

20 March 2026

REF: SHA/26818

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**APPEAL AGAINST NORTH WEST LONDON ICB
DECISION TO REFUSE AN APPLICATION BY
CLINIDIRECT PHARMA UK LTD FOR INCLUSION
IN THE PHARMACEUTICAL LIST AT UNIT 22,
HALLMARK TRADING ESTATE, FOURTH WAY,
WEMBLEY, MIDDLESEX, HA9 0LB 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 refused.

A copy of this decision is being sent to:

Clinidirect Pharma UK Ltd
PCSE on behalf of North West London ICB

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REGULATION 25**

1 The Application

By application dated 11 June 2025, Clinidirect Pharma UK Ltd (“the Applicant”) applied to North West London ICB (“the Commissioner”) for inclusion in the pharmaceutical list at Unit 22, Hallmark Trading Estate, Fourth Way, Wembley, Middlesex, HA9 0LB 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 left this blank.
- 1.2 In response to why the application should not be refused pursuant to Regulation 31 the Applicant left this blank.
- 1.3 In response to why the application should not be refused pursuant to Regulation 25(2)(a) the Applicant left this blank.
- 1.4 In response to “Please give details of any advanced and enhanced services you intend to provide” the Applicant stated:

Service	Accredited to provide (Y/N/NA)	Premises accredited (Y/N/NA)
New Medicine Service (NMS)	Y	N
Appliance use Reviews (AURs)	Y	N
Stoma Customisation	Y	N
Community Pharmacy Seasonal Influenza Vaccination Advanced Service	Y	N
NHS Community Pharmacy Hypertension Case-Finding Advanced service	Y	N
NHS Pharmacy Contraception Service – Ongoing Supply and initial of Oral Contraception	Y	N
Lateral Flow Device (LFD) Tests Supply Service	Y	N

NHS Pharmacy First Service	Y	N
Independent Prescribing Service	Y	N
Home Delivery Service	Y	N
Medication Review Service	Y	N
Patient Group Direction Service	Y	N
Schools Service	Y	N

Pharmacy procedures

- 1.5 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.
- 1.6 Please describe the procedure that will be followed where a patient attends the premises and asks for one or more of the essential services.
- 1.7 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.
- 1.8 You must ensure that you provide sufficient information within this application form to satisfy NHS England or the relevant delegated integrated care board on the above points. You are not required to submit your standard operating procedures for the premises but if you do they will be circulated to interested parties unless NHS England or the relevant delegated integrated care board is satisfied that the full disclosure principle does not apply.
- 1.9 "Provision of Essential Services and Advanced Services (DSP Application Statement) - (A)
- 1.10 As a registered Distance Selling Pharmacy (DSP), our pharmacy operates without any face-to-face interaction at the premises. We are fully compliant with the NHS regulations governing DSPs, and we ensure the uninterrupted provision of essential services to patients anywhere in England through the following procedures:
- 1.11 Remote Access: All essential services (including dispensing, repeat dispensing, disposal of unwanted medicines, healthy lifestyle promotion, and self-care support) are delivered remotely via our website, email, or telephone helpline during all contracted opening hours.

- 1.12 Electronic Prescription Service (EPS): Prescriptions are received electronically, clinically checked by a pharmacist, and processed promptly without the need for in person contact.
 - 1.13 Tracked Home Delivery: All medications are dispensed and dispatched using secure, tracked delivery services directly to the patient's address. Special safeguards are in place for the delivery of CDs and cold chain items.
 - 1.14 Trained Staff & Workflow Planning: Sufficient trained staff are available during all opening hours to manage incoming prescriptions, queries, and communications, ensuring continuous service provision.
 - 1.15 Business Continuity: Robust contingency planning is in place to ensure continued operation during staff shortages, system downtime, or delivery delays.
 - 1.16 (B) No Face-to-Face Interaction: In compliance with DSP regulations, no patient attends the premises. All services are provided remotely.
 - 1.17 Remote Communication: Clinical checks, advice, and support are offered via telephone or secure video call when necessary. Patients may also communicate via email or webchat.
 - 1.18 Safe Dispensing & Delivery: Medications are dispensed following standard SOPs and delivered securely to the patient's address with patient verification procedures in place"
- 2 Following the change to the Regulations, the Applicant provided further information to the Commissioner in a letter dated 6 July 2025:
- 2.1 "Further to your letter dated 3rd July 2025, regarding our application to provide pharmaceutical services under the updated Regulation 25 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, we are pleased to provide the requested information in line with the revised requirements effective from 23rd June 2025.
 - 2.2 As a registered Distance Selling Pharmacy (DSP), CliniDirect Pharma UK Ltd is committed to full compliance with all relevant regulations, including the clear stipulation that there must be no face-to-face contact with patients or their representatives at or in the vicinity of the premises Provision of Advanced and/or Enhanced Services
 - 2.3 We confirm that all pharmaceutical services provided by CliniDirect Pharma UK Ltd will be carried out remotely only, and that no face-to-face interactions will occur at the pharmacy premises or its surrounding area under any circumstances.
 - 2.4 1. Remote Service Provision
 - 2.4.1 Should any advanced, enhanced, or locally commissioned services be provided in the future, they will be delivered solely through telephone consultations, video conferencing, or other secure, NHS-compliant digital platforms.

- 2.4.2 Informed patient consent will be obtained remotely, and all records will be securely documented.
- 2.5 2. Supply and Delivery
 - 2.5.1 All medicines and appliances will be supplied to patients exclusively via secure, tracked courier or postal services, ensuring complete separation from the physical premises.
- 2.6 3. Standard Operating Procedures
 - 2.6.1 We operate under a comprehensive set of robust clinical SOPs, which cover all aspects of safe, effective, and compliant remote service delivery.
 - 2.6.2 These SOPs are reviewed regularly to reflect changes in regulation and best practice.
- 2.7 4. Clarification on Service Provision at Premises
 - 2.7.1 For absolute clarity, we confirm that CliniDirect Pharma UK Ltd will not provide any advanced, enhanced, or locally commissioned services at the pharmacy premises under any circumstances.
 - 2.7.2 Our operating model is fully aligned with the DSP framework, and all services will be facilitated through remote means only.
- 2.8 We trust this information satisfies the requirements of Regulation 25 and supports the safe and effective provision of pharmaceutical services without any on-site interaction. If further clarification is required, please do not hesitate to contact us."
- 2.9 [SOPs provided].

3 Comments to the Commissioner

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

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

3.1 THE APPLICANT

- 3.1.1 "From the experiences shared by families and patients living with severe and complex conditions such as **Epidermolysis Bullosa (EB)** and **Ichthyosis**, it is clear that the services I provide have been essential in ensuring continuity of care, dignity, and improved quality of life. For over 12 years, I have worked closely with hospitals, clinicians, and specialist centres to deliver the medicines, dressings, and

dermatology products that patients need — reliably, safely, and compassionately.

- 3.1.2 Going forward, I remain committed to extending this high standard of care to patients **across the country**, supporting EB services and other specialist dermatology and rare condition clinics. My focus will always be on ensuring that vulnerable patients and their families can rely on consistent, specialist-led pharmacy support that makes a meaningful difference to their lives.
- 3.1.3 By the way, I will be a support to all pharmacists and local chemists who require support rather than taking any business away from anyone. My aim is to fully support and enhance my role in giving the utmost care to patients who are in need of support.
- 3.1.4 Please kindly contact myself for any further queries or information that needs to be submitted. I am happy to send you any further documentation that is required/needed to support.”

