Committee was not required to refuse the application under provisions of Regulation 24(1) (a) as there is no evidence to suggest that patient groups that are accustomed to accessing pharmaceutical services at the existing premises would find the relocation significantly less accessible.

2.18 **Regulation 24(1)(b**)

2.19 The Committee noted that the proposed premises are not within 1.6km of a controlled locality in the area of a neighbouring HWB. Therefore, the Committee noted that Regulation 24(1)(b) should not cause the application to be refused.

2.20 **Regulation 24(1)(c)**

2.21 The Committee noted that the applicant had stated within their application:

2.22 *"We are relocating to a next-door property in order to enhance availability of space in our working area. We are not making changes to any pharmaceutical service provision currently provided by us. We are a DSP and offer distance level service to nationwide and our majority of customer cohort is care and residential homes".*

2.23 The Committee was not required to refuse the application under the provisions of Regulation 24(1)(c).

2.24 **Regulation 24(1)(d) and (e)**

2.25 The Committee noted the applicant has ticked the boxes to state that the same services will be provided and that services will not be disrupted or interrupted during the proposed relocation.

2.26 The Committee was not required to refuse the application under the provisions of Regulation 24(1)(d) and (e).

2.27 **Regulations 24(2) – 24(3)(c)**

2.28 Regulation 24(2) – relocations to a neighbouring HWB's area - not applicable.

2.29 Regulation 24(3)(a) – relocations involving a pharmacy that applied under the previous out of town retail area exemption – not applicable.

2.30 Regulation 24(3)(b) – relocations involving a pharmacy that applied under the previous one stop primary care centre exemption – not applicable.

2.31 Regulation 24(3)(c) - relocations involving a pharmacy that relocation within the 12 months prior to this application – not applicable.

2.32 **Regulation 24(3)(d) – relocations involving a distance selling premises.**

2.33 The pharmacy premises to which this application relates are distance selling premises and therefore this regulation was considered by the Committee.

2.34 **Regulations 25 – distant selling premises**

2.35 The pharmacy premises to which the application relates are distance selling premises and therefore regulation 25 was considered.

2.36 **Reg 252(a) [sic]**

2.37 The Committee noted that the proposed premises are not on the same site or in the same building as the premises of a provider of primary medical services with a patient list. There were no grounds to refuse the application by virtue of this regulation.

2.38 **Regulation 25(2)(b)**

2.39 The Committee considered the information which had been provided by the applicant in relation to its procedures for the provision of essential services, including any Standard Operating Procedures (SOPs) that it intends to use at the proposed pharmacy premises.

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

2.41 In support of their application the applicant has stated:

2.41.1 *"we currently use delivery drive, Royal Mail and parcel force couriers to deliver dispensed medications in England. We have telephone and email facilities for customers or patients to contact up via mail, telephone call or post. We also have ability to provide remove consultation via a secure video link (provided by approved IT Provider) allowing us to provide advanced services such as Pharmacy First. We ensure our service provisions are safe and effective by adhering to our SOPs. We constantly review our processes and incidents to*

learn from them. As visible in our drawings of layout we have kept our consultation rooms separate to our main dispensing unit, this allows member of public to see the clear separation of both services. Furthermore, anyone attends the premises requesting essential services will be assessed and will be directed to nearby pharmacy where they can be provided with face-to-face essential service. We have a list of local pharmacies with their addresses and opening hours. Risk assessment of all advance services includes the risk of providing essential services such as selfcare and sale of pharmacy medicines. Any pharmacy staff carrying out advance services will be appropriately trained on how to identify any element of the service they are providing may be an element of essential service. This will enable service provider to be aware of the possible scenarios and how to deal with them, e.g. referring a patient to another nearby pharmacy.

2.42 The Committee noted the following aspects of the essential services, which are considered more difficult to provide safely and effectively in a distance selling context.

2.43 **Dispensing of drugs and appliances**

2.44 The Committee considered whether the applicant has explained how non-electronic prescriptions will be presented by the patient and how products will be provided.

2.45 The Committee noted from the information provided within the application it stated*:*

2.45.1 *"we currently use delivery driver, royal mail and parcel force couriers to deliver dispensed medications in England. We ensure our service provisions are safe and effective by adhering to our SOPs. We are constantly reviewing our processes and incidents to learn from them".*

2.46 The Committee was not satisfied that it has been provided with information sufficient to show that there would be compliance with Paragraph 5(2)(3) of Schedule 4.

2.47 **Urgent supply without a prescription**

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

2.49 The Committee noted that the applicant has not provided details relating to urgent supply without a prescription.

2.50 The Committee was not satisfied that it has been provided with information sufficient to show that there would be compliance with Paragraph 6 of Schedule 4.

2.51 **Preliminary matters before providing ordered drugs or appliances.**

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

2.53 The Committee noted that the applicant has provided details relating to preliminary matters before providing ordered drugs or appliances and their process for 'Verification of Declarations of Prescription Exemptions'.

2.54 The Committee was satisfied that it has been provided with information sufficient to show that there would be compliance with Paragraph 7(3) of Schedule 4.

2.55 **Providing ordered drugs or appliances**

2.56 The Committee considered whether the applicant has 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).

2.57 The Committee noted that applicant [sic] has not provided supporting information within their application relating to providing ordered drugs or appliances. The Committee was not satisfied that it has been provided with information sufficient to show that there would be compliance to this regard.

