NHS Resolution

27 February 2026

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REF: SHA/26785

APPEAL AGAINST LANCASHIRE AND SOUTH CUMBRIA ICB DECISION TO REFUSE AN APPLICATION BY MPHARMA1 LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT 141 ST JAMES STREET, BURNLEY, BB11 1PD UNDER REGULATION 25

1 Outcome

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

1.2 The Committee determined that the application should be granted.

A copy of this decision is being sent to:

MPharma 1 Ltd
PCSE, on behalf of Lancashire and South Cumbria ICB
Community Pharmacy Lancashire and South Cumbria

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1 The Application

By application dated 10 June 2025, MPharma1 Ltd ("the Applicant") applied to Lancashire and South Cumbria ICB ("the Commissioner") for inclusion in the pharmaceutical list at 141 St James Street, Burnley, BB11 1PD under Regulation 25. In support of the application it was stated:

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

1.2 "Drug Tariff part IX*

1.3 *EXCEPT items that require measuring or fitting."

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

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

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

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

Pharmacy procedures

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

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

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

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

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

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

1.12 "SEE ATTACHED INFORMATION"

1.13 [SOPs provided]

2 Comments to the Commissioner

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

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

2.1 "We acknowledge the 14-day letter dated 18 August 2025 inviting comments on representations. We respectfully submit this consolidated response to the objections received regarding the application for a Distance Selling Pharmacy (DSP) at 141 St James Street, Burnley, Lancashire, BB11 1PD by MPharma1 Ltd.

2.2 **Correct Legal Test**

2.3 We respectfully note that the correct legal test for the Committee is compliance with Regulation 25 and the conditions of Regulation 64 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013. General objections to DSPs, references to other contractors, or commentary on the wider DSP sector are not relevant to this application. Our SOPs provide evidence that MPharma1 Ltd meets the legal requirements in full.

2.4 **A. Community Pharmacy Lancashire & South Cumbria (CPLSC) – 14 August 2025**

2.5 Concerns raised include: superintendent oversight of more than one DSP, presence of many local pharmacies, alleged failure to demonstrate Regulation 25 compliance, adequacy of consultation space, cold-chain procedures, benefit of 40 core hours, security, and references to prior appeal refusals and the 2023 CCA report.

2.6 **Response:**

2.7 Superintendent role – It is lawful for a superintendent to oversee more than one pharmacy. Formal GPhC annotation occurs after NHS approval. If governance requires, the role can be reassigned. What matters is that SOPs and governance apply consistently. Our SOP 'Governance & Quality Assurance' provides assurance of continuity regardless of personnel.

2.8 Local density – The Regulations do not require demonstration of unmet need for DSPs. DSPs are expressly exempt from the pharmaceutical needs test. MPharma1 Ltd will operate nationally and not as a local face-to-face provider.

2.9 Regulation 25 compliance – Our SOP 'Communication Channels & Patient Contact' confirms no essential services will be delivered face-to-face. Our SOP 'Emergency Planning & Service Continuity' ensures uninterrupted access during declared hours. Our governance framework covers accuracy, clinical safety, safeguarding, and complaints handling.

2.10 Cold chain – Our SOP 'Safe Medicine Storage & Cold Chain Management' sets out validated packaging, temperature monitoring, courier SLAs, excursion protocols, and audit, ensuring no compromised item is dispensed.

2.11 Security – GPhC premises registration includes assessment of security. Our SOPs set out secure CD storage, CCTV, staff access and alarm procedures.

2.12 Opening hours – The 40 core hours comply with the Regulations and provide reliable access to patients nationally, including housebound and remote patients.

2.13 Prior appeals – These were cases-specific. Our SOPs address the cited concerns directly (non-face-to-face compliance, cold chain integrity, safe procedures).

2.14 We therefore respectfully submit that the concerns raised do not demonstrate non-compliance with Regulation 25 or 64.

2.15 **B. Boots UK Ltd – 10 July 2025**

2.16 Boots requested assurance that Regulation 25 and 64 will be complied with.

2.17 Response: We agree. Our SOPs 'Communication Channels & Patient Contact' and 'Governance & Quality Assurance' demonstrate full compliance, ensuring national non-face-to-face provision and robust audit.

2.18 **C. Cohens – 16 July 2025**

2.19 Cohens requested assurance that the application meets the requirements of Regulation 25 and the conditions of Regulation 64, specifically that the full range of NHS pharmacy services must be provided, services must not be supplied from a traditional “shop-front” with direct access for patients, the premises should be registered with the GPhC, there must be no Local Pharmaceutical Services (LPS) sites prohibiting the application, and the location must not be the same or adjacent premises to an existing pharmacy or GP practice. In response, MPharma1 Ltd confirms that the full range of NHS pharmacy services, including all essential services, will be provided, supported

by our SOP “Governance & Quality Assurance” which ensures compliance with NHS Terms of Service overseen by the superintendent. No essential services will be delivered face-to-face at or near the premises, with our SOP “Communication Channels & Patient Contact” setting out that all services will be delivered remotely via telephone, secure online systems, email, postal or courier. The premises will be registered with the GPhC before commencing services, and NHS listing cannot proceed without this approval, which includes security and compliance review. We confirm there are no LPS sites prohibiting this application, and the pharmacy site is not the same or adjacent to any existing pharmacy or GP practice, having been chosen to comply fully with DSP requirements. In conclusion, Cohens’ representation is noted, and we respectfully confirm that MPharma1 Ltd complies fully with Regulation 25 and Regulation 64, supported by our SOP framework.

2.20 **Peak Plus Pharma – 11 August 2025**

2.21 Peak Plus objected on the grounds that there is no local need, that a DSP risks fragmenting care, and that it may undermine local community pharmacies. DSPs are, however, exempt from the pharmaceutical needs test, and the correct legal test is compliance with Regulation 25 and 64. MPharma1 Ltd is designed as a national service and not to compete locally. Our SOP “Governance & Quality Assurance” ensures structured communication with prescribers and record-keeping for safe integration, while our SOP “Communication Channels & Patient Contact” ensures patients, including vulnerable patients, can reliably access support, with remote consultations available for medication reviews and clinical advice. MPharma1 Ltd does not intend to divert local footfall, and our model is national, with monitoring of prescription geography to avoid local concentration. We therefore respectfully submit that the Peak Plus concerns, while noted, do not demonstrate any non-compliance with the legal test.

2.22 **Appendix: Compliance with Regulation 25 and Regulation 64**

2.23 **Regulation 25 requires DSPs to:**

2.23.1 Provide essential services without face-to-face contact at or near the premises.

2.23.2 Be capable of providing services to anyone in England.

2.23.3 Ensure uninterrupted access during opening hours.

2.23.4 Maintain safe and effective procedures.

2.24 MPharma1 Ltd meets these through SOPs: 'Communication Channels & Patient Contact', 'Safe Medicine Storage & Cold Chain Management', 'Emergency Planning & Service Continuity', and 'Delivery & Distribution Services'.

2.25 Regulation 64 requires contractors to comply with Terms of Service and not to breach DSP requirements. Our SOP 'Governance & Quality Assurance' provides monitoring, audit, and superintendent oversight to ensure compliance.