3.2 THE APPLICANT

- 3.2.1 “I am writing on behalf of CliniDirect Pharma UK Ltd in response to the representation submitted by Boots UK Ltd dated 28th August 2025, concerning our application for inclusion in the pharmaceutical list as a Distance Selling Pharmacy (DSP) at Unit 22, Hallmark Trading Estate, Fourth Way, Wembley, Middlesex, HA9 0LB.
- 3.2.2 We note their request that the application be assessed against the requirements of Regulation 25 and the conditions set out under Regulation 64 of the NHS (Pharmaceutical Services) Regulations 2013, as amended in June 2025.
- 3.2.3 We wish to confirm that our application, policies, and operating procedures have been developed in full compliance with these regulations, including:
 - 3.2.3.1 Meeting all essential service requirements as defined under the DSP framework.
 - 3.2.3.2 Ensuring no face-to-face provision of essential services at, in, or from the premises.
 - 3.2.3.3 Demonstrating clear arrangements for the safe, effective, and secure provision of services remotely to patients across England.
 - 3.2.3.4 Embedding the new requirements introduced under the June 2025 amendments, including governance, safeguarding, and medicines delivery protocols.
- 3.2.4 CliniDirect Pharma UK Ltd is committed to maintaining the highest standards of patient safety, regulatory compliance, and accessibility in all aspects of service delivery.

- 3.2.5 We trust this provides assurance that our DSP application has been carefully prepared in accordance with all current legal and regulatory requirements.”

3.3 THE APPLICANT

- 3.3.1 “I am writing in response to the objection submitted by Health First Pharmacy (Wembley) dated 27th August 2025, regarding our application for market entry as a Distance Selling Pharmacy (DSP) under CLIN Direct Pharma UK Ltd.

- 3.3.2 We would like to respectfully address the concerns raised:

3.3.3 1. Patient Safety

3.3.3.1 CLIN Direct Pharma UK Ltd has robust systems in place to ensure safe and secure dispensing, including strict identity verification, secure courier delivery, real-time tracking, and clinical screening of all prescriptions by qualified pharmacists. For controlled drugs and high-risk medicines, additional safeguards such as two-step verification, patient counselling calls, and delivery confirmation protocols are embedded into our processes.

3.3.3.2 We will not be dispensing high volumes of CD'S. As I am already an inspector and regulatory officer, I make sure that this is done to an exceptional level with full protocol in place.

3.3.4 2. Accessibility for Vulnerable Groups

3.3.4.1 While our services are primarily delivered remotely, we are committed to ensuring inclusivity. Patients who may face barriers with digital technology can access support via telephone consultations, written communication, and translation services where required.

3.3.4.2 Our systems are designed to accommodate the needs of vulnerable patients, ensuring no one is excluded from accessing essential services.

3.3.5 3. Regulatory Compliance

3.3.5.1 Our application and operating model fully adhere to NHS England and GPhC regulations.

3.3.5.2 We have clear policies for governance, confidentiality, safeguarding, and medicines optimisation, with regular audits and quality assurance checks. We are confident that our DSP model not only meets but exceeds the standards required for safe, effective, and compliant service delivery. I at present look after the regulatory involvement and CD inspections across all surgical sites in the UK.

3.3.6 4. Impact on Local Pharmacies

3.3.6.1 The DSP model operates under a different service framework from traditional community pharmacies. Our role is to complement existing NHS pharmacy provision by offering patients additional choice and convenience, particularly for those who prefer or require remote services. We remain committed to working collaboratively within the NHS framework to ensure that all patients continue to have access to safe and effective pharmacy care. My aim is not to take business away from any local pharmacy, rather support them if required, my intention was to support EB patients across the UK, this is what I have been doing over the past 13 years when I had my DSP in Harrow. This was closed due to Covid and relocation, I had applied at the time but could not go further due to issues with relocation. In conclusion, CLIN Direct Pharma UK Ltd is fully committed to patient safety, accessibility, and regulatory compliance. We believe our DSP service will strengthen overall patient choice and enhance access to essential medicines, without compromising the valuable role played by local community pharmacies.

3.3.7 Please let me know if any further information or supporting documentation is required.”

4 The Decision

The Commissioner considered and decided to refuse the application. The decision letter dated 26 November 2025 states:

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

4.1 “North West London ICB has considered the above application, and I am writing to confirm that it has been refused. Please see the enclosed report for the full reasoning.”

Extract from the London Pharmaceutical Services Regulations Committee report

4.2 “CAS reference number: ME3924 - CAS-369153-B4F6C8

4.3 Name of applicant: Clinidirect Pharma UK Ltd

4.4 Fitness to practise: Cleared for inclusion.

4.5 Address of proposed premises: Unit 22, Hallmark Trading, Estate, Fourth Way, Wembley, Middlesex, HA9 0LB

4.6 Status of location: Non-controlled locality.

4.7 Relevant regulations and guidance

4.7.1 Regulations 25 – distance selling premises.

4.7.2 Regulation 31 – refusal: same or adjacent premises.

4.7.3 DH market entry guidance chapter 11.

Additional information

4.8 Consider impact of decision on those with protected characteristics under the Equalities Act 2010 and is this in accordance with NHS Public Sector Equality Duty

4.9 Consider impact of decision on NHS duty on health inequality

Additional information

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

4.11 The comments received from parties is available to the PSRC panel to review.

With regard to Regulation 31

4.12 (Refusal: same or adjacent premises) and to the provisions of Schedule 2 to the Regulations:

4.13 "Applications seeking the listing of premises that are already, or are in close proximity to, listed chemist premises.

Boots Comments

4.14 Boots UK Ltd would like to respectfully request that members of the deciding committee are satisfied that this application fully meets the criteria set out in Regulation 25 and the conditions set out in Regulation 64 when determining this application. As the regulatory change came into effect in June 2025, we also ask that these changes are also met should this application be approved.

Health First Pharmacy Comments

4.15 I am writing on behalf of Health First Pharmacy, located at 95 Wembley Park Drive, Wembley, HA9 8HF, to formally object to the application for market entry by Clinidirect Pharma UK Ltd as a Distance Selling Pharmacy (DSP).

4.16 Our concerns are primarily based on the following:

4.16.1 Patient Safety: While the application outlines the provision of essential services remotely, we are concerned about the risks associated with the dispensing of controlled drugs and other medications that require additional safeguards. The lack of face-to-face interaction limits the ability to ensure proper patient identification and safe delivery, increasing the risk of errors.