2.58 **Refusal to provide drugs or appliances ordered.**

2.59 The Committee considered how the applicant will be satisfied that when dispensing a repeatable prescription other than on the first occasion, that the patient is still using the medication, is not suffering from any side effects, the medicine regime has not changed in any way and there has been no changes to the patient's health, which may indicate the desirability of review the patients treatment. The Committee noted that the applicant has not provided supporting information relating to the refusal to provide drugs or appliances ordered. The Committee was not satisfied that it has been provided with information sufficient to show that there would be compliance with.

2.60 Paragraph 9(4) of Schedule 4.

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

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

2.63 The Committee noted that the applicant has not provided any supporting information relating to further activities carried out in connection with the provision of dispensing services. The Committee was not satisfied that it has been provided with information sufficient to show that there would be compliance with 10(1) of Schedule 4.

2.64 **Disposal service in respect of unwanted drugs**

2.65 The Committee considered whether the applicant has explained how it will safely and effectively accept and dispose of unwanted drugs presented to it for disposal.

2.66 The Committee noted that the applicant has not provided any supporting information relating to the disposal service in respect of unwanted drugs. The Committee was not satisfied that it has been provided with information sufficient to show that there would be compliance with Paragraphs 13 - 15 of Schedule 4.

2.67 **Promotion of healthy lifestyles**

2.68 The Committee considered whether the applicant has explained how it will safely and effectively promote healthy lifestyles.

2.69 The Committee noted that the applicant has not provided any supporting information relating to the promotion of healthy lifestyles. The Committee was not satisfied that it

had been provided with information sufficient to show that there would be compliance with Paragraph 16 – 18 of Schedule 4.

2.70 **Prescription linked intervention.**

2.71 The Committee considered whether the applicant has 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.

2.72 The Committee noted that the applicant has not provided information relating to prescription linked interventions. The Committee was not satisfied that it has been provided with information sufficient to show that there would be compliance with paragraph 17 of Schedule

2.73 **Public health campaigns**

2.74 The Committee considered whether the applicant has explained how it will safely and effectively participate in public health campaigns, if and to the extent required by the NHSCB. [sic]

2.75 The Committee noted that the applicant has not provided information relating to public health campaigns. The Committee was not satisfied that it has been provided with information sufficient to show that there would be compliance with Paragraph 18 of Schedule 4.

2.76 **Signposting**

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

2.78 The Committee noted that the applicant has not provided information on Signposting patients within their application. However, the applicant had stated that:

2.78.1 *"any pharmacy staff carrying out advanced services will be appropriately trained on how to identify any element of the service they are providing may be an element of essential services. This will enable service provider to be aware of the possible scenarios and how to deal with them e.g. referring patient to another nearby pharmacy".*

2.79 Based on the information before it, the Committee was not satisfied that it has been provided with information sufficient to show that there would be compliance with Paragraphs 19 – 20 of Schedule 4.

2.80 **Support for self-care.**

2.81 The Committee considered whether the applicant has explained how it will provide advice and support to people caring for their families.

2.82 The Committee noted that the applicant has not provided information on support for self-care within their application. The Committee was not satisfied that it has been provided with information sufficient to show that there would be compliance with Paragraphs 21 – 22 of Schedule 4.

2.83 It is recommended that if the application was one to which regulation 24(1) applied, it would be refused pursuant to regulation 25(2).

2.84 **Regulation 50: Discontinuation of arrangements for the provision of pharmaceutical services by doctors**

2.85 The Committee noted that Regulation 50 does not apply as the application is not within a controlled locality.

2.86 **Regulation 66: Conditions relating to providing directed services.**

2.87 The Committee noted that Regulation 66 does not apply as the applicant will not be providing directed services.

2.88 **Representation**

2.89 The Committee noted representation was received from:

2.90 Boots Support Office who stated:

2.90.1 *''Thank you for informing us of the application. We do not have any comments to make but would be grateful if you would keep us informed of the progress of this relocation".*

2.91 **Decision**

2.92 The Committee refused the application by virtue of Regulation 24(3)(d), because if the application was one to which Regulation 25(1) applied, it would be refused pursuant to Regulation 25(2).

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

(a) if the premises in respect of which the application is made are on the same site or in the same building as the premises of a provider of primary medical services with a patient list; and (b) unless NHS England is satisfied that the pharmacy procedures for the pharmacy premises are likely to secure—

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

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

2.93 The Committee agreed that appeal rights are granted to the applicant, Sigcare Ltd."

3 **The Appeal**

In a letter dated 21 November 2024, addressed to NHS Resolution, Rushport Advisory LLP on the Applicant's behalf appealed against the Commissioner's decision. The grounds of appeal are:

3.1 "I act for Sigcare Limited and have been instructed by my client to submit this appeal against the decision of the Commissioner to refuse the above application. The decision was communicated to my client by letter dated 8 November 2024 (decision attached).

3.2 My client wishes to relocate to new premises which are approximately 280 metres from their current premises and located in the same industrial estate. The journey on foot

between the current and proposed premises takes 4 minutes on foot as shown below. [photograph provided]

3.3 Having read the Commissioner's Decision Report, my client acknowledges that they did not provide sufficient information to enable the Commissioner to approve their application and we have addressed the missing information within this appeal and in the attached SOPs [provided].