2.26 **Closing Statement:**

2.27 MPharma1 Ltd complies fully with Regulation 25 and 64. Our SOPs provide robust, enforceable systems for safe, effective, national service provision. We respectfully request that our application be approved."

3 The Decision

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

3.1 "Lancashire and South Cumbria ICB has considered the above application and I am writing to confirm that it has been refused. Please see the enclosed report for the full reasoning.

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

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

Determination – Pharmaceutical Services Group

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

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

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

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

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

3.5 Using the NHS website, there are 13 other pharmacy contractors within 1 mile of the proposed premises. There are 13 GP practices currently listed within 1 mile of the proposed premises.

3.6 Using googlemaps, the proposed premises appears to be part of a row of shops retail units along a main road. Access to the proposed premises is at street level.

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

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

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

3.10 All representations were considered, including from the Applicant.

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

3.11.1 Boots

3.11.2 Cohens

3.11.3 Community Pharmacy Lancashire and South Cumbria (CPLSC)

3.11.4 Peak Plus Pharmacy

3.12 Outline of Representations

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

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

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

3.16 **CPLSC** notes that:

3.16.1 The named Superintendent is not listed as such on GPhC Register.

3.16.2 The floorplan should be considered with regards to security.

3.16.3 The applicant has failed to demonstrate compliance with regulations, especially uninterrupted service provision along with safe and effective provision.

3.16.4 The application does not sufficiently explain how essential services will be delivered in a manner that meets the requirements of Regulation 25(2)(b), particularly the obligation to avoid face-to-face contact at the pharmacy premises.

3.16.5 Given these deficiencies, CPLSC believes the application does not meet the regulatory standards and should therefore be refused.

3.16.6 Provides a summary of and a report from 2023 regarding DSPs and contractual obligations

3.17 In summary, **CPLSC** submits that the application lacks sufficient detail on how essential services will be delivered uninterruptedly and safely without face-to-face contact, as required under Regulation 25(2)(b).

3.18 **Peak Plus Pharmacy** objects to the application based on the potential to interrupt the existing provision/access to pharmaceutical services. There is no unmet need to justify this application, and its approval could negatively impact local healthcare provision.

3.19 In response to the representations from interested parties, the **Applicant** outlines their view of the correct legal test and accordingly disputes the relevance of some of the representations.

3.20 Further, the **Applicant** supports its submission with individual points covering, amongst others:

3.20.1 Regulation 25 Compliance

3.20.2 Superintendent role

3.20.3 Security

3.20.4 Cold Chain

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

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

3.21.2 It is observed that the SOPs provided are ‘generic’.

3.21.3 Premises floor plan does not indicate sufficient assurances for premises security.

3.21.4 SOPs are generic and provide few if any sufficient assurances for services provision. Closer to a list of what they should do.

3.21.5 Inadequate definition for cold chain arrangements.

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

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

3.22 Regulation 31

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

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

3.25 *"Distance selling premises applications*

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

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

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

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

3.27 *(2) The NHSCB* [sic] *must refuse an application to which paragraph (1) applies—*

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

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

3.29 *(b) unless the NHSCB* [sic] *is satisfied that the pharmacy procedures for the pharmacy premises are likely to secure—*

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

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

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

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

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

3.32 **Decision – REFUSED.**

3.33 Appeal Rights to the Applicant."

4 The Appeal

In an email dated 18 November 2025, the Applicant appealed against the Commissioner's decision. The grounds of appeal are:

4.1 "**We are writing on behalf of Mpharma1 Ltd to formally lodge an appeal against the decision of the Lancashire and South Cumbria Integrated Care Board (ICB) to refuse our application for a distance-selling pharmacy at 141 St James Street, Burnley (Ref: CAS-370858-R2K4X6). We kindly submit this appeal within the required 30-day period.**

4.2 Thank you for the opportunity to present our case. We have carefully reviewed the ICB's report and would like to outline the grounds for our appeal, which we hope will provide further clarity on our application.

4.3 Our appeal is based on the belief that our application did, in fact, meet the statutory requirements, and we would like to highlight a few key points for your consideration:

4.3.1 **Meeting the Statutory Test:** We note from the ICB's report that our application was found to satisfy all aspects of Regulation 25 except for 25(2)(b)(ii). We provided detailed procedures addressing security, the cold chain, and uninterrupted service delivery. While the ICB felt these were "generic," we believe they represent a robust framework that demonstrates how safe and effective services will be delivered, which is the core requirement of the regulations. We are committed to operationalising these plans fully and in compliance with all GPhC standards.

4.3.2 **Addressing Concerns Raised:** In our previous communications, we provided specific responses to the concerns raised during the consultation period, including the registration of our Superintendent Pharmacist and our operational model designed for distance-selling. We are confident that these responses adequately addressed the points raised and demonstrated our capability and preparedness.

4.3.3 **A Collaborative Spirit:** Our primary goal is to enhance pharmaceutical service provision. We want to assure you that we are fully committed to working collaboratively with the ICB to provide any additional information or reassurances required. We believe there may have been a gap between the evidence we supplied and the ICB's level of assurance, and we are eager to bridge that gap.

4.4 We truly believe that granting this application would allow us to provide a valuable and complementary service to patients. We are asking for the chance to demonstrate this.

4.5 We have attached the ICB's decision letter and report for your ease of reference. We are hopeful for a positive review and are ready to answer any further questions you may have.

4.6 Thank you for your time and consideration."

4.7 [Updated SOPs, additional supporting information, Business Continuity Plan and floor plan provided]

5 Summary of Representations

This is a summary of representations received on the appeal.

Representations were also sought from the Applicant on the amendments to Regulation 25 as the Commissioner considered the application against the previous regulatory test.

5.1 The Applicant

5.1.1 "We acknowledge receipt of your correspondence and note the amendments to Regulation 25 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, which came into force on 23 June 2025.

5.1.2 We have carefully reviewed the requirements of the amended Regulation 25(2)(b), as detailed in your letter. We confirm that the documentation previously submitted as part of our appeal, dated 18 November 2025 (a copy of which you kindly enclosed with your letter), comprehensively addresses the criteria established by the new test.

5.1.3 Specifically, our submitted documents and comments provide full details and assurances regarding:

5.1.3.1 The uninterrupted provision of essential services during the opening hours of the premises to persons anywhere in England who request those services. Our operational plan, standard operating procedures, and IT infrastructure details within the appeal submission demonstrate our robust capability to meet this requirement.

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

appeal documentation includes explicit protocols for remote consultations, secure prescription handling, safe dispensing processes, and delivery logistics, all designed to ensure safety and efficacy without the need for physical contact at 141 St James Street.

5.1.4 Please do not hesitate to contact us if you require any clarification regarding the contents of our original appeal submission."

Letters attached to email

5.1.5 "Please find enclosed our comprehensive response to your letter dated 26 November 2025 regarding the above Distance Selling Pharmacy application and the amendments to Regulation 25 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, which came into effect on 23 June 2025.