- 4.16.2 Limited Accessibility for Vulnerable Groups: The remote model may not adequately serve vulnerable patients who require face-to-face consultations or have limited access to digital technologies. This poses a risk to patient care, as these individuals may find it difficult to engage with online or telephone-based services.
 - 4.16.3 Regulatory Compliance: While the DSP model is permitted under the regulations, we believe that the current application does not fully address how it will comply with all aspects of the Pharmacy Market Entry Regulations related to the safe, effective, and secure provision of services, particularly concerning high-risk medications.
 - 4.16.4 Business Viability: The proximity of Clinidirect Pharma UK Ltd to Health First Pharmacy and the nature of their services presents a direct competitive threat. A DSP offering remote services to the same patient population could significantly impact the financial viability of our pharmacy, particularly as we are committed to providing comprehensive, face-to-face consultations and patient care. This shift in service delivery could undermine our ability to meet the needs of local patients and sustain our business.
- 4.17 We respectfully request that the application be reconsidered, taking into account these concerns regarding patient safety, regulatory compliance, and the potential adverse effect on the viability of existing local pharmacies.

Applicants' Response

4.18 Response to Health First Pharmacy

- 4.18.1 Patient safety CLIN Direct Pharma UK Ltd has robust systems in place to ensure safe and secure dispensing including strict identity verification, secure courier delivery, real-time tracking and clinical screening of all prescriptions by qualified pharmacists. For controlled drugs and high-risk medicines, additional safeguards such as two-step verification, patient counselling calls, [sic] and delivery confirmation protocols are embedded into our processes.
- 4.18.2 We will not be dispensing high volumes of CDs. As I am already an inspector and regulatory office, [sic] I make sure that this is done to an exceptional level with full protocol in place.
- 4.18.3 Accessibility for Vulnerable Groups While our services are primarily delivered remotely, we are committed to ensuring inclusivity. Patients who may face barriers with digital technology can access support via telephone consultations, written communications and translation services where required. Our systems are designed to accommodate the needs of vulnerable patients, ensuring no one is excluded from accessing essential services.
- 4.18.4 Regulatory Compliance – Our application and operating model fully adhere to NHS England and GPhC regulations. We have clear policies for governance, confidentiality, safeguarding and medicines optimisation, with regular audits and quality assurance checks. We are

confident that our DSP model not only meets but exceeds the standards required for safe, effective and compliant service delivery. I at present look after the regulatory involvement and CD inspections across all surgical sites in the UK.

4.18.5 Impact on local Pharmacies – The DSP model operates under a different service framework from traditional community pharmacies. Our role is to compliment existing NHS pharmacy provision by offering patients additional choice and convenience, particularly for those who prefer or require remote services. We remain committed to working collaboratively within the NHS framework to ensure that all patients continue to have access to safe and effective pharmacy care. My aim is not to take business away from any local pharmacy, rather support them if required, my intention was to support EB patients across the UK, this is what I have been doing over the past 13 years when i had my DSP in Harrow. This was closed due to Covid and relocation. I had applied at the time but could not go further due to issues with relocation. In conclusion, CLIN Direct Pharma UK Ltd i fully committed to patient safety, accessibility and regulatory compliance. We believe our DSP service will strengthen overall patient choice and enhance access to essential medicines, without compromising the valuable role played local community pharmacies. [sic]

4.19 Response to Boots

4.19.1 We wish to confirm that our application, policies, and operating procedures have been developed in full compliance with these regulations including:

4.19.1.1 Meeting all essential service requirements as defined under the DSP framework Ensuring no face to face provision of essential services at, in or from the premises Demonstrating clear arrangements for the safe, effective and secure provision of services remotely to patients across England.

4.19.1.2 Embedding the new requirements introduced under the June 2025 amendments, including governance, safeguarding and medicines delivery protocols.

4.19.2 CliniDirect Pharma UK Ltd is committed to maintaining the highest standards of patient safety, regulatory compliance and accessibility in all aspects of service delivery.

4.19.3 Additionally, two testimonials have been provided. [see Appendix B].

4.19.4 From the experience shared by families and patients living with severe and complex conditions such as Epidermolysis Bullosa (EB) and Ichthyosis, it is clear that the services I provide have been essential in ensuing continuity of care, dignity, and improved quality of life. For over 12 years, I have worked closely with hospitals, clinicians, and specialist centres to deliver the medicines, dressings, and dermatology products that patients need – reliably, safely, and compassionately.

- 4.19.5 Going forward, I remain committed to extending this high standard of care to patients accross the country, supporting EB services and other specialits dematology and rear condition clinics. My focus will always be on ensuring that vulnerable patients and their families can rely on consistent, specialist-led pharmacy support that makes a meaningful difference to their lives. [sic]
- 4.19.6 By the way, I will be a support to all pharmacists and local chemists who require support rather than taking any business away from anyone. My aim is to fully support and enhance my role in giving the utmost care to patients who are in need of support.
- 4.20 Response to Request for Information Regarding Provision of Advanced and/or Enhanced Services Without Face-to-Face Contact
- 4.20.1 We are pleased to provide the requested information in line with the revised requirements effective from 23rd June 2025.
- 4.20.2 As a registered Distance Selling Pharmacy (DSP), CliniDirect Pharma UK Ltd is committed to full compliance with all relevant regulations, including the clear stipulation that there must be no face-to- face contact with patients or their representatives at or in the vicinity of the premises.
- Provision of Advanced and/or Enhanced Services
- 4.20.3 We confirm that all pharmaceutical services provided by CliniDirect Pharma UK Ltd will be carried out remotely only, and that no face-to-face interactions will occur at the pharmacy premises or its surrounding area under any circumstances.
- 4.20.4 Remote Service Provision
- 4.20.4.1Should any advanced, enhanced, or locally commissioned services be provided in the future, they will be delivered solely through telephone consultations, video conferencing, or other secure, NHS-compliant digital platforms.
- 4.20.4.2Informed patient consent will be obtained remotely, and all records will be securely documented.
- 4.20.5 Supply and Delivery
- 4.20.5.1All medicines and appliances will be supplied to patients exclusively via secure, tracked courier or postal services, ensuring complete separation from the physical premises.
- 4.20.6 Standard Operating Procedures
- 4.20.6.1We operate under a comprehensive set of robust clinical SOPs, which cover all aspects of safe, effective, and compliant remote service delivery.

4.20.6.2 These SOPs are reviewed regularly to reflect changes in regulation and best practice.

4.20.7 Clarification on Service Provision at Premises

4.20.7.1 For absolute clarity, we confirm that CliniDirect Pharma UK Ltd will not provide any advanced, enhanced, or locally commissioned services at the pharmacy premises under any circumstances.

4.20.7.2 Our operating model is fully aligned with the DSP framework, and all services will be facilitated through remote means only.

4.20.8 We trust this information satisfies the requirements of Regulation 25 and supports the safe and effective provision of pharmaceutical services without any on-site interaction.

4.21 With regard to Regulation 31

4.22 (Refusal: same or adjacent premises) and to the provisions of Schedule 2 to the Regulations:

“Applications seeking the listing of premises that are already, or are in close proximity to, listed chemist premises.”

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

4.24 Distance Selling premises applications

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

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

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

in respect of pharmacy premises that are distance selling premises.