3.4 My client operates as a distance selling pharmacy and does not provide any essential services to patients on a face to face basis at their current premises.

3.5 My client provides a number of advanced services that do require patients to attend their premises and we have considered those patients as a distinct patient group below.

3.6 In order to show that my client's application meets all parts of the regulatory test my client has:

3.6.1 Defined their Patient Groups;

3.6.2 Shown that, for these Patient Groups the proposed location for the pharmacy will not be significantly less accessible;

3.6.3 Demonstrated that the application meets all parts of the test under Regulation 24;

3.6.4 Provided evidence to demonstrate that essential services will be provided to any persons in England who request them without face to face contact and in a safe and effective manner.

3.7 **Patient Group(s)**

3.8 When considering the definition of the relevant 'patient groups' the Committee is required to consider accessibility "for the patient groups that are accustomed to accessing pharmaceutical services at the existing premises".

3.9 My client provides a national service and any person in England who requests essential services can access them remotely. As my client does not provide any essential services to patients attending at the current pharmacy premises there is no patient group that is "accustomed to accessing pharmaceutical services at the existing premises" in respect of essential services.

3.10 My client also provides NMS, which are carried out remotely and there is therefore no patient group that is "accustomed to accessing pharmaceutical services at the existing premises" in respect of NMS.

3.11 My client also provides the following services that are accessed by patients in person at the pharmacy premises;

3.11.1 Flu Vaccination;

3.11.2 Hypertension Case Finding;

3.11.3 Pharmacy First (replaces CPCS that was stated on the application form.

3.12 **Pharmacy First Specific Notes**

3.13 Distance selling pharmacies (DSPs) can provide the Pharmacy First service but there are some limitations on how the service is provided. My client does not provide any clinical pathways consultations face to face (as this also involves support for self-care), nor do they provide the acute otitis media, nor can the pharmacy claim for referral fees to another provider (See Community Pharmacy England website and statements on Pharmacy First for DSPs).

3.14 **Patient Groups**

3.15 The only patient group relevant to the test under regulation 24 is therefore made up of those who access the permitted Advanced services provided by my client. In considering this patient group we have considered all such services together as it serves no useful purpose to separate out these services given that access is identical for each.

3.16 **Access by Various Means of Transport**

3.17 As the current and proposed location are only 280 metres apart along normal roads and footpaths with street lighting and dropped curbs, the proposed premises will be as accessible as the current premises.

3.18 Access by car will be slightly improved as my client will have their own dedicated parking spaces.

3.19 My client does not see any patients who access their pharmacy using public transport other than those who working the industrial estate and travel to and from work using public transport. Access for such patients would barely change whether they were travelling from Watford Junction (approximately 1 mile walk) or the nearest bus stops on Radlett Road / Raphael Drive (approximately 700 metres from both current and proposed premises)

3.20 In addition, the Committee will also consider the other matters required under Regulation 24:

3.21 **In the opinion of the NHSCB,** [sic] **granting the application would not result in a significant change to the arrangements that are in place for the provision of pharmaceutical services**

3.22 There is no evidence that granting the application would result in a significant change to the arrangements that are in place for the provision of pharmaceutical services. The same services will be provided from the new premises and will be provided in the same manner.

3.23 **The NHSCB [sic] is satisfied that granting the application would not cause significant detriment to proper planning in respect of the provision of pharmaceutical services in the HWB's area**

3.24 My client is not aware of any plans in respect of the provision of pharmaceutical services to which significant detriment would be caused should their application be granted.

3.25 **The services the applicant undertakes to provide at the new premises are the same as the services the applicant has been providing at the existing premises**

3.26 My client undertakes to provide the same services at the new premises as are provided at the existing premises.

3.27 **The provision of pharmaceutical services will not be interrupted (except for such period as the NHSCB [sic] may for good cause allow)**

3.28 My client confirms that the provision of pharmaceutical services will not be interrupted during the proposed relocation.

3.29 Finally, the Committee is required to consider whether the relocated pharmacy will continue to provide safe and effective services. I have therefore attached Standard Operating Procedures that have been approved by my client for use in the pharmacy and which demonstrate that the legal test is met in full.

3.30 For the reasons given above we request that the Committee allows the appeal and look forward to hearing from you in due course."

4 Summary of Representations

This is a summary of representations received on the appeal.

The Commissioner

4.1 "Thank you for your letter dated 28 November 2024 advising us that Sigcare Limited have submitted an appeal against the decision by Herts and West Essex Integrated Care Board (HWE ICB) to refuse their application for a no significant change relocation.

4.2 HWE ICB note that Rushport Advisory LLP are acting on behalf of Sigcare Ltd (the Appellant).

4.3 The Appellant is a distance selling pharmacy and as set out in the decision wording, the requirements of regulation 25(2)(b) of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended (the Regulations) were not met. The decision wording set out that all other regulatory requirements were met.

4.4 HWE ICB note that the Appellant has acknowledged *"that they did not provide sufficient information to enable the commissioner to approve their application and we have addressed the missing information within this appeal and in the attached SOPs."* (Page 1, Appeal).

