NHS Resolution

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

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

12 December 2025

REF: SHA/26712

APPEAL AGAINST SOMERSET ICB DECISION TO REFUSE AN APPLICATION BY PATIENT CHOICE DIRECT LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST OFFERING UNFORESEEN BENEFITS UNDER REGULATION 18 AT UNIT 1, BLOCK B, WESTPARK, CHELSTON, WELLINGTON, TA21 9FN

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:

Patient Choice Direct Ltd
PCSE, on behalf of Somerset ICB

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

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

REF: SHA/26712

APPEAL AGAINST SOMERSET ICB DECISION TO REFUSE AN APPLICATION BY PATIENT CHOICE DIRECT LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST OFFERING UNFORESEEN BENEFITS UNDER REGULATION 18 AT UNIT 1, BLOCK B, WESTPARK, CHELSTON, WELLINGTON, TA21 9FN

1 The Application

By application dated 10 March 2025, Patient Choice Direct Ltd ("the Applicant") applied to Somerset ICB ("the Commissioner") for inclusion in the pharmaceutical list offering unforeseen benefits under Regulation 18 at Unit 1, Block B, Westpark, Chelston, Wellington, TA21 9FN. In support of the application it was stated:

1.1 In response to section 4 'Pharmaceutical services to be provided at these premises', the Applicant states that it undertakes to provide the following services:

1.1.1 "*Elastic Hosiery*

1.1.2 *Lymphoedema Garments*

1.1.3 *Dressings and Woundcare*

1.1.4 *Any other appliances requested*"

1.2 In response to section 5 'Applications in relation to premises that are in close proximity to other listed chemist premises', the Applicant left the section blank.

Information in support of the application

Please describe the unforeseen benefit(s) that you are offering to secure and how it will secure improvements or better access to pharmaceutical services, or pharmaceutical services of a specified type in the HWB's area.

1.3 "Patient Choice Direct's application meets the need for unforeseen benefits under Regulation 18(2)(b) of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013. This regulation allows NHS England to grant applications where unforeseen benefits demonstrably improve patient care or access.

1.4 Additionally, Chapter 8 of the NHS Market Entry Guidance confirms that unforeseen benefits applications should not be dismissed solely because they were not foreseen in the Pharmaceutical Needs Assessment (PNA). Given the documented inefficiencies in compression garment supply, PCD's service

directly aligns with NHS England's commitment to improving patient outcomes and reducing errors.

1.5 Unforeseen Benefits

1.6 Patient Choice Direct (PCD) is an online retailer of compression hosiery and Lymphoedema garments via its website, www.patientchoicedirect.com. As the existing model for dispensing compression garments through pharmacies and DACs is plagued by high prescription error rates, delays and inefficiencies that negatively impact patient care, PCD began incorporating NHS prescriptions into its service in 2016, delivering substantial benefits not anticipated in the HWB's Pharmaceutical Needs Assessment (PNA). These include:

1.7 Elimination of Prescription errors

1.8 Dispensing compression garments has [sic] historically been plagued by inefficiencies and errors. Professional studies highlight the scale of the problem:

1.8.1 A Wounds International study revealed that only 17% of patients received their compression garments without problems, while:

1.8.2 30% received the wrong item.

1.8.3 8% received no item at all.

1.8.4 17% of delays were caused by misplaced or lost paperwork at GP surgeries, with 11% caused by similar issues at pharmacies.

1.8.5 Another 17% of delays had no identified cause.

1.9 These findings expose the pervasive inefficiencies in traditional systems that lead to widespread patient dissatisfaction and compromised care.

1.10 Similarly, a Journal of Community Nursing (JCN) study in 2021 highlighted that up to 50% of compression prescriptions were dispensed inaccurately due to complexities in product codes and prescription details, with over 70% of clinicians anticipating problems with their patients' compression prescriptions.

1.11 By implementing robust validation processes, PCD ensures 100% accuracy in the prescriptions it processes. All prescriptions are validated against the original clinical requirements, with inaccuracies corrected before dispensing. This eliminates errors at the dispensing stage, reducing waste an inefficiencies, and is already preventing over £1 million in wasted prescriptions annually.

1.12 Testimonial – [SL] (Clinician:

1.13 "Switching to Patient Choice Direct has been hugely beneficial. I know the garment will be the correct one. There won't be any errors, and it's a very quick, seamless service."

1.14 Timely Access to Vital Therapy

1.15 Delays in receiving compression garments have a significant impact on patient outcomes. Evidence from professional audits and research highlights:

1.15.1 Delays often lead to garments no longer fitting correctly, requiring new measurements and prescriptions, which compromise the continuity of therapy, and a new prescription being generated at NHS expense.

1.15.2 Traditional dispensing systems cause extended delays, with some patients waiting up to six weeks or longer for garments.