(2) The ICB 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

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

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

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

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

- 4.27 (b) The applicant provided information via their application and the notification process. This information has been reviewed. As the regulations changed in June 2025, we did ask for further information in connection with the advanced or enhanced services to be offered and advised that the applicant needed to provide further information regarding essential services for us to be assured that they will comply with the regulations.
- 4.28 We note that the applicant needs to demonstrate that all the essential, advanced and enhanced services can be provided without face to face contact to anyone in England that requests them. The applicant has mentioned services and parts of the essential services, but has provided very little details of how these will be provided. As there was very little additional information provided with this application, there is very little to make that assurance.
- 4.29 Paragraph 5(2)(3) of Schedule 4 – no information provided.
- 4.30 Paragraph 6 of Schedule 4 no information provided.
- 4.31 Paragraph 7(3) of Schedule 4 – no information provided.
- 4.32 Paragraph 7(5)(b) of Schedule 4 – no information provided.
- 4.33 Paragraph 8(1) of Schedule 4 – no information provided.
- 4.34 Paragraph 8(5) of Schedule 4 – no information provided.
- 4.35 Paragraph 8(15) of Schedule 4 – no information provided.
- 4.36 Paragraph 9(4) of Schedule 4 – no information provided.
- 4.37 Paragraph 10(1) of Schedule 4– no information provided.
- 4.38 Paragraph 13 & 14 of Schedule 4– very limited information provided.
- 4.39 Paragraph 16 of Schedule 4– no information provided.
- 4.40 Paragraph 17 of Schedule 4– no information provided.
- 4.41 Paragraph 18 of Schedule 4– no information provided.
- 4.42 Paragraph 19 & 20 of Schedule 4– no information provided.
- 4.43 Paragraph 21 of Schedule 4– no information provided.
- 4.44 Paragraph 20(1) and Paragraph 22 of Schedule 4 – no information provided.

- 4.45 Paragraph 22B & 22C of Schedule 4 – no information provided.
- 4.46 Pharmacy Website and health promotion zones – very limited information provided.
- 4.47 Advanced and Enhanced Services offered - very limited information provided.
- 4.48 It may be concluded that the PSRC is not satisfied that pharmacy procedures for the pharmacy are likely to secure the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services.
- 4.49 It may also be concluded that the applicant is likely to not satisfy the criteria as set out in the Terms of Service of Pharmacists for the safe and effective provision of all essential services without face to face contact.
- 4.50 Therefore, the PSRC have determined that it is not satisfied that the pharmacy procedures for the pharmacy premises are likely to secure the safe and effective receiving the services, whether on their own or on someone else's behalf, and the applicant or the applicant's staff.

Decision

Regulation 31.

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

Regulation 25(2)(1)(a)

- 4.52 The proposed site is not on the same site or in the same building as the premises of a provider of Primary Medical Services with a patient list. Therefore, this regulation does not apply for this application.

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

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

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

- 4.54 The PSRC is not satisfied that the applicant is likely to satisfy the criteria as set out in the Terms of Service of Pharmacists for the provision of all essential services without face to face contact.
- 4.55 The PSRC is not satisfied that the pharmacy procedures for the pharmacy premises are likely to secure the safe and effective provision of essential services without face to face contact between any person receiving the services, whether on their own or on someone else's behalf, and the applicant or the applicant's staff. Therefore, the application should be refused.

- 4.56 Determination made by London PSRC on behalf of NHS North West London ICB Conditions of approval for a Distance Selling Pharmacy (although this has been refused)
- 4.57 As this application is in respect of distance selling premises, by virtue of regulation 64(3) of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended, if the applicant is subsequently included in the pharmaceutical list for the area of Brent Health and Wellbeing board in respect of the premises included in the application, that inclusion will be subject to the following conditions:
- 4.57.1 The applicant must not offer to provide pharmaceutical services to persons who are present at (which includes in the vicinity of) the proposed premises.
- 4.57.2 The means by which the applicant provides pharmaceutical services must be such that any person receiving those services does so otherwise than at the proposed premises.
- 4.57.3 The proposed premises must not be on the same site or in the same building as the premises of a provider of primary medical services with a patient list.
- 4.57.4 The pharmacy procedures for the premises must be such as to secure:
- 4.57.4.1 the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services, and
- 4.57.4.2 the safe and effective provision of pharmaceutical services without face-to face contact at the proposed premises between any person receiving the services, whether on their own or on someone else's behalf, and the applicant or the applicant's staff; and
- 4.57.5 Nothing in the applicant's practice leaflet, in the applicant's publicity material in respect of the proposed premises, in material published on behalf of the applicant publicising services provided at or from the proposed premises or in any communication (written or oral) from the applicant or the applicant's staff to any person seeking the provision of essential services from the applicant must represent, either expressly or impliedly, that:
- 4.57.5.1 the essential services provided at or from the premises are only available to persons in particular areas of England, or
- 4.57.5.2 the applicant is likely to refuse, for reasons other than those provided for in the applicant's terms of service, to provide drugs or appliances ordered on prescription forms or repeatable prescription forms which are presented by particular categories of patients (eg because the availability of essential services from the applicant is limited to other categories of patients)."

5 The Appeal

In a letter dated 9 December 2025, the Applicant appealed against the Commissioner's decision. The grounds of appeal are:

- 5.1 "I write to formally appeal the decision of the London PSRC, acting on behalf of NHS Northwest London ICB, to refuse Clinidirect Pharma UK Ltd's application for inclusion in the pharmaceutical list as a Distance Selling Premises (DSP).
- 5.2 This appeal sets out clear evidence that the concerns raised are fully resolved and that the proposed DSP meets all requirements under Regulation 25(2)(1)(b), Regulation 64(3), and Schedule 4 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (as amended).
- 5.3 Full Compliance with DSP Requirements and Essential Services
 - 5.3.1 All essential NHS services will be delivered remotely and safely.
 - 5.3.2 Services available to all patients in England without restriction.
 - 5.3.3 Premises will not be open to the public at any time.
 - 5.3.4 National courier arrangements ensure uninterrupted delivery.
 - 5.3.5 Comprehensive SOPs cover clinical checks, safeguarding, IG, RP absence, and business continuity. We have all SOP'S available if required.
- 5.4 Full Schedule 4 Compliance – All Missing Information Now Supplied
 - 5.4.1 Complete DSP-specific documentation for all Schedule 4 requirements, including dispensing procedures, communication channels, delivery processes, staffing, complaints, IG compliance, and business continuity.
- 5.5 Website, Online Presence, and Practice Leaflet – Fully DSP Compliant
 - 5.5.1 Website will clearly say DSP status and remote-only service.
 - 5.5.2 Patients cannot attend the premises.
 - 5.5.3 Health promotion and patient information fully digital.
 - 5.5.4 Practice leaflet contains contact details, GPhC registration, services, delivery, complaints procedure.
- 5.6 Proportionality – The Decision Was Based on Omissions Now Fully Remedied
 - 5.6.1 Full Schedule 4 compliance pack supplied.
 - 5.6.2 DSP-specific SOP summaries provided.