4.5 The HWE ICB was required to make a decision based on the information available to it at the time. When the Pharmaceutical Services Regulations Committee (PSRC) made the determination, it did not have the information now supplied on appeal by the Appellant (circa 210 pages). It is recognised that had this information been available to PSRC, a different determination may have been made.

4.6 We note that NHS Resolution will have regard to all information provided to date including the additional information submitted by the Appellant as part of this appeal."

5 Late Observations on representations

Rushport Advisory LLP on behalf of the Applicant

5.1 "I act for Sigcare Limited in the above application and have been instructed to submit these comments for the attention of the Committee following the recent decisions issued in SHA/26376, SHA/26374 and SHA/26364 (the "Recent Decisions").

5.2 This letter and the update to the attached SOPs is not new evidence, rather it provides clarification to existing evidence that should be helpful to the Committee in determining my client's application.

5.3 The Recent Decisions were refusals of applications where the Applicant had used identical wording in their SOPs to the wording used in my client's application. The Recent Decisions refused the applications on two grounds which are dealt with in turn below.

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

5.5 In the Recent Decisions the Committee found as follows;

5.5.1 *The above extract at 5.21 raised some concerns for the Committee as it contradicted 5.20.1 and 5.20.2. The Committee noted SOP 31 states "As a Distance Selling pharmacy, we must provide uninterrupted service throughout the opening hours of the pharmacy. For this reason, the RP is not allowed to leave the premises in the same way as an RP at a non-Distance Selling pharmacy is allowed to (for up to 2 hours per day) unless another pharmacist is present". Whereas SOP 32 states "Monitor the time that the RP has been absent… If the absence exceeds 2 hours… The second pharmacist must assume the role of RP and the Superintendent Pharmacist should be contacted and informed that there is only one pharmacist on duty". SOP 31 suggested to the Committee that the Responsible Pharmacist must not leave the premises unless another pharmacist is present to assume that role. However, SOP 32 outlines what would happen in the event that the Responsible Pharmacist is absent. This suggested to the Committee that during a two hour period, a Responsible Pharmacist would not be present, meaning the Applicant would be unable to provide all essential services in line with the Regulations.*

5.6 The wording of the SOPs makes it clear that if the RP were to be away from the premises for more than 2 hours then the second pharmacist must sign in as the RP. In other words, whilst the RP might have left the premises, the second pharmacist was still on the premises and services would therefore have been uninterrupted. The SOPs correctly identified that a pharmacist must remain on the premises and that services must be uninterrupted. The Terms of Service make no reference to the RP being absent and instead refer to services being uninterrupted and this is exactly what happens when an RP is absent but a second pharmacist remains at the premises.

5.7 **Delivery of Cold Chain Medicines**

5.8 In the Recent Decisions the Committee found as follows;

5.8.1 *"…The Committee was concerned that the statement "Ensure that any deliveries for fridge items and CDs are taken out of storage when appropriate" indicated that the local delivery driver would be handling and delivering cold chain items. As the Committee must be satisfied that the Applicant had explained how drugs/appliances will be provided to the patient (including to ensure that the 'cold chain' is maintained), the Committee considered that the wording creates sufficient ambiguity as to the Applicant's intentions. The Committee noted that the Applicant had not provided any information on the process that would be followed for deliveries of cold chain items by its own driver."*

5.9 The Committee had previously acknowledged that

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

5.10 In addition to this the SOP "Cold Chain Delivery via Courier" stated (but it was not noted in the decision letters);

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

5.11 We submit that it is clear from the SOPs that Fridge Lines are to be delivered via courier. It is not appropriate to remove fridge lines from the fridge until they are to be handed to the courier. This is why the relevant SOP states the CD and fridge lines should only be removed from the fridge "when appropriate". This would apply if some items on a prescription were fridge lines and others were not.

5.12 **Clarification to SOPs**

5.13 The Committee is required to be satisfied on the balance of probabilities that the procedures used are safe and effective. Irrespective of our views on the approach adopted by the Committee in the Recent Decisions, we and the clients we act for must strive to ensure that there is no ambiguity in the evidence provided to the Committee. For this reason, we have updated the attached SOPs in order to ensure that there is no ambiguity about the procedures to be followed. These SOPs go beyond the requirements of the Terms of Service. We ask the Committee to note again that this is not new evidence and simply clarifies the position of our client on each of the points raised in the Recent Decisions.

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

6 Consideration

6.1 The Pharmacy Appeals Committee ("Committee") appointed by NHS Resolution had before it the papers considered by the Commissioner, together with a plan of the area showing existing pharmacies and doctors' surgeries and the location of the proposed pharmacy.

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

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

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

Regulation 31

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

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

(2) This paragraph applies where -

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

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

(ii) adjacent premises; and

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

6.6 The Committee noted that the Applicant had not provided any information in the application form on this point but the Committee noted that the wording of the application form only required the Applicant to include information in the relevant section if the proposed premises were adjacent to, or in close proximity to, another pharmacy or dispensing appliance contractor premises. The Committee considered it reasonable to determine that the lack of information in the application form on this point when read with the wording of the application form allowed it to be reasonably satisfied that the Applicant considered that the proposed premises were not adjacent to, or in close proximity to, another pharmacy or dispensing appliance contractor premises. The Commissioner in its decision report stated that "*there are no persons on the pharmaceutical list providing pharmaceutical services in the same or adjacent premises*" which the Committee noted had not been disputed by any party.