1.16 PCD has addressed this by introducing a streamlined service that ensures prescription garments are delivered straight to the patient's home, or their clinician as required. The majority of ready to wear garments are delivered within 1 week, and most "made to measure" garments arrive in less than 14 days. This prompt turnaround time allows therapy to begin without unnecessary delays, improving treatment adherence and outcomes.

1.17 Testimonial – [RH] (Clinician):

1.18 "By the time the compression came – four to six months later – it no longer fit, and we had to start all over again. Patient Choice Direct has streamlined the process and ensured patients get what they need."

1.19 Significant Cost Savings for the NHS

1.20 PCD's prescription validation and error prevention processes have yielded significant financial benefits for the NHS. Examples include:

1.20.1 Over £103,000 saved in January 2025 by preventing the dispensing of incorrect prescriptions.

1.20.1.1 Dec 2024: £97,619

1.20.1.2 Nov 2024: £118,336

1.20.1.3 Oct 2024: £101,248

1.20.2 Annualised savings far exceeding £1 million, achieved by reducing waste and improving efficiency.

1.21 These cost savings allow NHS resources to be reallocated to other critical areas.

1.22 Improved Patient Safety

1.23 Errors and delays in dispensing compression garments pose direct risks to patient safety, including discomfort, harm, and non-adherence to prescribed therapy. PCD eliminates these risks by ensuring that patients receive accurate and clinically appropriate garments promptly, safeguarding treatment outcomes.

1.24 Testimonial – Patient (Anonymous):

1.25 “Since I switched, I’ve had no problems at all. The service is reliable, and if there’s ever a query, there’s someone helpful on the other end to sort it out.”

5. Enhanced Experience for Clinicians and Patients

1.26 PCD’s streamlined approach benefits both patients and clinicians:

1.26.1 Patients experience a seamless, stress-free service that removes barriers to accessing their prescribed compression garments.

1.26.2 Clinicians are relieved of significant administrative burdens, such as resolving prescription errors or delays, enabling them to focus on providing patient care.

1.27 Testimonial – [SL] (Clinician):

1.28 “We were spending several hours a week on the telephone clearing up prescription queries. Patient Choice Direct has taken that burden away.”

1.29 Superior Alternative to Previous Projects

1.30 Past attempts across the UK to solve issues with lymphoedema prescriptions have included allocating local budgets for nurse-led purchasing, trust-level tender arrangements with restricted formularies, and negotiated pricing per trust. While these efforts sought improvements, they often added significant administrative burdens to clinicians and support staff. By contrast, PCD’s approach demonstrates phenomenal results by leveraging the existing system and optimising it for accuracy and speed without additional bureaucracy.

1.31 Summary of Unforeseen Benefits

1.32 PCD provides a groundbreaking and essential service that:

1.32.1 Ensures accurate prescriptions, eliminating NHS waste.

1.32.2 Speeds up access to compression therapy, reducing patient harm.

1.32.3 Saves over £1 million annually, freeing up NHS resources.

1.32.4 Improves patient safety, preventing treatment delays.

1.32.5 Closes a critical supply chain gap, providing competition and choice.

1.32.6 Reduces GP and pharmacy workload, streamlining prescription management.

1.33 References

1.33.1 Board, J. et al. (2022). Exploring delays in receiving compression therapy garments: A survey of patients’ experiences. Wounds International, 13(1), 54-58.

1.33.2 Inaccuracies in dispensing compression garments: Survey results. Journal of Community Nursing, November 2021, Vol. 35, No. 5, 64-67.

1.33.3 Patient Choice Direct Service Evaluation, 2024/2025.

1.33.4 Woods, M. (2018). Audit cycle of the provision of compression garments on prescription. British Journal of Nursing, 27(15), 869-875."

Please explain how you intend to secure the unforeseen benefit(s).

1.34 "Why a New DAC is Essential:

1.35 Confidentiality Notice

1.36 [Confidential section redacted]

1.37 Measures to Secure Benefits

1.38 Dedicated DAC premises

1.39 PCD PCD [sic] operates a purpose-built facility in Somerset for the efficient, high-volume dispensing of both ready-to-wear and made-to-measure compression garments.

1.40 This is the first service of its kind in the UK, ensuring faster and more accurate supply than existing NHS alternatives.

1.41 Local home delivery and collection service

1.42 The Somerset PNA 2022-2025 identifies gaps in pharmaceutical access, particularly for specialist appliances.

1.43 PCD will provide same-day or next-day local home delivery, using its own drivers in the South West.

1.44 Other regions have independent DACs offering personalised delivery, such as:

1.44.1 Ainsworth Surgical Supplies (North West)

1.44.2 South Yorkshire Ostomy Supplies (North East)

1.44.3 Rapidcare (South East)

1.45 No such service exists in the South West, meaning patients rely on national courier DACs, which lack local, same-day delivery options.