- 5.6.3 Website and leaflet wording confirmed.
- 5.6.4 Remote-only service confirmed.
- 5.7 Commitment to Supporting National Patient Need
 - 5.7.1 No advanced or enhanced services provided.
 - 5.7.2 Focus on chronic dermatological and dressing supply needs, including EB communities.
- 5.8 Request for Reconsideration
 - 5.8.1 Sets aside the refusal decision.
 - 5.8.2 Direct inclusion in the pharmaceutical list under DSP conditions.
- 5.9 We would like to emphasize [sic] that this DSP is established to support the community of EB patients across England and the UK. Our aim is to improve the lives of patients, providing specialist advice on dermatological needs and making a valued contribution to healthcare at large.
- 5.10 As a DSP and a surgical consultant, Clinidirect Pharma UK Ltd does not intend to offer any Enhanced or Advanced services to the public. We will maintain strict DSP status and support the pharmacy workforce, ensuring essential services are delivered safely, remotely, and nationally."
- 5.11 Annex 1 – Schedule 4 Compliance Table

Schedule 4 Paragraph	Description	Evidence Provided
5	Dispensing procedures & clinical checks	SOP Summary attached
6	Remote communication channels	Phone, email, secure forms, digital portals
7	Delivery procedures & cold chain handling	Courier contracts & SOPs
8	Staff roles & training	Staff matrix & training certificates
9	Governance & SOP compliance	SOP manual, audit logs
10	Business continuity & disaster recovery	Continuity plan & contingency procedures
13-22C	Safeguarding, complaints, info	Safeguarding policy, complaints SOP, GDPR

	governance, promotion	health	compliance, leaflets	digital
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Annex 2 – DSP Standard Operating Procedures (SOP) Summary

5.12 Dispensing & Clinical Checks

5.12.1 All prescriptions reviewed by RP or accredited pharmacist.

5.12.2 Repeat dispensing and EPS fully digital.

5.12.3 Prescription audits conducted regularly.

5.13 Remote Communication & Patient Access

5.13.1 Secure online forms, email, telephone, EPS.

5.13.2 Digital counselling and advice available.

5.14 Medicine Delivery & Returns

5.14.1 Tracked national courier.

5.14.2 Cold-chain management per SOP

5.14.3 Returns managed per NHS regulations.

5.15 Staffing, Training & Competency

5.15.1 Defined roles and responsibilities.

5.15.2 Mandatory training and competency assessments.

5.16 Governance & SOP Compliance

5.16.1 SOPs reviewed annually.

5.16.2 Audit logs maintained.

5.17 Safeguarding & Complaints

5.17.1 Staff trained in safeguarding.

5.17.2 Digital complaints reporting, NHS escalation pathway

5.18 Information Governance & Data Protection

5.18.1 GDPR and NHS IG compliance.

5.18.2 Secure electronic records.

5.19 Business Continuity & Disaster Recovery

5.19.1 Contingency plans for IT failure, staff absence, courier delays.

5.19.2 Ensures uninterrupted services.

5.20 Health Promotion & Patient Advice

5.20.1 Digital health promotion and patient guidance.

5.20.2 Signposting to NHS and community resources.

Annex 3 – Website & Practice Leaflet Compliance

5.20.3 Website: 'Clinidirect Pharma UK Ltd – Distance Selling Pharmacy. Services provided remotely to all patients in England. No walk-in access.'

5.20.4 Practice leaflet (digital) to include:

5.20.4.1 Contact details

5.20.4.2 GPhC registration number

5.20.4.3 Services offered (dispensing, repeat dispensing, advice)

5.20.4.4 Delivery arrangements

5.20.4.5 Complaints procedure.”

6 Summary of Representations

This is a summary of representations received on the appeal.

6.1 THE COMMISSIONER

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

6.1.2 The original application for the distance selling pharmacy (DSP) was refused as the applicant did not provide information pertaining to how essential, advanced and enhanced services would be available without face to face. The applicant has in their appeal referred to documents, sops and policies etc but has not provided these as evidence, so we are unable to ascertain if these would provide the assurance that services are available to anyone in England that request them without face to face.

6.1.3 The application form submitted for this DSP stated that advanced and enhanced services were to be provided, but in the appeal documentation it states that these are not going to be provided, which is contradicting. As the original application included advanced and enhanced services, the original refusal we had included information

relating to the lack of information regarding advanced and enhanced services.

- 6.1.4 As there is a lack of information and evidence, we cannot be assured that services will be provided in accordance with the regulations. For completeness we list below the areas of the regulations where there appears to be no or insufficient information.

6.1.4.1 Paragraph 5(2)(3) of Schedule 4 – no information provided.

6.1.4.2 Paragraph 6 of Schedule 4 no information provided.

6.1.4.3 Paragraph 7(3) of Schedule 4 – no information provided.

6.1.4.4 Paragraph 7(5)(b) of Schedule 4 – no information provided.

6.1.4.5 Paragraph 8(1) of Schedule 4 – no information provided.

6.1.4.6 Paragraph 8(5) of Schedule 4 – no information provided.

6.1.4.7 Paragraph 8(15) of Schedule 4 – no information provided.

6.1.4.8 Paragraph 9(4) of Schedule 4 – no information provided.

6.1.4.9 Paragraph 10(1) of Schedule 4– no information provided.

6.1.4.10 Paragraph 13 & 14 of Schedule 4– very limited information provided.

6.1.4.11 Paragraph 16 of Schedule 4– no information provided.

6.1.4.12 Paragraph 17 of Schedule 4– no information provided.

6.1.4.13 Paragraph 18 of Schedule 4– no information provided.

6.1.4.14 Paragraph 19 & 20 of Schedule 4– no information provided.

6.1.4.15 Paragraph 21 of Schedule 4– no information provided.

6.1.4.16 Paragraph 20(1) and Paragraph 22 of Schedule 4 – no information provided.

6.1.4.17 Paragraph 22B & 22C of Schedule 4 – no information provided.

6.1.4.18 Pharmacy Website and health promotion zones – very limited information provided.

6.1.4.19 Advanced and Enhanced Services offered - very limited information provided.

- 6.1.5 We would request that this appeal is dismissed and the application refused.”

7 Summary of Observations

This is summary of observations received.

7.1 THE APPLICANT

7.1.1 “Thank you for your letter dated 11 February 2026, enclosing representations received from NHS Northeast London ICB.

7.1.2 In accordance with your instructions, we restrict our observations to rebuttal of matters already raised.

Operational Model and Regulatory Compliance

7.1.2.1 Since submission of the original application, the operational model has been refined to reflect evolving expectations for Distance Selling Pharmacies (DSPs) and to ensure full compliance with the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.

7.1.3 For clarity:

7.1.3.1 All services will be delivered remotely; no essential, advanced, or enhanced services will be provided face-to-face.

7.1.3.2 Medicines will not be handed to patients at the premises.

7.1.3.3 Access to services will be via secure online platform, telephone, and remote consultation only.

7.1.3.4 Medicines will be supplied through secure delivery arrangements, accessible nationally.

7.1.3.5 Services will be provided in full compliance with all regulatory requirements, including the issuance of online prescriptions where appropriate.

7.1.4 There is no intention to provide face-to-face advanced services. The purpose is to deliver professional pharmaceutical help to those in need, safely, lawfully, and transparently.

Alleged Lack of Information under Schedule 4

7.1.5 It has been suggested that information is missing in respect of several paragraphs of Schedule 4.

7.1.6 We respectfully submit that the application and supporting documentation clearly set out:

7.1.6.1 The fully remote service model.

7.1.6.2 Governance, Standard Operating Procedures (SOPs), and operational controls.

7.1.6.3 National access arrangements for essential services.

7.1.6.4 Delivery and communication processes.

7.1.7 The ICB's assertion of "no information" reflects the level of detail provided in the initial submission, but all critical arrangements were proportionately described, consistent with DSP application requirements.