6.7 The Committee therefore determined that it was not required to refuse the application under the provisions of Regulation 31.

6.8 The Committee had regard to Regulation 24(1) which requires the following five conditions to be met:

(a) for the patient groups that are accustomed to accessing pharmaceutical services at the existing premises, the location of the new premises is not significantly less accessible;

(b) in the opinion of NHS England, granting the application would not result in a significant change to the arrangements that are in place for the provision of local pharmaceutical services or of pharmaceutical services other than those provided by a person on a dispensing doctor list—

(i) in any part of the area of HWB1, or

(ii) in a controlled locality of a neighbouring HWB, where that controlled locality is within 1.6 kilometres of the premises to which the applicant is seeking to relocate;

(c) NHS England is not of the opinion that granting the application would cause significant detriment to proper planning in respect of the provision of pharmaceutical services in the area of HWB1;

(d) the services the applicant undertakes to provide at the new premises are the same as the services the applicant has been providing at the existing premises (whether or not, in the case of enhanced services, NHS England chooses to commission them); and

(e) the provision of pharmaceutical services will not be interrupted (except for such period as NHS England may for good cause allow).

Regulation 24(1)(a)

6.9 In relation to 'distance-selling' of essential services, the Committee considered that no issues arose as no such services are being accessed at the existing premises.

6.10 In relation to those accessing Advanced services from the existing premises the Applicant stated *"The only patient group relevant to the test under regulation 24 is therefore made up of those who access the permitted Advanced services provided by my client. In considering this patient group we have considered all such services together as it serves no useful purpose to separate out these services given that access is identical for each."*

6.11 The Committee noted that there was no dispute regarding the Applicant's above definition of patient groups. The Committee agreed that carrying out separate considerations for these groups in accordance with the requirements of Regulation 24 would serve no useful purpose. The Committee was mindful though that it also has a duty to consider accessibility for the elderly and those with physical impairments who may access pharmaceutical services at the Applicant's existing pharmacy.

6.12 The Committee next considered whether the information provided by the Applicant to show that the proposed pharmacy site is not significantly less accessible for the patient groups that are accustomed to accessing pharmaceutical services at the existing premises. The Committee noted the Applicant's comment on appeal that the current and proposed locations are only 280 metres apart along normal roads and footpaths with street lighting, dropped and curbs. Access by car was said by the Applicant to be slightly improved as the Applicant will have its own dedicated parking spaces. With regard to public transport the Committee noted the Applicant's uncontested comments that it does not see any patients who access its pharmacy using public transport other than those who work at the industrial estate and travel to and from work using public transport. According to the Applicant, access for such patients would barely change whether they were travelling from Watford Junction (approximately 1 mile walk) or the nearest bus stops on Radlett Road / Raphael Drive (approximately 700 metres from both current and proposed premises.)

6.13 The Committee was able to be satisfied that, for patient groups who are accustomed to accessing the present site, the proposed site is not significantly less accessible.

6.14 The Committee was therefore of the view that condition (a) is met.

Regulation 24(1)(b)

6.15 The Committee noted the decision of the Commissioner in respect of condition (b), that the granting of this application would not result in a significant change to the arrangements that are in place, and that this had not been disputed by any party. On the information provided the Committee was of the opinion that the granting of the application would not result in a significant change to the arrangements in place for the provision of local pharmaceutical services or of pharmaceutical services in any part of the area of HWB or in a controlled locality of a neighbouring HWB, where that controlled

locality is within 1.6 kilometres of the premises to which the applicant is seeking to relocate. The Committee concluded that condition (b) is met.

Regulation 24(1)(c)

6.16 The Committee noted the decision of the Commissioner in respect of condition (c) that the granting of the relocation would not lead to significant detriment to proper planning in respect of the pharmaceutical services in the area. The Committee noted that this had not been disputed by any party either on appeal or in subsequent representations. On the information provided the Committee was of the opinion that the granting of the application would not cause a significant detriment to the proper planning in respect of the provision of pharmaceutical services in the area of HWB1 and therefore concluded that condition (c) is met.

Regulation 24(1)(d)

6.17 The Committee noted that the Applicant had given an undertaking, in their original application form, that the same services will be provided at the proposed site. On the information provided, the Committee determined that condition (d) is met.

Regulation 24(1)(e)

6.18 In relation to condition (e), the Committee noted the Applicant had confirmed in their application, and subsequent representations, that there will be no interruption to service provision. On the information provided the Committee determined that condition (e) is met.

Regulation 24(3)(d)

6.19 The Committee noted that the application is for the relocation of a distance selling pharmacy.

6.20 The Committee therefore needed to have regard to Regulation 24(3)(d) which states:

(3) An application pursuant to this regulation must be refused if the existing pharmacy premises from which the applicant is seeking to relocate (P3)—

(d) are distance selling premises, unless—

(i) the premises to which the applicant is seeking to relocate are also distance selling premises, and

(ii) if the application was one to which regulation 25(1) applied, it would not be refused pursuant to regulation 25(2).

6.21 In relation to Regulation 24(3)(d)(i), the Committee was satisfied that Applicant's current premises and the premises to which the Applicant is seeking to relocate are both distance selling premises.