5.1.6 The enclosed documents demonstrate how MPharma1 Ltd satisfies the amended Regulation 25(2)(b), including the uninterrupted provision of essential services to persons anywhere in England and the safe and effective provision of pharmaceutical services without face-to-face contact at the pharmacy premises.

5.1.7 The submission includes:

5.1.7.1 Regulation 25 Compliance Statement (detailed response to amended Regulation 25(2)(b)

5.1.7.2 Updated Business Continuity Plan (BCP) for the Distance Selling Pharmacy.

5.1.7.3 Enhanced Distance Selling Pharmacy Essential Services Model SOP (v1.1).

5.1.7.4 Premises Layout and Access Statement confirming no face-to-face access at the premises.

5.1.7.5 Regulation 25 Mapping Document showing where each requirement is met within our SOPs and governance framework.

5.1.8 We trust that this information provides the clarity and assurance requested. We remain available to provide any further detail or clarification that the Appeals Panel may require."

5.1.9 "Thank you for your correspondence dated 26 November 2025, advising that the Commissioner considered our application under the previous Regulation 25 wording and requesting comments following the 23 June 2025 amendments.

5.1.10 We welcome this opportunity to present a detailed response. This letter demonstrates, with clear evidence and reference to our DSP Essential Services SOP V2, that MPharma1 Ltd fully satisfies the amended Regulation 25(2)(b):

5.1.10.1 25(2)(b)(i): The uninterrupted provision of essential services to persons anywhere in England

5.1.10.2 25(2)(b)(ii): The safe and effective provision of pharmaceutical services without face-to-face contact at the pharmacy premises

5.1.11 Our business model, premises design, governance framework, remote operating systems and SOPs collectively ensure compliance with the new legal test.

5.1.12 B. Cold Chain Safety – Clarification and Assurance

5.1.13 We appreciate the Commissioner's commitment to ensuring the safe and effective provision of medicines.

5.1.14 To support this expectation, we wish to clarify that cold chain management is fully addressed within our operational SOPs, and the processes we have in place meet and exceed accepted professional standards.

5.1.15 Our cold-chain system includes:

5.1.15.1 Medical-grade refrigeration with continuous temperature monitoring

5.1.15.2 Automated alerts for deviation from validated temperature ranges

5.1.15.3 Documented daily checks overseen by the Responsible Pharmacist

5.1.15.4 Validated insulated packaging designed for safe transit across England

5.1.15.5 Trackable courier services trained in handling temperature-sensitive medicines

5.1.15.6 Time-controlled dispatch procedures

5.1.15.7 Delivery contingency arrangements including backup couriers

5.1.16 Any item that may not have remained within the required temperature range is immediately quarantined, and the patient is contacted for a safe replacement.

5.1.17 A. Security of Premises – Clarification of Regulatory Responsibilities

5.1.18 We respectfully acknowledge the Commissioner's interest in ensuring that premises used for the dispensing and supply of medicines are appropriately secure.

5.1.19 For clarity, premises security is a regulatory function overseen by the General Pharmaceutical Council (GPhC). Before any pharmacy may begin operating, it must undergo a GPhC inspection assessing:

5.1.19.1 Physical security and controlled access

5.1.19.2 Safe installation of the Controlled Drug cabinet

5.1.19.3 CCTV compliance

5.1.19.4 Segregation of public and private areas

5.1.19.5 Suitability of the premises for pharmacy activity

5.1.20 Once all criteria are met, the GPhC issues a premises registration number, which must be provided to the Commissioner as part of the Notice of Commencement.

5.1.21 We fully comply with the GPhC's requirements and will meet all security standards before commencing service.

5.1.22 We trust this clarification is helpful and demonstrates that MPharma1 Ltd will fully satisfy all regulatory requirements."

5.1.23 [Supporting documents provided]

6 Unsolicited comments

6.1 Community Pharmacy Lancashire and South Cumbria

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

Letter to the Commissioner dated 12 July 2025

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

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

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

6.1.5 ***The 2023 CCA Report on the Impact of "pseudo" distance selling pharmacies***

6.1.6 ***Concluded with evidence that the majority of DSP (Distance Selling Pharmacies) are operating in breach of their NHS Contracts***

putting brick and mortar pharmacies and therefore local care at risk.

6.1.7 **"Failure to regulate rogue businesses is leading to pharmacy closures."**

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

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

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

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

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

6.1.13 There are thirteen other pharmacies within 1 mile of the pharmacy (NHS Services Website).

6.1.14 We note the provision of a wholly generic standard set of SOP's.

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

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

6.1.17 There is no lack of DSP pharmacies already operating in Lancashire and South Cumbria.

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

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

7 Summary of Observations

No observations were received by NHS Resolution in response to the representations received on appeal.

8 Consideration

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

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

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

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

Regulation 31

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

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

(2) This paragraph applies where -

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

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

(ii) adjacent premises; and

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

8.6 The Committee noted that the Applicant had stated "*Not applicable as no other pharmacy in same or adjacent premises*" and that the Commissioner had determined that "*Regulation 31 does not apply, as the applicant is not undertaking to provide pharmaceutical services from the same or adjacent premises to existing services they provide.*" Given that there was no dispute on the matter, the Committee determined that it was not required to refuse the application under the provisions of Regulation 31.

Regulation 25

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

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

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

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

in respect of pharmacy premises that are distance selling premises.

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

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

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

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

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

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

Additional information to be included with excepted applications

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

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

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

Nature of details to be supplied

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

Regulation 25(1)

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

Regulation 25(2)(a)

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

Regulation 25(2)(b)

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

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

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

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

8.15 It is not for the Committee to 'approve' or 'disapprove' of these SOPs (as they may contain matters not relevant to the Committee's consideration, and there are many ways an applicant can choose to organise itself in order to comply with the various requirements of the Regulations) and the Committee has not sought to do so. The Committee has sought evidence within the 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.

8.16 With regard to uninterrupted provision, the Committee noted that the information provided with the appeal states:

8.16.1 "*A Responsible Pharmacist is present and in charge with pharmacy staff during the core opening hours of the premises to ensure there is uninterrupted provision of essential services to patients who live anywhere in England who require and request the essential services. If and when required, more staff will be hired to aid the Responsible Pharmacist in his/her role of uninterrupted provision. Uninterrupted NHS Essential Services will be provided by the Pharmacist and qualified, knowledgeable, experienced support staff on duty throughout the opening hours of the pharmacy premises without having 'face to face' contact with the patient or their representative.*"

8.17 The Committee further noted the SOP for Responsible Pharmacist states:

8.17.1 "*5.* ***Ceasing the duties of the RP***

You must cease to be the RP if:

The role of RP is to be assumed immediately by another pharmacist,

It is the close of trading at the end of the day,

You are no longer able to continue your duties (e.g. sickness).

6. ***Sign off and take down your notice.***

Remove or amend the RP notice on display when you cease to act as RP that day. Sign off as responsible pharmacist on PMR, or make an entry in the record book recording the time (using the 24-hour clock) that you ceased to be the RP.

7. ***Create handover notes if necessary.***

Communicate any necessary handover notes, instructions or information via the communications book or in-person if another pharmacist is assuming the role of RP immediately. Leave contact details in the communications book for the next RP in case contact is required to resolve any outstanding issues.