Advanced and Enhanced Services

7.1.8 The ICB refers to an alleged contradiction regarding advanced and enhanced services.

7.1.9 For clarity:

7.1.9.1 The original application indicated potential provision of advanced services.

7.1.9.2 The appeal clarified that only services capable of full remote delivery in compliance with DSP regulations will be undertaken.

7.1.9.3 No enhanced services are proposed.

7.1.10 This represents a refinement for regulatory compliance, not a contradiction.

Website and Health Promotion

7.1.11 It is acknowledged that the website was not fully populated at the time of application.

7.1.12 Prior to commencement of NHS services, the website will:

7.1.12.1 Clearly identify the pharmacy as a Distance Selling Pharmacy.

7.1.12.2 Explain how essential services can be accessed remotely.

7.1.12.3 Provide complaints procedures and contact details.

7.1.12.4 Detail delivery arrangements.

7.1.12.5 Display GPhC registration information.

7.1.12.6 Include appropriate health promotion content and NHS signposting.

7.1.13 The website will fully reflect the remote-only service model before any services are delivered.

Patient Benefit and National Access

7.1.14 The applicant's purpose is to provide safe, professional pharmaceutical services to those in need, including issuing online prescriptions in accordance with all regulatory requirements.

7.1.15 This model enables national access, supporting patients with specialist needs, including individuals living with Epidermolysis Bullosa or other complex long-term conditions, who benefit from consistent remote advice and medicine supply.

7.1.16 There is no intention to circumvent regulatory safeguards; all services will be delivered lawfully, transparently, and in full alignment with DSP requirements.

Conclusion

7.1.17 The statutory test is whether satisfactory arrangements are in place to provide essential services to any person in England without face-to-face contact.

7.1.18 We respectfully submit that CliniDirect Pharma UK Ltd:

7.1.18.1 Operates an entirely remote, compliant model.

7.1.18.2 Provides robust governance and SOPs.

7.1.18.3 Ensures national patient access.

7.1.18.4 Delivers services lawfully and professionally.

7.1.19 On this basis, we request that the Pharmacy Appeals Committee quash the Commissioner's decision and direct inclusion of CliniDirect Pharma UK Ltd in the Pharmaceutical List as a Distance Selling Pharmacy.

7.1.20 We remain available should the Committee consider oral representations would assist in determination of the 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 not provided any information in the application form on this point but the Committee noted that the wording of the application form only required the Applicant to include information in the relevant section if the proposed premises were adjacent to, or in close proximity to, another pharmacy or dispensing appliance contractor premises. The Committee considered it reasonable to determine that the lack of information in the application form on this point when read with the wording of the application form allowed it to be reasonably satisfied that the Applicant considered that the proposed premises were not adjacent to, or in close proximity to, another pharmacy or dispensing appliance contractor premises.

8.7 The Committee noted the conclusion of the Commissioner that "*There are no current pharmacies listed as the proposed premises or adjacent to the proposed premises. Therefore regulation 31 does not apply for this application.*" The Committee noted that this had not been disputed on appeal or in subsequent representations. The Committee therefore determined that it was not required to refuse the application under the provisions of Regulation 31.

Regulation 25

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

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

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

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

in respect of pharmacy premises that are distance selling premises.

- (2) *NHS England must refuse an application to which paragraph (1) applies—*
- (a) *if the premises in respect of which the application is made are on the same site or in the same building as the premises of a provider of primary medical services with a patient list; and*
 - (b) *unless NHS England is satisfied that the pharmacy procedures for the pharmacy premises are likely to secure—*
 - (i) *the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services, and*
 - (ii) *the safe and effective provision of pharmaceutical services without face to face contact at the pharmacy premises between any person receiving the services, whether on their own or on someone else's behalf, and the applicant or the applicant's staff."*

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

Additional information to be included with excepted applications

8. *If the applicant (A) is making an excepted application, A must include in that application details that explain—*
- (a) *A's belief that the application satisfies the criteria included in one of the regulations in Part 4 which need to be satisfied if section 129(2A) and (2B) of the 2006 Act (regulations as to pharmaceutical services) are not to apply in relation to that application; and*
 - (b) *if the regulation includes reasons for which the application must be refused, why the application should not be refused for those reasons.*

Nature of details to be supplied

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

Regulation 25(1)

- 8.10 In relation to Regulation 25(1), the Applicant is applying for inclusion in the relevant pharmaceutical list, as a person not already included in a pharmaceutical list, and paragraph (1)(a) therefore operates to disapply the

specified provisions of section 129 of the National Health Service Act 2006, provided that paragraph (2) does not require the application to be refused.

Regulation 25(2)(a)

- 8.11 The Committee noted that the Applicant had not included any information in the relevant section of the application form that deals with this point. The Committee noted that the application form states that the relevant section should only be completed if the proposed premises are on the same site or in the same building as the premises of a provider of primary medical services with a patient list. The Committee considered that, where the Applicant did not include any information in this section, it was reasonable to consider that the Applicant was indicating that the proposed premises were not on the same site or in the same building as the premises of a provider of primary medical services with a patient list. The Commissioner had concluded that *“the proposed site is not on the same site or in the same building as the premises of a provider of Primary Medical Services with a patient. Therefore, this regulation does not apply for this application”*. Based on the information available to it, the Committee therefore determined that the proposed premises were not on the same site as, or in the same building as the premises of a provider of primary medical services with a patient list.

Regulation 25(2)(b)

- 8.12 As far as Regulation 25(2)(b) is concerned, the Committee considered the information which had been provided by the Applicant in relation to its procedures for the provision of essential services and pharmaceutical services, including the seven Standard Operating Procedures (SOPs) that it intends to use at the proposed pharmacy premises.
- 8.13 The Regulations require the Committee to be satisfied as to a number of matters, including that essential services will be provided on an uninterrupted basis, across England, and that pharmaceutical services will be provided in a safe and effective way without face to face contact.
- 8.14 Paragraph 8 of Schedule 2 requires an applicant to provide details in relation to an application, and paragraph 10 of Schedule 2 indicates that the obligation is only discharged if the information or documentation provided is sufficient to satisfy the Commissioner in receipt of it, with good cause, that no relevant information or documentation is missing, having regard to the uses that the Commissioner may need to make of the information or documentation when carrying out its functions.
- 8.15 The Committee noted the references throughout the application form, subsequent correspondence and the appeal from the Applicant that *“we operate under a comprehensive set of robust clinical SOPs ...”*. The Committee noted that some SOPs had been provided by the Applicant. The Applicant, on appeal, had stated *“We have all SOPs available if required”* and had also provided “Annex 1 - Schedule of Compliance” and “Annex 2 – DSP Standard Operating Procedures (SOP) Summary”.
- 8.16 The Committee was of the view that it is a matter for the Applicant to provide the relevant information required, either in the first instance to the

Commissioner or on appeal, to demonstrate that there would be compliance with Regulation 25. The Committee was of the view that this does not have to be in the form of SOPs and further that 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.