6.22 In relation to Regulation 24(3)(d)(ii), the Committee had regard to Regulation 25, which states:

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

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

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

6.23 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 the NHSCB may need to make of the information or documentation when carrying out its functions.

Regulation 25(1)

6.24 In relation to Regulation 25(1), the Applicant is applying for inclusion in the relevant pharmaceutical list as 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, and paragraph (1)(b) 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)

6.25 As far as Regulation 25(2)(a) is concerned, the Committee noted that the Applicant had not included any information in the relevant section of the application form that deals with this point. The Committee noted that the application form states that the relevant section should only be completed if the proposed premises are on the same site or in the same building as the premises of a provider of primary medical services with a patient list. The Committee considered that, where the Applicant did not include any information in this section, it was reasonable to consider that the Applicant was indicating that the proposed premises were not on the same site or in the same building as the premises of a provider of primary medical services with a patient list. The Commissioner in its decision report also stated *"The Committee noted that the proposed premises are not on the same site or in the same building as the premises of a provider of primary medical services with a patient list. There were no grounds to refuse the application by virtue of this regulation."* Based on the information available to it, the Committee therefore determined that the proposed premises were not on the same site as, or in the same building as the premises of a provider of primary medical services with a patient list.

Regulation 25(2)(b)

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

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

6.28 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.

6.29 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.

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

6.31 The Committee noted in the SOPs provided by the Applicant that SOP 1 'Introduction and Background to SOPs' point 1.3 states that the pharmacy must provide: *"The uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services."* Also; *"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 owner of this pharmacy or any member of staff either on or in the vicinity of the premises."

6.32 Further, SOP 3 'Procedures for NHS Essential Services' states: "*NHS Essential Services will be provided to any patient living in England who requests such services, this is made clear on the website and in the Practice leaflet*. *Patients who wish to send paper prescriptions to the pharmacy by post should be sent stamped addressed envelopes to enable them to do so*."

6.33 In its SOP 31 'The Responsible Pharmacist' point 31.9, the Applicant states: "*As a Distance Selling pharmacy, we must provide uninterrupted service throughout the opening hours of the pharmacy. Whilst the GPhC permits the absence of the RP from the pharmacy in particular situations, the NHS Terms of Service still require a pharmacist to be present so that services are not interrupted."* [emphasis in SOPs].

6.34 SOP 31 goes on to state*: "If, for any reason, the RP wishes to leave the premises or wishes to take a break then the second pharmacist must sign in as the RP and arrangements must be made for this prior to one RP leaving the premises and another RP signing in."*

6.35 The Committee noted the revised wording of the SOPs as provided by the Applicant with regard to the absence of the Responsible Pharmacist as well as confirmation from the Applicant's representative that a second pharmacist would be present at the pharmacy and therefore there would be no interruption of services.

6.36 Based on the revised information before it, including the updated SOPs, the Committee was satisfied that the provision of services would be without interruption.

6.37 The Committee went on to consider whether services would be available to persons anywhere in England and without face to face contact.

6.38 The Committee noted that throughout the SOPs the Applicant states that essential services will be provided without face to face contact between any patient and the pharmacy staff. SOP 1 'Introduction and Background to SOPs' point 1.3 states: "*All staff must be made aware that face to face contact between patients (or their representatives) is prohibited in respect of any and all Essential Services either on or in the vicinity of the premises*.

6.39 *Face to face contact with patients or their representatives either at the premises is* ***only*** [Applicants emphasis*] allowed in respect of the provision of services other than Essential Services.*

6.40 *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*."

6.41 The Committee noted, as per SOP 3 'Procedures for NHS Essential Services', that patients would be able to utilise multiple methods to contact the pharmacy that did not result in face to face communication. The SOP, under the heading 'Communication Channels' point 3.1 states: *"All communication regarding NHS Essential Services should be carried out using the most suitable non face to face method for the patient and the service being provided with particular consideration to maintaining confidentiality. This may be telephone, email, video-conferencing or other types of non-face to face communications such as text messages.*

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

6.43 The Committee considered the information provided in the SOPs, alongside the information submitted with the application, were sufficient to provide assurance that the Applicant, if granted, would be offering pharmaceutical services without face to face contact.

6.44 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.

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

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

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

Dispensing of drugs and appliances

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

6.49 From the information contained in the SOPs provided by the Applicant, SOP 3 'Procedures for NHS Essential Services' in the first paragraph states: *"Patients who wish to send paper prescriptions to the pharmacy by post should be sent stamped addressed envelopes to enable them to do so."*

6.50 SOP 6 'Online Order Receipt & Exemption Checking', point 6.2 under the heading 'Scope' states:

6.50.1 *"… Requests to collect and dispense NHS Prescriptions.*

6.50.2 *Requests to dispense a prescription received in the post.*

6.50.3 *Any requests from the "contact us" section of the website."*

6.51 The Committee had regard to SOP 17 'Order Delivery' which under the heading 'Choice of Delivery Method' at point 17.6 states: *"For items **other than** cold chain / "fridge line" items, local deliveries (up to 30 miles radius, but may be extended at the discretion of the RP) the delivery driver should deliver medication. Outside this area Royal Mail should be used unless the prescription is for a controlled drug, in which case the nominated controlled drugs courier should be used (see SOP for Delivery of Controlled Drugs), or the items are fridge lines, in which case the cold chain courier must be used."*

6.52 The Committee was satisfied that the Applicant was proposing to offer the service to all of England, as per the information contained in the SOPs, and was of the view that the Applicant would not be just serving the immediate locality using a local delivery driver.