8. ***Changeover of the RP***

The RP taking over from the previous RP needs to follow 'Assuming duties of the RP' as set out above. To maintain continuity, a second pharmacist will be available during all operating hours. If the RP needs to leave or take a break under the Working Time Directive, the second pharmacist must sign in as the RP"

8.18 Based on the information before it, the Committee was therefore satisfied that the provision of essential services would be without interruption.

8.19 The Committee next considered whether the provision of essential services would be available to persons anywhere in England and noted that the information provided with the appeal states "*Patients in England will be able to register receive* [sic] *NHS Essential Services via the website or by contacting the pharmacy via email, telephone, postal services, or social media.*"

8.20 Further, the SOP for Provision of Essential, Advanced and Enhanced Services without face to face contact states:

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

Telephone, including text messaging where appropriate

Live Video Call

Website inbox (through contact us)

Real-time chat box on website

Email

Electronic Prescription Service (EPS)

Royal Mail postal service

Courier service

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

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

8.22 The Committee next considered how the Applicant would provide pharmaceutical services without face to face contact. The Committee noted that in its decision report the Commissioner had expressed concern regarding the security of the premises.

8.23 The Committee noted again that the SOPs refer to communicating with patients by telephone, video call, website, email and post. The Committee also noted the following information in the SOP for Provision of Essential, Advanced and Enhanced Services without face to face contact:

8.23.1 "*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, Advanced and Enhanced Services either on or in the vicinity of the premises.*

Where any SOP could be considered to imply that face-to-face contact with a patient or their representative may take place either on or in the vicinity of the premises, then this should be immediately referred to the Responsible Pharmacist (RP) before any further action is taken.

The premises operate exclusively as a distance-selling pharmacy and are not open for public walk-in access, in strict compliance with all relevant NHS and GPhC regulatory requirements.

Access to the pharmacy premises is strictly controlled, only authorised pharmacy personnel are permitted entry, using secure access systems, including locks, key codes, and physical keys. These access controls ensure the security of the premises, the safety of pharmacy stock, and the confidentiality of patient data.

The premises have been fully converted, refurbished, and secured to meet all the regulatory standards required for a registered pharmacy, including appropriate security, storage, environmental controls, and standard operating procedures. The street-level window is fully blacked out and clear signage indicates that the premises are not open to the public, preventing any misunderstanding or inadvertent entry.

As a Distance Selling Pharmacy, all NHS pharmaceutical services are provided remotely without face-to-face contact. There is no facility for patient attendance, walk-in services, or collection of medication at the premises, and the internal layout contains no retail areas, counters, or features that could imply public services are available. All dispensing, clinical checks, and patient consultations are conducted remotely, and all medicines are delivered to patients via secure, approved delivery services.

Pharmacy premise will operate with an intercom system, a patient will not be able to attend the premises directly. The pharmacy staff will be trained not to provide NHS essential services face to face. In the unlikely event that a patient does attempt to contact the pharmacy via the intercom system to request one or more services, it will be explained that due to our Distance Selling Regulations we are unable to provide face-to-face NHS Directed Services. It will also be explained to the patient that essential services are provided remotely by the pharmacy. Details how to access the essential services remotely will be provided to the patients. The patient will be signposted to other pharmacies who provide NHS services within the area. Staff training will be reviewed once a year or sooner if an incident arise.

It is also noted that the Department of Health & Social Care has confirmed that from October 2025, DSP will not be able to deliver advanced and enhanced services to persons present or in the vicinity

of the distance selling premises; such services must be provided remotely in line with the delivery of essential services.

In line with the service specifications, the pharmacy will only offer Advanced and Enhanced services that can be delivered remotely, without requiring patients to attend the premises.

There are various methods to inform general public that pharmacy cannot provide face-to-face essential services within the premises:

Notice on Premises

Notice on Website

Post on Social Media

Pharmacy leaflet and fryers

Alarm system is installed and connected to a monitoring service which would be triggered by unauthorised access attempts, break-ins or fire alarms. Surveillance cameras are installed at strategic locations both inside and outside the pharmacy to deter potential intruders and in operation at all times. Doors and windows are equipped with secure locks to prevent forced entry. All pharmacy staff are trained on security protocols, emphasising the importance of not sharing access codes or keys or forbes [sic] *and being vigilant about identifying and reporting suspicious activity. Any incidents involving attempted public access are formally recorded and investigated as part of our clinical governance processes, and routine security audits and risk assessments are undertaken to ensure ongoing improvements in the safety and security of the pharmacy*."

8.24 The Committee was mindful of the regulatory changes as of 1 October 2025, that distance selling pharmacies can no longer provide Directed services (Advanced, National Enhanced and Enhanced Services, with the exception of Covid-19 and Flu vaccination services) face-to-face with the patient at the pharmacy premises. As a result of this amendment, the Committee noted that the Applicant would not be able to provide any pharmaceutical services at its premises.

8.25 In its application the Applicant stated that it intended to provide "*NMS (remotely with consent where required)*".

8.26 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.

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

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

Dispensing of drugs and appliances

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

8.30 The Committee noted the SOP for Dispensing of Prescriptions states:

8.30.1 "*1. Receipt of prescription*

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

8.31 The Committee noted the information provided with the appeal states:

8.31.1 "***Delivery***

To ensure the safe and appropriate delivery of medicines, local deliveries will be handled by pharmacy own delivery driver. If our delivery driver is unavailable for their shift, we will utilise City Sprint as a backup to ensure uninterrupted delivery services. Nationwide deliveries will be sent via recorded delivery from Royal Mail, requiring a signature from the patient, their notified carer, or an authorised representative."

8.32 The Committee noted the information also refers to cold chain deliveries "*via a specialist medical cold chain courier service*" and also states "*Delivery of controlled drugs in local area will be managed by pharmacy delivery driver, otherwise will be handled by DHL…*"

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

Urgent supply without a prescription

8.34 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.

8.35 The Committee noted the SOP for Emergency Supply at the Request of a Patient (including 'Part II – SUPPLY OF EMERGENCY MEDICATION AT THE REQUEST OF A PRESCRIBER') which describes how the Applicant will process such a request. The Committee noted that the SOPs refer to pharmaceutical services being delivered by several means of non-face-to-face communication including telephone and email, and considered that it was reasonable to infer that these methods would be used to receive requests from prescribers for the urgent supply of drugs.

8.36 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

8.37 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.

8.38 The Committee noted the SOP for Checking NHS Exemptions Ensuring No Patient Contact states:

8.38.1 "*2. **Electronic checking**.*

In accordance with regulation 3(1) or (1A) of the Charges Regulations(1), before providing any drugs or fulfilling a prescription form or a repeatable prescription, our Responsible Pharmacist will determine whether any person who makes a declaration that the person named on the prescription form or the repeatable prescription does not have to pay the charges specified.