- 8.17 The Committee has asked itself whether it has sufficient information and documentation which would address the criteria in Regulation 25(2)(b). If the Committee is to be satisfied of the matters in that paragraph, the Committee must be provided with evidence to demonstrate these matters. In this case, that evidence put forward has taken the form of the original application and the SOPs which the Applicant has prepared or commissioned.
- 8.18 The Committee has sought evidence within the SOPs, application and subsequent appeal in order to satisfy itself that it is appropriate to grant the application, the absence of which would require it to reject it.
- 8.19 The Committee first considered how the Applicant would provide essential services without interruption.
- 8.20 In respect of uninterrupted provision of services, the Committee noted that the Commissioner *"is not satisfied that pharmacy procedures for the pharmacy are likely to secure the uninterrupted provision of essential services during the opening hours of the premises ..."*.
- 8.21 The Committee noted that the Applicant, on appeal, states *"National Courier arrangements ensure uninterrupted delivery."* The Committee noted that the application form stated *"...all essential services... are delivered remotely via our website, email or telephone helpline during all contracted opening hours"* and went on to state:
- 8.21.1 *"Trained Staff & Workflow Planning: Sufficient trained staff are available during all opening hours to manage incoming prescriptions, queries, and communications, ensuring continuous service provision."*
- Business Continuity: Robust contingency planning is in place to ensure continued operation during staff shortages, system downtime, or delivery delays."*
- 8.22 The Committee noted that the Applicant had not expanded upon this in its appeal and was mindful that the uninterrupted provision of services was greater than patients being able to communicate with the pharmacy. Whilst reference had been made to *"sufficient trained staff"* being available, no information had been provided by the Applicant with regard to the Responsible Pharmacist (RP) and, in the RPs absence, a second pharmacist and how they would ensure that essential services would be available without disruption.
- 8.23 Based on the lack of information before it, the Committee was not satisfied that the provision of services would be without interruption.

- 8.24 With regard to services being available to persons anywhere in England, the Commissioner had concluded “...PSRC is not satisfied that pharmacy procedures for the pharmacy are likely to secure the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services.”
- 8.25 The Committee noted the statements from the Applicant in the application form that
- 8.25.1 *“Remote Access All Essential services are delivered remotely via our website, email or telephone helpline during all contracted opening hours.*
- Tracked Home Delivery: All medications are dispensed and dispatched using secure, tracked delivery services directly to the patient’s address.*
- ...
- Safe Dispensing & Delivery: Medications are dispensed following standard SOPs and delivery securely to the patient’s address ...”*
- 8.26 The Committee further noted SOP 1 Provision of NHS Essential Services as provided by the Applicant which states:
- 8.26.1 *“All essential services (e.g. dispensing, repeat dispensing, public health advice, signposting) must be available to any patient in England without face-to-face interaction.”*
- 8.27 On balance, the Committee was satisfied that the provision of essential services would be available to persons anywhere in England.
- 8.28 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 stated *“It may also be concluded that the applicant is likely to not satisfy the criteria as set out in the Terms of Service of Pharmacists for the safe and effective provision of all essential services without face to face contact.”*
- 8.29 The Committee noted the response from the Applicant on appeal that *“Premises will not be open to the public at any time”* and *“Remote only service confirmed”*. Whilst the Committee noted the comments from the Commissioner, the Committee was of the view, based on the information before it, that there was nothing provided which demonstrated that pharmaceutical services would be provided by face to face contact at the pharmacy premises.
- 8.30 The Committee was also mindful of the regulatory changes as of 1 October 2025, that distance selling pharmacies can no longer provide Directed services (Advance, 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 to patients present at its premises.

- 8.31 The Committee noted that in the application form the Applicant had stated that they would be providing various services, as set out at 1.4 above and had confirmed to the Commissioner that *“Should any advanced, enhanced, or locally commissioned services be provided in the future, they will be delivered solely through telephone consultations, video conferencing, or other secure, NHS-compliant digital platforms.”* and had gone on to state *“For absolute clarity ... will not provide any advanced, enhanced or locally commissioned services at the pharmacy premises under any circumstances”*. The Committee noted that further information had been provided by the Applicant in this regard in SOP 3 “Provision of Directed Services (Flu and Covid-19 only)”.
- 8.32 The Committee noted however that the Applicant had then gone on to state, on appeal, *“No advanced or enhanced services provided. Focus on chronic dermatological and dressing supply needs, including EB communities.”* and further *“As a DSP and a surgical consultant, Clinidirect Pharma UK Ltd does not intend to offer any Enhanced or Advanced services to the public.”* The Committee was of the view that it was ambiguous with regard to the services that the Applicant was proposing to offer. However, based on the information provided, the Committee was of the view that the Applicant would not be able to provide any advanced or enhanced services at the premises.
- 8.33 The Committee was mindful 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.
- 8.34 The Committee was of the view, based on the information before it, that the provision of pharmaceutical services would be without face to face contact.
- 8.35 The Committee went on to consider whether safe and effective provision of pharmaceutical services was likely to be secured.
- 8.36 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.
- 8.37 The Committee paid particular attention to the following aspects of the essential services, which it considered were more difficult to provide safely and effectively in a distance selling context:
- 8.37.1 Dispensing of drugs and appliances
 - 8.37.2 Urgent supply without a prescription
 - 8.37.3 Preliminary matters before providing ordered drugs or appliances
 - 8.37.4 Providing ordered drugs or appliances
 - 8.37.5 Refusal to provide drugs or appliances ordered
 - 8.37.6 Further activities to be carried out in connection with the provision of dispensing services
 - 8.37.7 Disposal service in respect of unwanted drugs

8.37.8 Promotion of healthy lifestyles

8.37.9 Prescription linked intervention

8.37.10 Health campaigns

8.37.11 Signposting

8.37.12 Support for self-care

8.37.13 Discharge medicines service

8.37.14 Websites and health promotion zones

- 8.38 The Committee was of the opinion that the procedures adopted by the pharmacy were not likely to secure the safe and effective provision by the Applicant of the following essential services:

Dispensing of drugs and appliances

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

- 8.40 Whilst the Committee noted the comments from the Applicant that “*All medicines and appliances will be supplied to patients exclusively via secure, tracked courier or postal services ...*” no information had been provided by the Applicant as to how non electronic prescriptions would be presented at the pharmacy. Therefore the Committee was not 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

- 8.41 The Committee considered whether the Applicant had explained how it proposes safely and effectively to receive requests from prescribers for urgent supplies of drugs and appliances.

- 8.42 The Committee noted that the Applicant had made no reference, either in its original application form or on appeal as to how it would safely and effectively receive requests from prescribers for urgent supplies of drugs and appliances.

- 8.43 The Committee was not 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

- 8.44 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.

- 8.45 The Committee noted that there was no information provided by the Applicant as to how the exemption evidence would be obtained from the patient.
- 8.46 Given the lack of information the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 7(3) of Schedule 4.
- 8.47 The Committee considered whether the Applicant had explained how charges will be paid and noted that there was no information provided as to how payment was to be taken by the Applicant or how they would ascertain that payment had then been made.
- 8.48 The Committee was not 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

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

8.50.1 *"Tracked Home Delivery: All medications are dispensed and dispatched using secure, tracked delivery services directly to the patient's address. Special safeguards are in place for the delivery of CDs and cold chain items."*

- 8.51 The Applicant had further stated *"All medicines and appliances will be supplied to patients exclusively via secure, tracked courier or postal services..."*. The Committee noted that, on appeal, the Applicant had go on to state *"National courier arrangements ensure uninterrupted delivery."* The Committee noted 'Annex 1 – Schedule 4 Compliance Table' which stated:

Schedule 4 Paragraph	Description	Evidence Provided
7	Delivery procedures & cold chain handling	Courier contracts & SOPs

- 8.52 In Annex 2 - DSP Standard Operating Procedures (SOP) Summary, the Applicant had stated:

8.52.1 *"Medicine Delivery & Returns*

Tracked national courier.