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

Urgent supply without a prescription

6.54 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.

6.55 The Committee had regard to SOP 14 "Emergency Supply and Urgent Supply" which describes how the Applicant will process such a request. The Committee noted that the SOPs refer to Essential Services being delivered by several methods of non face-to-face communication including telephone and email, and considered that it was reasonable to infer that these methods would be used to receive requests from prescribers for the urgent supply of drugs.

6.56 SOP 14 under the heading 'Delivery of Urgent and Emergency Supply Items' also states:

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

6.57 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

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

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

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

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

6.62 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.

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

6.64 The Committee noted SOP 6 under the heading 'Paid NHS Prescription' states:

6.64.1 *"Check the prescription to confirm how many charges are due.*

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

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

6.64.4 *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."*

6.65 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

6.66 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).

6.67 The Committee noted that SOP 17 'Order Delivery' under the heading 'Transfer to the Delivery Driver' at point 17.10 states:

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

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

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

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

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

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

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

6.67.8 *At hand-over to the driver / courier ensure that any current falsified medicines regulation or guidance is followed."*

6.68 Further SOP 17 at point 17.14, under the heading 'Delivery of a prescription via Royal Mail (Not for cold chain or CDs) states:

6.68.1 *"Follow preparation for delivery process. The pharmacist should contact any patients for whom there are relevant messages or counselling required.*

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

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

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

6.68.5 *Confirm details of all prescriptions to be delivered.*

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

6.68.7 *Ensure Royal Mail driver signs Delivery Log sheet for all prescriptions being accepted for delivery. Store Delivery Log sheet for a minimum of 3 months from dispatch date.*

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

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

6.69 The Committee noted that the SOP then, under the heading 'Cold chain delivery via courier', at point 17.16 states:

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

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

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

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

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

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

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

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

6.69.9 *Confirm details of all prescriptions to be delivered.*

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

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

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

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

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

6.69.15 *Give all fridge line deliveries to the courier.*

6.69.16 *Store Delivery Log sheet for a minimum of 3 months from dispatch date.*

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

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

6.70 The Committee noted SOP 17.7 under the heading '*Unsuccessful cold chain delivery via courier'* states:

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

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

6.71 The Committee noted SOP 17.18 under the heading 'Breach of Integrity of Cold Chain' states:

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

6.71.2 *The cold chain service is a dedicated, fully monitored and temperature controlled delivery service. However, in the event of any breach in the integrity of this service, the system automatically alerts the delivery driver that the cold chain has not been kept intact.*

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

6.72 The Committee noted that SOP 21 'Controlled Drugs: Delivery' under the heading 'Delivery of Schedule 2 & 3 CDs' at point 21.5 states:

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

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

6.72.3 *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.*

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

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

6.72.6 *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.*

6.72.7 *Any falsified medicines rules introduced by the UK must be followed.*

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

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

6.73 The Committee noted SOP 21.6 under the heading 'Successful Schedule 2 & 3 Delivery' states*:*

6.73.1 *"The delivery driver/courier must check the identity of the person accepting the delivery to ensure that it is the patient or authorised representative. A delivery cannot be left with anyone who is not the patient or authorised representative.*

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

6.74 The Committee noted SOP 21.7 under the heading 'Unsuccessful Schedule 2 & 3 Delivery via pharmacy driver' states:

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

6.75 The Committee noted SOP 21.8 under the heading 'Unsuccessful Schedule 2 & 3 Delivery via courier' states:

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

6.77 *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. …*

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

6.79 The Committee noted the comments from the Applicant's representative in subsequent observations with regard to the delivery of cold chain and that they had reiterated that all cold chain items would be delivered by a specialist courier thereby ensuring that the integrity is maintained both up to the point of the item being transferred to the courier all the way up to the receipt of the medication by the patient. The Committee was of the view that the additional information from the Applicant's representative clarified the position with regard to the delivery of cold chain items by specialist courier only.

6.80 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.

6.81 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.

6.82 The Committee noted that the Applicant did not intend to provide appliances having left its application form blank on this point. In the event that the application is granted, the Applicant would not therefore, be able to provide appliances to patients.

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

6.84 The Committee noted that SOP 16 'Bagging Up' under the heading 'Choice of Packaging' at point 16.7 states:

6.84.1 *"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.*

6.84.2 *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.*

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

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

6.84.5 *For postal items, either:*

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

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

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

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

6.85 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

6.86 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.

6.87 The Committee noted that SOP 32 'Repeat Dispensing' states under the heading 'Pharmaceutical & Legal Assessment' at point 32.11:

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

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

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

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

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

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

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

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

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

6.88 The Committee further noted SOP 32 under the heading 'Prescription Reception' at point 32.10 states:

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

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

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

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

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

6.89 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

6.90 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.

6.91 The Committee noted SOP 32 'Repeat Dispensing' under the heading 'Prescription Reception' at point 32.10 states:

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

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

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

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

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

6.92 Further, the Committee noted SOP 32 goes on under 'Pharmaceutical and Legal Assessment' at point 32.11 to states:

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

6.94 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

6.95 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.