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

***under 16, over 60** - our system checks the patients date of birth (D.O.B.) in accordance with their ID verification. aged 16 to 18 and in full-time education - our system verifies D.O.B. alongside a patient declaration of full-time education attendance.*

*in possession of a **Prescription prepayment certificate (PPC)** - patients are asked to upload a photo of their prepayment certificate our system checks and confirm it.*

***income support**, **income-based Jobseeker's Allowance**, income-related Employment and Support Allowance, Pension Credit Guarantee Credit, Universal Credit, NHS certificate for partial help with health costs (HC3) valid NHS tax credit exemption certificate - our system checks the patients D.O.B. in accordance with their ID verification. are pregnant or have had a baby in the previous 12 months and have a valid maternity exemption certificate (MatEx) - our system checks D.O.B for gender and child bearing age*

*hold a valid **war pension exemption certificate** and the prescription is for your accepted disability - our system checks D.O.B.*

*have a specified **medical condition** and have a valid medical exemption certificate (MedEx), or have a continuing physical disability that prevents you going out without help from another person and have a valid medical exemption certificate (MedEx) – our system checks the medicine on the prescription against the exempted condition.*"

8.39 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.

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

8.41 The Committee noted the SOP for Taking an NHS Prescription Charge states:

8.41.1 "***2. Taking an NHS prescription charge remotely.***

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

3. NHS charge discrepancies.

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."

8.42 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

8.43 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).

8.44 The Committee noted the SOP for The Delivery of Medicines states:

8.44.1 "*5.* ***Driver arrival.***

When the driver arrives, confirm with patient/representative for their name and address, check the label on the bag against the prescription, branch record sheet and book. File prescriptions. Cold chain medications will be separated from local delivery and to be done via courier. Check and tick against the branch record sheet label when transferring items to the delivery driver. The driver signs and dates the

branch record sheet at this stage to confirm the pickup. Ask the patient or representative to sign their details on the delivery sheet.

6. ***Controlled drugs delivery.***

If a CD is included, phone the patient beforehand to confirm they are in. The driver should sign the blue box on the back of the script and write 'delivery' to complete the audit trail. The driver's name and 'delivery' is written in the CD register as the person collecting the medication. If delivery is unsuccessful, the CD is returned to the pharmacy, booked back into the CD register and signed out again on retry.

7. ***Driver departure.***

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

IF THE PATIENT IS IN:

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

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

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

4. The driver should not offer medical advice unless qualified to do so. If the patient has a query about their delivered medication, the driver can provide the telephone number of the pharmacy (which is printed on all medication labels) and ask the patient to phone the pharmacy for advice. If the driver is asked to give written advice to a patient in the form of a note or letter from the pharmacy, then the pharmacy should phone the patient after delivery to ensure the note has been received and understood. Medicines should be kept securely in the vehicle, and doors and windows are closed/locked at all times. The medication should be kept out of sight, e.g. in the boot.

IF THE PATIENT IS OUT:

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

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

DO NOT- Leave the delivery items.

unattended in porches or on doorsteps

with children

neighbours - Unless arrangements have been made by the patient/carer …

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

The pharmacist should contact patients before delivery to confirm dispatch and provide any necessary counseling. [sic]

Ensure that the RP is available to oversee the handover of all items for delivery.

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

Clearly print a return address on the outer packaging.

Verify the details of all prescriptions to be delivered.

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

Ensure the Royal Mail driver signs the Delivery Log sheet for all prescriptions accepted for delivery. Retain the Delivery Log sheet for at least 3 months from the dispatch date.

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

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

Unsuccessful Delivery via Royal Mail

If a delivery attempt is unsuccessful, Royal Mail will leave a 'Sorry We Missed You' card, indicating the date and time of the attempt. The patient can then either choose to collect and sign for their medication at their local post office or reschedule the delivery for a convenient time by phone or email."

8.45 The SOP for Cold Chain Delivery states:

8.45.1 "***3. Temperature Record according to "Cold Chain Maintenance SOP"***

All staff will ensure that the temperature of refrigerators used for medication storage is monitored, reset daily, and maintained between 2°–8° C. These temperatures will be recorded daily, and any discrepancies will be addressed according to the SOP.

4. Product dispatch

Ensure any items for cold chain delivery via courier are stored in the fridge and accompanying items are appropriately marked with a fridge line sticker. Accompanying items should include a note to explain that fridge items will be delivered separately to the rest of their items to enable the cold chain to be maintained. Patients will be contacted to inform and arrange for cold chain deliveries. All cold chain deliveries should be booked on courier specific portal. The cold chain medication should be kept in the fridge until the courier arrives to accept the delivery. Pharmacy staff verify with the courier that the delivery will be kept within the specified temperature range. Details of all prescriptions scheduled for delivery will be confirmed with courier driver. The courier must scan a barcode sticker for each item, with the pharmacy retaining a copy of the barcode, which also serves as the tracking number. Ensure the on-duty pharmacist is available to oversee the handover of all items for delivery and match against the delivery log and prescription. Pharmacy staff record all tracking numbers for prescriptions being delivered by the courier on the Delivery Log sheet and confirm the courier signs the Delivery Log sheet for all prescriptions accepted for delivery. Patients will be contacted with dispatch confirmation with their Tracking number when the prescriptions have left the premises. Live tracking with estimated ETA is available via the courier website. All deliveries will require a signature from the patient to confirm receipt of their prescription. Delivery log is stored for a minimum of 3 months from dispatch date.

5. Using courier service

All cold chain deliveries must be done via specialist medical cold chain courier service. Provisions such as DHL COLDCHAIN (or a similar specialist cold chain courier service) maintain the integrity, quality, and effectiveness of temperature-sensitive medications. These services ensure proper packing, transportation, and delivery under fully monitored, temperature-controlled conditions. Real-time monitoring devices are used to track temperature, humidity, and other environmental factors, alongside GPS tracking for precise location updates as well as electronic proof of delivery. Vehicles are equipped with built-in refrigeration systems to maintain the necessary temperature throughout transit. Courier operates under an ISO 9001:2015 certified Quality Management System, ensuring robust processes and quality oversight. In addition, all pharmaceutical warehousing and cold chain distribution used for this service are fully MHRA licensed under Wholesale Distribution Authorisation (WDA(H)) and GDP-compliant, ensuring full regulatory compliance for the storage and distribution of temperature-sensitive medicinal products.

Each cold chain product will be individually bagged, sealed with tamper-evident packaging, and clearly labelled with a "fridge item" sticker to ensure all handlers are aware that it requires cold chain management. The pharmacist will only remove the item from cold storage once the delivery courier is present. The pharmacist or trained staff will oversee the transfer of the item to the temperature-controlled vehicle, ensuring that the cold chain is maintained throughout the handover process. Delivery drivers are properly trained and would only remove the item from their vehicle upon arrival when the patient has answered the door and verified their identity.

In the event of a cold chain breach, the driver will be immediately notified, and any affected delivery will be cancelled. The pharmacy will be promptly informed of the breach. Medications are stored in temperature-controlled warehouses for interim storage or in cases of failed deliveries.

A list of approved cold chain couriers is maintained by the Pharmacy and will be periodically updated. Each approved courier meets strict criteria to guarantee a fully monitored and dedicated cold chain service.