Cold-chain management per SOP

Returns managed per NHS regulations”

- 8.53 Whilst the Committee noted that some information had been provided as to how deliveries would be made, this had not been expanded upon. The Committee noted that there was a lack of information provided with regard to the security of Controlled Drugs whilst they were in transit. The Committee was also mindful that there was no information provided with regard to missed or failed deliveries or how the Applicant would ensure that the integrity of thermolabile products would remain within the recommended temperature limits, how this would be monitored or what would happen if the cold chain was not maintained.
- 8.54 Given the lack of information, the Committee was not satisfied that there would be compliance with paragraph 8(1) of Schedule 4.
- 8.55 The Committee noted that the Applicant had not responded to the question on the application form as to whether they were undertaking to provide appliances. In further information, the Applicant had stated “*All medicines and appliances will be supplied ...*” The Committee noted that the Applicant had not provided any further information with regard to appliances and how they would supply them if it required measuring or fitting by a registered pharmacist. Further, the Applicant had provided no information regarding signposting for those patients who did require an appliance which may require measuring or fitting that the Applicant was unable to provide. Based on the lack of information before it, the Committee was of the view that it had not been provided with information sufficient to show that there would be compliance with paragraph 8(4) of Schedule 4.
- 8.56 The Committee considered whether the Applicant had explained what containers will be suitable for posted/delivered items.
- 8.57 The Committee noted that the Applicant had provided no information with regard to this aspect of the terms of service in either the original application form or on appeal.
- 8.58 Given the lack of information the Committee was not 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

- 8.59 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 to review the patients treatment.
- 8.60 The Committee noted that no information had been provided either in the original application form, or on appeal.

- 8.61 Therefore, the Committee was not 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

- 8.62 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 a long term, stable medical condition (that is, a medical condition that is unlikely to change in the short to medium term), and (ii) requires regular medicine in respect of that medical condition.

- 8.63 The Committee noted that in the application form, the Applicant had stated:

8.63.1 *Remote Access: All essential services (including ..., repeat dispensing, ...) are delivered remotely via our website, email, or telephone helpline during all contracted opening hours."*

- 8.64 The Committee noted that this had not been expanded upon and further that there was no mention by the Applicant either in the application form or on appeal with regard to how they would provide appropriate advice about the benefits of repeat dispensing.

- 8.65 The Committee was not 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

- 8.66 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.

- 8.67 The Committee noted the Applicant, in the original application form had stated:

8.67.1 *"Remote Access: All essential services (including ... disposal of unwanted medicines, ...) are delivered remotely via our website, email, or telephone helpline during all contracted opening hours."*

- 8.68 In Annex 2 – DSP Standard Operating Procedures (SOP) summary the Applicant stated:

"Medicine Delivery & Returns

...

Returns managed per NHS Regulations"

- 8.69 The Committee noted that this had not been expanded upon and no further information had been provided by the Applicant with regard to how returns of unwanted drugs would be received and disposed of.

- 8.70 Given the lack of information, the Committee was not satisfied that there would be compliance with paragraphs 13 – 15 of Schedule 4.

Promotion of healthy lifestyles

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

- 8.72 The Committee noted the application form stated:

8.72.1 *“Remote Access: All essential services (including ... healthy lifestyle promotion, ...) are delivered remotely via our website, email, or telephone helpline during all contracted opening hours.”*

- 8.73 On appeal, in Annex 2 - DSP Standard Operating Procedures (SOP) summary the Applicant stated:

8.73.1 *“Health Promotion & Patient Advice*

Digital health promotion and patient guidance

Signposting to NHS and community resources”

- 8.74 The Committee noted that this had not been expanded upon and no further information had been provided by the Applicant either in the original application form or on appeal.

- 8.75 The Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 16-18 of Schedule 4.

Prescription linked intervention

- 8.76 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.

- 8.77 The Committee noted that no information had been provided by the Applicant in respect of this aspect of the terms of service. Therefore, the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 17 of Schedule 4.

Health campaigns

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

- 8.79 The Committee noted that no information had been provided by the Applicant in respect of this aspect of the terms of service. The Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 18 of Schedule 4.

Signposting

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

8.81 The Committee noted that Annex 2 - DSP Standard Operating Procedures (SOP) summary it stated:

8.81.1 *“Health Promotion & Patient Advice*

...

Signposting to NHS and community resources”

8.82 The Committee noted that no further information regarding signposting in the context of the terms of service had been provided by the Applicant.

8.83 The Committee was not 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

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

8.85 The Committee noted the statement in the Applicant’s original application form that:

8.85.1 *“Remote Access: All essential services (including ... and self-care support) are delivered remotely via our website, email, or telephone helpline during all contracted opening hours.”*

8.86 The Committee noted that this had not been expanded upon and no further information had been provided on appeal.

8.87 Given the lack of information the Committee was not 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

8.88 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 regimen by the staff of an NHS trust or NHS foundation trust as part of arrangements linked to the transfer of care between different providers of NHS services.

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

8.90 The Committee noted that the Applicant had provided no information either in its original application form, or on appeal with regard to the Discharge Medicines Service. Given the lack of information the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 22B and 22C of Schedule 4.

8.91 *Other considerations*

8.92 The Committee noted the information provided by the Applicant with regard to the other services that they were proposing to offer and in particular the Applicants *“Focus on chronic dermatological and dressing supply needs, including EB communities.”*

8.93 The Applicant had further gone on to state:

8.93.1 *“We would like to emphasize that this DSP is established to support the community of EB patients across England and the UK. Our aim is to improve the lives of patients, providing specialist advice on dermatological needs and making a valued contribution to healthcare at large.”*

8.94 Whilst the Committee commended the Applicant for their intention to support this group of patients, it was mindful that this was not a relevant criteria for a distance selling pharmacy as set out in the Regulations. The Committee was of the view that it was the Terms of Service, as set out in the Regulations, to which it had to have regard and to assess the application against this criteria.

8.95 In relation to websites and health promotion zones, the Committee was, on balance, satisfied that the procedure adopted by the pharmacy (and general adherence to the Terms of Service) would be “likely to secure” safe and effective provision.

Summary

8.96 On the information before it, the Committee could not be satisfied that there are procedures likely to secure the safe and effective provision of pharmaceutical services as required by Regulation 25(2)(b).

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

8.97.1 confirm the Commissioner’s decision;

8.97.2 quash the Commissioner’s decision and redetermine the application;

8.97.3 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.

- 8.98 Although the decision reached by the Commissioner is the same as that of the Committee, it has reached that decision for different reasons, as set out above. In those circumstances, the Committee determined that the decision of the Commissioner must be quashed.
- 8.99 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.
- 8.100 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.
- 8.101 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 not 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 not 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 refused.

Case Manager Primary Care Appeals