6.96 For the return of controlled drugs, the Committee noted that in SOP 22 'Controlled Drugs: Collection and Disposal of Patient Returns', particularly under the heading 'Patient Returned Medication', at point 22.5 states:

6.96.1 "*This service is available to <u>all</u> [Applicants emphasis] patients living in England.*

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

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

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

6.96.5 *The process for returning medication should be explained to the patient.*

6.96.6 *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…"*

6.97 The Committee notes that SOP 22 goes on under the heading 'Return by Royal Mail' to state at point 22.7:

6.97.1 *"The pharmacist must*:

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

6.97.1.2 *Assess the items for suitability for return by Royal Mail*

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

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

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

6.97.4 *Contact the patient to ensure that the packaging has been received*

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

6.98 The Committee noted that SOP 22 under the heading 'Handling Patient-Returned CDs from Delivery Driver' states at point 22.8:

6.99 *"Drivers need to*:

6.99.1 *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*.

6.99.2 *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.*"

6.100 The Committee noted that SOP 23 'The Safe and Effective Receipt and Disposal of Medicines' under the heading 'Process for Patients to Return Medication' at point 23.6 states:

6.100.1 *"Patient Returned Medication*

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

6.100.3 This service is available to all patients living in England.

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

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

6.100.6 *Patients may*

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

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

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

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

6.101 The Committee noted that SOP 23 goes on under the heading 'Process for accepting patient returns by the Driver' at point 23.7 to state:

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

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

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

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

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

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

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

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

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

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

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

6.102 The Committee noted SOP 23 under 'Disposal of returned medicines' at point 23.10, states:

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

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

6.103 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

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

6.105 The Committee noted that SOP 25 'Promotion of Healthy Living, Lifestyles & Health Campaigns' under the heading 'Health Campaigns and Community Engagement Exercise' states at point 25.4:

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

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

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

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

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

6.105.5.1 *a clinical audit carried out in a manner which is compatible with the NHSCB's* [sic] *arrangements for the receiving and processing of data from the audit, or*

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

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

6.106 Further, in SOP 25, under the heading 'Identification of patients for promotion of healthy lifestyles' states at point 25.3):

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

6.107 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

6.108 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.

6.109 The Committee noted SOP 25 'Promotion of Healthy Living, Lifestyle & Health Campaigns' at point 25.3 under the heading 'Identification of patients for promotion of Healthy Lifestyles' states:

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

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

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

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

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

6.110 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

6.111 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.

6.112 The Committee noted that in SOP 25 'Promotion of Healthy Living, Lifestyle & Health Campaigns' under the heading 'Health Campaigns and Community Engagement Exercise', at point 25.4 states:

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

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

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

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

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

6.113 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

6.114 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.

6.115 The Committee noted that in SOP 24 'Support for Self-Care, Signposting and Health Promotion' under the heading 'Patient Identification' at point 24.13, states:

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

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

6.115.2.1*requires advice, treatment or support that we cannot provide; but we are aware of another provider of health services who is likely to be able to provide that advice, treatment or support.*

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

6.116 The Committee noted that in SOP 24 under the heading 'Other Provider Organisations and Support Details' at point 24.10 states:

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

6.117 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

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

6.119 The Committee noted the Applicant's SOP 24, point 24.9 the heading 'Service outline' states:

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

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

6.120 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

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

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

6.123 The Committee noted SOP 26 'Discharge Medicines Service ("DMS").

6.124 The Committee noted point 26.3 states:

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

6.125 The Committee noted point 26.5 states:

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

6.126 The Committee noted point 26.10 under the heading 'Additional Advice assistance and support' states:

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

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

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

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

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

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

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

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

6.126.1.8 *Discuss common or expected side effects*

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

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

6.126.1.11 *Inform the patient/carer*

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

6.126.1.13 Additional advice, assistance and support

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

6.126.1.15 Follow up

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

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

6.127 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

6.128 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.

6.129 The Committee noted SOP 24 'Support for Self-care, signposting and health promotion' states under the heading 'Health Promotion Zone on our website' at point 24.11:

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

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

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

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

6.130 The Committee also noted further mention of health promotion zones is made in SOP 25 'Promotion of Healthy Living, Lifestyle & Health Campaigns' under the heading 'Identification of patients for promotion of healthy lifestyles' at point 25.3 which states:

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

6.131 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.

6.132 On the information before it, the Committee could be satisfied that there are procedures likely to secure safe and effective provision of essential services as required by Regulation 25(2)(b).

6.133 The Committee therefore determined that it was not required to refuse the application under Regulation 24(3)(d).

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

6.134.1 confirm the Commissioner's decision;

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

6.134.3 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.

6.135 Based on the revised SOPs, the Committee has reached a different conclusion from the Commissioner regarding the application. In those circumstances the Committee determined that the decision of the Commissioner must be quashed.

6.136 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.

6.137 The Committee noted that representations on Regulation 24 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 24.

6.138 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 quashes the decision of the Commissioner and redetermines the application.

7.3 The Committee has determined that the conditions set out in Regulation 24(1) (a), (b), (c), (d) and (e) are satisfied.

7.4 The Committee has determined that it was not required to refuse the application under Regulation 24(3)(d) after considering the grounds set out in Regulation 25.

7.5 The application is granted.

Case Manager
Primary Care Appeals