6. Unsuccessful cold chain delivery via courier

If a delivery attempt fails, the cold chain courier (e.g., DHL COLDCHAIN) will leave a 'Missed Delivery' card with the date, time, and instructions to reschedule. Medications will not be left unattended if the patient is unavailable to receive the delivery. Patients can rearrange delivery via phone or online. Medications are stored in temperature-controlled warehouses in the interim and maintained for up to 48 hours. If undelivered within this period, items are returned to the pharmacy with the cold chain maintained throughout the journey, which will contact the patient to arrange a new delivery. The entire journey, from transfer within the warehouse to loading onto the transport vehicle, and throughout transit, is continuously monitored with real-time temperature tracking and alarm systems to ensure the cold chain is consistently maintained.

7. Breach of Integrity of Cold Chain

DHL vehicles are equipped with built-in refrigeration systems to ensure the required temperature is maintained during road transportation. The system automatically alerts the delivery driver that the cold chain has been breached and affected deliveries will be cancelled. The patient and pharmacy will be promptly informed of the breach, or the patient will receive a 'Missed Delivery' card. The pharmacy must arrange for an immediate re-delivery of the items via courier and ensure the return of undelivered items to the pharmacy. Items compromised by a cold chain breach are not reused and must be segregated from the pharmacy stock upon their return. If the breach of the cold chain is discovered after the medication has been given to the patient, then the Incident Reporting Policy should be followed. The patient must be referred to the responsible pharmacist for review. Regularly review and audit on

courier temperature and tracking data to identify patterns of risk or non-compliance. Conduct stimulated drills or mock scenarios at least once a year to test protocols and response times for breaches or equipment failures."

8.46 The SOP for Delivering Controlled Drugs states:

8.46.1 "***1. Organise CD deliveries.*** *…*

Controlled Drugs are stored in a compliant CD cabinet fixed to structural walls, meeting all legal security requirements, with access restricted to authorised registrants only. CD items must remain in the CD cabinet until delivery. The prescription should be retained with the item(s) to allow a final check and entry in the CD register. Check that dispensed medicinal products have been bagged and labelled and that the name and address on the bag label corresponds to the prescription. Ensure the bag label has the full address including the postcode. Agree or inform the patient of the expected date and time for delivery if this has not already been done and check that someone will be present to accept the delivery. The prescription should 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.

2. Dispatch the item.

Give the correctly labelled and bagged item to the driver along with the delivery sheet. Make sure that the driver understands that this is not a regular delivery and needs to be signed for. Make sure that the deliverer understands that CDs and any other medicines on that patient's delivery must be stored in the lockable compartment of the delivery van and not out of sight. The delivery van must be kept locked at all times when the driver is not in the vehicle and will not be left unattended.

3. Driver delivers the item

The person who is delivering the controlled drug should double-check the address to be delivered to and ask the person who is present for identification if necessary. A signature should be obtained from the patient who receives their item. Where the recipient is not the patient, their full name should be recorded on the delivery record form, along with their signature. If the patient has a carer and is incapable of signing then the delivery driver is effectively the patient's nominated representative authorised to collect the CD on their behalf. As such the driver should sign the 'collected by' section on the reverse of the prescription. The delivery driver/courier must check the identity of the person accepting the delivery to ensure that it is the patient or authorised representative (passport, driving licence or government approved photo ID card are acceptable forms of ID). A delivery cannot be left with anyone who is not the patient or their authorised representative.

4. Report back to the pharmacist.

The pharmacist has a legal responsibility to make sure that the patient has received their medication. If the patient/carer is home to accept the delivery, the driver must confirm the patient details and ensure the delivery record form is signed by the recipient. Once delivered, the driver must return the signed delivery note to the pharmacy. File the delivery record form as evidence of successful delivery of the controlled drug. The forms should be stored for a minimum of six months in case the delivery is later queried.

5. Entry into the CD register

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

6. Failure to Deliver

If the patient is not home during the agreed delivery slot– the CD must be returned to the pharmacy on the same day and at the earliest opportunity. Do NOT push the medicines through the letterbox. Do NOT leave the medicines outside the door. Inform the authorised pharmacy staff upon return to the pharmacy. The CD register entry for failed CD deliveries should be annotated by marginal note or footnote to state that the delivery was not made and the CD entry is not accurate. If the pharmacist is satisfied that the product has been stored correctly and is suitable to be issued to the patient at a later date the item should be re-entered in the supplied section of the CD register.

7. Following delivery or attempted delivery

Check the Driver's delivery schedule against the detached prescriptions. Prescriptions for packages which been successfully delivered may be treated as completed and filed. Prescriptions for packages which have not been delivered should be reattached to the package. Contact the patient to confirm the next details for the next delivery. Return the prescription and package to the delivery storage area or the fridge if applicable.

8. CD delivery with Courier

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

DHL meets all Home Office safe custody and record-keeping requirements. Controlled drugs delivered by DHL Courier Services are all being tracked, with verifiable audit trails. GPS, image & signature data would be checked by the pharmacy team after delivery to ensure that the patient has received the CD delivery.

Unsuccessful deliveries sent with a courier should 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 and return the next day.

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."

8.47 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.

8.48 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.

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

8.50 The Committee noted the SOP for Remote Appliance Fitting and Dispensing Appliances which states:

8.50.1 "***2. Receiving a New Appliance Prescription***

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

(a) With the patient's consent, refer the prescription to another NHS pharmacist or NHS appliance contractor; and

(b) If the patient does not consent to a referral, give the patient contact details of at least two NHS pharmacists or NHS appliance contractors who can provide the required appliance or customisation, if the pharmacist knows these details.

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

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

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

8.53 The Committee noted that the SOP for Dispensing of Prescriptions states:

8.53.1 "***Bagging-up NHS prescriptions***

For bagging-up prescriptions, use cartons that fit appropriately, making sure the sides are sealed and no medication can come out of the parcel. Make sure the Royal Mail address label is placed on the seal to prevent unauthorised opening of the parcel. The packaging should be discreet with no indication on the outside that medicines are being delivered in this parcel. Ensure that all medicines have been supplied with Patient information leaflets and any relevant advice leaflet in relation to health promotion, whether it is general advice to all patients and/or targeted specific advice based on patient's disease state.

Choice of packaging

Choice of packaging will depend on the nature of the items being delivered and the appropriate level of protection must be used to ensure that the item can withstand the normal rigours of the delivery process. If needed plain brown paper can be used to stuff the box to ensure the medicines is protected during transport. All packaging must have the tamper proof seals provided in the pharmacy attached to the packaging so that any tampering with the packaging will be evident. For postal/courier items, at a minimum, use padded envelopes for non-fragile items to protect the manufacturer's packaging. For most items, use bubble wrap and, if necessary, polystyrene filler inside a reinforced cardboard box. Large or any fragile medicines should be packed into cardboard boxes with bubble packaging and filling materials to protect from damage.

Small flat parcels - Small square cartons (Kite Packaging)

Medium and large flat parcels – medium and large Defender boxes

Small parcels - CD1 boxes

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

Large parcels – C1 boxes"

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

Refusal to provide drugs or appliances ordered

8.55 The Committee asked itself how the Applicant will be satisfied that when dispensing a repeatable prescription other than on the first occasion, that the patient is still using the medication, is not suffering from any side effects, the medicine regime has not changed in any way and there has been no changes

to the patient's health, which may indicate the desirability of review the patients treatment.

8.56 The Committee noted the SOP for Repeat Dispensing states:

8.56.1 "***Procedure***

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

Repeat Dispensing will be delivered safe and effectively via the staff completing sufficient clinical and legal assessments before dispensing the medicine. …

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

Pharmacist must ensure that the patient is not suffering any side effects from the treatment otherwise which may suggest the need for a review of treatment.

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

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

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

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

8.57 The SOP for Remote Patient Assessment of Repeat Dispensing Need states:

8.57.1 "***1. Assessing a patient as to their need for a repeat prescription.***

Repeat prescriptions will be dispensed as per our Dispensing of Prescriptions and Repeat Dispensing SOPs with the addition of offering

the service to patients for storing the documentation if required. An appropriate pharmacy record card will be completed and attached to a RA and an entry made on each occasion a dispensing takes place. Any amendments to the RD, e.g. items not issued or change to expected interval will be recorded in the comment section of the pharmacy copy of the card.

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

> *Did you experience any side effects from your last prescription?*
>
> *Are you experiencing any issues with your last prescription?*
>
> *Did your last prescription arrive at your delivery address damaged?*
>
> *Have there been any changes to your health since the issuance of this prescription which would lead to you not requiring it?*

2. Responding to a patient indicated need.

If any of the above questions are returned by the patient indicating a need, the Responsible Pharmacist will telephone/video call the patient before issuing a repeat and ensure:

> *They are taking or using, and likely to continue to take or use the medicine or appliances appropriately.*
>
> *Advise the patient that they should only order items that they need.*
>
> *Check that the patient is not suffering any side effects which may suggest they need a review of their medication.*
>
> *Check that the patient's regimen has not been changed since the prescriber authorised the repeatable medication.*
>
> *Check that there has not been any change to the patient's health since the prescription was authorised.*
>
> *Provide advice and encourage patients with long term, stable medical conditions to discuss repeat dispensing of their medicine with their prescriber.*

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

8.58 The Committee was 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

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

8.60 The Committee noted the SOP for Remote Patient Assessment of Repeat Dispensing Need states:

8.60.1 "*2. Responding to a patient indicated need.*

If any of the above questions are returned by the patient indicating a need, the Responsible Pharmacist will telephone/video call the patient before issuing a repeat and ensure: …

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

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

8.61 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

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

8.63 The Committee noted the SOP for Disposal of Unwanted Medicines Returned to the Pharmacy states:

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

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

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

A specialised waste management company will safely and securely dispose of unwanted medicines by collecting them from patients and residential homes.

Patients who wish to return unwanted medicines to the pharmacy can do so via courier, with the cost covered by the pharmacy.

Patients in the local area can arrange for pharmacy staff or delivery driver to collect unwanted medicines from their home or workplace by contacting the pharmacy via phone or email.

Patients will receive appropriate packaging in advance, and information about the service and how to schedule a collection at patient's place will be available on the Pharmacy website.

Medical waste must be accepted from members of the public, from care homes without nursing, from hospices if wholly or partly charity funded, or from healthcare professionals when acting as a representative of a patient (e.g. a district nurse). Although not obligatory, waste can also be accepted from care homes with nursing, hospices not operated by charities and GP/dental surgeries, after discussion with the local area authority about how the waste will be managed and its disposal paid for. Before accepting the container or bag of unwanted medicine, ask if it contains:

any sharps,

strong painkillers (controlled drugs),

poisons or chemicals,

liquids.

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

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

Assess the items for suitability for return by Royal Mail

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

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

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

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

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

KEY POINTS

Do not accept returned sharps unless you are part of a needle exchange scheme with allocated sharps box. Customers wishing to dispose of sharps should be signposted to their local GP surgery or to contact the local area authority.

Do not accept poisons/chemicals. Signpost members of the public to local authority waste services. These can be located by searching the website recyclenow.com and putting in the postcode of the customer, or visiting the website recycle-more.co.uk.

For certain chemicals, the customer may need to contact the local authority waste facility directly to find where their chemicals can be accepted.

If there are any CDs (schedule 2, 3 or 4) with the returned medicines, the pharmacist should be alerted, and the CDs set aside for denaturing and disposal (see SOP for Destruction of CDs).

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

The bag or container of returned medicines must be handled only by the handles or top, ensuring that there is no risk of the contents spilling.

Large quantities of the same medicine should be reported to the pharmacist as this may indicate a compliance issue.

Information about the patients and their returned medicines must NOT be disclosed to a third party (including carer or relative) without the patient's consent. If they ask questions about medicines, remember the pharmacy's duty of confidentiality.

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

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

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

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

8.64 The SOP for Return of Unwanted Controlled Drugs to the Pharmacy states:

8.64.1 "***PATIENT RETURNED CONTROLLED DRUGS*** *…*

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

Patients or their representatives will not return and medicines directly to the pharmacy

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

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

Each return will be made by booking an appointment for the pharmacy's driver to visit the patient's home to collect the returned medication or by sending the appropriate packaging to the patient to arrange for return by Royal Mail …

Handling Patient-Returned CDs from Delivery Driver

Drivers need to:

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

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

Pharmacy staff need to:

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

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

Return by DHL

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

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

Contact the patient to ensure that the packaging has been received

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

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

Promotion of healthy lifestyles

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

8.67 The Committee noted the supporting information with the appeal which states:

8.67.1 "***Promotion of Healthy Lifestyles***

Healthy lifestyle and public health advice will be provided to patients receiving prescriptions who may have diabetes, be at risk of coronary heart disease, or exhibit risk factors such as high blood pressure, smoking, or being overweight. This advice will be delivered without requiring face-to-face contact. Patients will be identified through three methods: passive, active, or as part of the repeat (or standard) dispensing process. This involves the use of lifestyle questionnaires, which can be completed through the website, emailed to patients, or sent by post and returned. Advice can be provided verbally over the phone or via video call, or through leaflets delivered to the patient's home. All advice given should be documented in the Patient Medication Record (PMR). The pharmacy's email newsletter and website will also promote healthy living. Patients can access advice and support during pharmacy opening hours, and health information will be available on the pharmacy's website at all times, ensuring continuous service provision across England. If it is not suitable for the pharmacist to provide advice, the patient will be directed to an appropriate health or social care provider, as outlined in the SOP on 'Signposting'. An intervention and referral form will be completed, detailing the information provided and the referral organisation.

The pharmacy's website and newsletter will offer information on support organisations, managing common illnesses, minor ailments, long-term medical conditions, and the appropriate use of over-the-counter (OTC) medications. The pharmacist on duty can be contacted by telephone for more advice and drug interactions.

The pharmacy website will be accessible to the public for accessing pharmaceutical services. It will feature an interactive platform with up-to-date resources promoting healthy lifestyles and addressing various health issues."

8.68 The Committee noted the SOP for Remote Promotion of Healthy Lifestyle and Public Health Campaigns states:

8.68.1 "***1. Prescription receipt***

If a non-electronic prescription or non-electronic repeatable prescription is presented to the pharmacy by post, the patient will be contacted via video consult. Upon consultation, if the pharmacist notices that the patient is suffering from diabetes, is at risk of coronary heart disease, or smokes or is overweight, the Responsible Pharmacist will provide advice without face to face contact with the aim of increasing that person's knowledge and understanding of the health issues which are relevant to that person's personal circumstances. This advice could be given verbally over phone or video call, or through written material e.g. leaflets to be delivered to patients' home and by referring the person to other sources of information or advice. Where advice is provided it should be recorded on the PMR for auditing purpose and follow-up care. The email newsletter and website will also be used to promote a healthy lifestyle. Information about support organisations, the treatment of common illnesses, minor ailments, long term medical conditions and appropriate usage of OTC medications will be available on the website, app and email newsletter. The pharmacist on duty can be contacted by telephone for more advice and drug interactions.

2. Promotion of healthy lifestyles on the web.

As an Online pharmacy, promoting healthy lifestyles is of the utmost importance. Pharmacy website will be available for use by the public for the purpose of accessing pharmaceutical services. Website will be an interactive page, provide public access to a range of up to date materials that promote healthy lifestyles by addressing a range of health issues. The Well-Being section of the website provides public health advice and support and targets the main health campaigns as set out by NHS England. Prescription-linked interventions will be spotted in pharmacy and patient contact will be made as according to SOP."

8.69 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

8.70 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.

8.71 The Committee noted the supporting information with the appeal which states:

8.71.1 "***Promotion of Healthy Lifestyles***

Healthy lifestyle and public health advice will be provided to patients receiving prescriptions who may have diabetes, be at risk of coronary heart disease, or exhibit risk factors such as high blood pressure, smoking, or being overweight. This advice will be delivered without requiring face-to-face contact. Patients will be identified through three methods: passive, active, or as part of the repeat (or standard) dispensing process. This involves the use of lifestyle questionnaires, which can be completed through the website, emailed to patients, or sent by post and returned. Advice can be provided verbally over the phone or via video call, or through leaflets delivered to the patient's home. All advice given should be documented in the Patient Medication Record (PMR). …"

8.72 The Committee noted the SOP for Remote Promotion of Healthy Lifestyle and Public Health Campaigns states:

8.72.1 "***1. Prescription receipt***

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

8.73 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

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

8.75 The Committee noted the SOP for Remote Promotion of Healthy Lifestyle and Public Health Campaigns states:

8.75.1 "***3. Health Campaigns***

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

Patients will receive guidance on accessing these learning resources via email, text messages, and other forms of non-face-to-face communication to ensure awareness of the campaigns.

Additionally, patients will be evaluated for participation in at least one clinical audit and any other audits specified by the NHSCB. These audits may include clinical audits conducted in accordance with NHSCB data processing arrangements or policy-based audits designed to support the development of NHSCB commissioning policies, all of which will comply with NHSCB data processing protocols."

8.76 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

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

8.78 The Committee noted the information provided with the appeal states:

8.78.1 "***Signposting***

When people who require assistance, which cannot be provided by the pharmacy but aware of other appropriate health and social care providers or support organisations who are likely to be able to provide that advice, treatment or support, pharmacy staff will be signposting to other appropriate healthcare professionals through non face-face contact. This can be done through telephone, video calls, website or email. Pharmacy staff must provide the patient with contact details of that provider and, where appropriate, refer the person to the provider. At least two providers should be identified if this is possible. Any help or advice that cannot be accessed on the website and app links will be available by telephoning the pharmacy and asking for advice. The pharmacy's website will contain links to other health care providers and also an A-to-Z healthcare section. Staff should create and keep a record of any information given or referral made and mark an appropriate follow-up date on the PMR system. Where advice cannot be provided should also be recorded as an Intervention on the patient record along

with the referral organisation. When signposting patients, use the 'Services Near You' application from NHS Choices to find suitable organisations in the locality of the patient. Please refer to "How to Navigate NHS Choices Website" document for guidance on how to use this application."

8.79 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

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

8.81 The Committee noted the SOP for Remote Support for Self Care which states:

8.81.1 "***1. Defining Self Care***

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

The advice provided encompasses:

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

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

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

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

2. Providing Self Care

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

information and support and also if the patient would like more in-depth scientific knowledge. Self-care our pharmacy intends to provide our patients include:

information-giving

addressing motivations and barriers to change

teaching coping strategies

designing action plans

dealing with emotional sequelae of illness

ongoing monitoring/support

engaging family and social support

3. Opportunistic self-care

The support for self-care will also be provided opportunistically if a patient or carer telephones the pharmacy for advice. A note will be made of any advice given to patients whether online or over the phone if deemed necessary. This service intertwines of course with signposting and public health promotion. A record should be made in the PMR."

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

Discharge medicines service

8.83 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.

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

8.85 The Committee noted the SOP for Remote Discharge Medicine Service which states:

8.85.1 "*1.* ***Preparation for the service.***

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

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

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

2. Patient Referrals

Check appropriate IT systems for patient referrals - Agree suitable timings within day

Confirm minimum requirements of information have been provided on the referral (Appendix 2) and start the DMS Stage 1

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

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

Check referral for clinical information and actions required

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

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

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

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

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

Ensure flag in place on record to alert staff of the need to complete Stages 2 and 3, when

first prescription received, or

first contact with patient/carer

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

Check medicines prescribed reflect appropriate changes made during the hospital discharge

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

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

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

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

Adopting a 'shared decision making' approach to improve compliance / adherence

For conversations conducted within the pharmacy premises, consultation room must be used

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

Gain patient consent to share, and record on notes.

Send notes using a secure method

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

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

6. All stages of DMR cannot be completed

If the above normal patient journey through the service cannot be complete

Pharmacist/pharmacy technician to use professional judgement to determine the appropriate actions to take. (see appendix 3 for details of examples)."

8.86 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

8.87 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

8.88 The Committee noted the SOP for Remote Promotion of Healthy Lifestyle and Public Health Campaigns which states:

8.88.1 "***2. Promotion of healthy lifestyles on the web.***

As an Online pharmacy, promoting healthy lifestyles is of the utmost importance. Pharmacy website will be available for use by the public for the purpose of accessing pharmaceutical services. Website will be an interactive page, provide public access to a range of up to date materials that promote healthy lifestyles by addressing a range of health issues. The Well-Being section of the website provides public health advice and support and targets the main health campaigns as set out by NHS England. Prescription-linked interventions will be spotted in pharmacy and patient contact will be made as according to SOP."

8.89 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 28C of Schedule 4.

Summary

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

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

8.91.1 confirm the Commissioner's decision;

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

8.91.3 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.

8.92 As the Committee has reached a different determination to the Commissioner, the Committee determined that the decision of the Commissioner must be quashed.

8.93 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.

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

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

9 Decision

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

9.2 The Committee:

9.2.1 quashes the decision of the Commissioner; and

9.2.2 redetermines the application as follows -

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

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

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

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

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

9.2.3 The application is granted.

Case Manager
Primary Care Appeals