1.46 Investment in Technology

1.47 DAC status will allow PCD to fully integrate its PMR system with the NHS Spine, enabling direct receipt and processing of Electronic Prescriptions (EPS).

1.48 This will eliminate administrative delays and further improve efficiency.

1.49 Streamlined Clinician Collaboration

1.50 PCD actively validates prescriptions before submission, preventing errors before dispensing.

1.51 No other service currently provides this level of intervention for lymphoedema patients.

1.52 Commitment to NHS Standards

1.53 The service aligns with NHS England's strategic priorities:

1.53.1 Reducing prescription errors

1.53.2 Eliminating unnecessary NHS waste

1.53.3 Improving healthcare access in underserved areas

1.53.4 PCD's service model is a proven, scalable solution that can be replicated across the NHS to improve patient care and efficiency.

1.54 Precedents and additional information:

1.55 Ward Mobility (Canvey Island, Essex)

1.56 Originally a mobility aids supplier, Ward Mobility offered NHS prescription dispensing for its continence and ostomy products by using an agency partner (Ward Surgical Ltd) to process the prescriptions.

1.57 Ward Surgical was sold and the agency relationship ended, So Ward Mobility applied for and successfully obtained a DAC listing to dispense NHS prescriptions independently to prevent its patients losing access to the service.

1.58 Ward Mobility's approval shows regulatory support for a DAC where an existing business is already effectively operating as a DAC under almost identical circumstances but lacks formal status, and proves that a business already engaged in prescription fulfilment via an agency model can be recognised as an independent DAC.

1.59 Parallels to PCD:

1.60 Like Ward Mobility, PCD currently relies on an external DAC partner (Patient Choice Ltd) for processing prescriptions, which creates operation inefficiencies, but PCD's model goes even further than Ward Mobility's, offering a validated prescription service that actively prevents errors and waste.

1.61 Nightingale Home Delivery Service (Bridgwater, Somerset)

1.62 Nightingale, with an exiting DAC site in Wales, faced Electronic Prescription Service (EPS) restrictions and successfully applied for a DAC licence in Bridgwater to enhance prescription fulfilment for its English patients.

1.63 Parallels to PCD:

1.64 PCD currently relies on an agency partner and lacks direct NHS integration, just as Nightingale did before gaining DAC status.

1.65 Approval of PCD's DAC would allow direct EPS integration, ensuring faster, more efficient dispensing.

1.66 Manfred Sauer UK (Northampton)

1.67 This was granted after the applicant proved that a standalone DAC would significantly improve service speed of and patient choice for urology devices.

1.68 Parallels to PCD:

1.69 PCD is demonstrating the same inefficiencies in the current compression hosiery supply chain, with long delays, errors and patient access issues. PCD's model offers immediate service improvements, just as Manfred Sauer's application did.

1.70 Conclusion

1.71 Patient Choice Direct's proven model addresses systemic inefficiencies in compression garment dispensing. Evidence from professional research, including the Wounds International and Journal of Community Nursing studies, supports the significant value of this application.

1.72 Approving this DAC licence is the logical and necessary step for NHS England to take. NHS Market Entry regulations explicitly allow for applications based on unforeseen benefits, and the precedence of Ward Mobility, Nightingale, and Manfred Sauer UK prove that similar cases have been granted DAC status. PCD's service has already demonstrated a reduction in prescription errors, a significant improvement in patient access, and documented NHS savings exceeding £1 million annually. Rejecting this application would force patients back into a broken system, increase NHS waste, and remove a proven solution that is actively fixing inefficiencies. Given that NHS England has approved DAC applications for less financially impactful and less efficiency-focused cases, there is no justifiable reason to refuse PCD's DAC status. Approval must be granted to ensure patient care is protected, NHS waste is reduced, and prescription errors are permanently eliminated.

1.73 PCD's application meets all NHS England market entry criteria under Regulation 18(2)(b) of the 2013 NHS Pharmaceutical Regulations. It will:

1.73.1 Eliminate prescription errors and save the NHS over £1 million annually.

1.73.2 Drastically improve access to compression therapy.

1.73.3 Reduce NHS waste and administrative burdens.

1.73.4 Operate sustainably under DAC status, securing the future of compression hosiery prescription services.

1.74 A rejection would risk forcing PCD to cease NHS Supply, leaving nearly 70,000 patients without a reliable alternative. Approval ensures a proven, cost-effective solution remains available to NHS patients and clinicians."

2 Applicant's '14 day comments' to the Commissioner

2.1 "We are grateful for the opportunity to respond to the representation submitted on behalf of Orange Private Ltd opposing our application under Regulation

18(2)(b) of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.

2.2 We respectfully submit that the representation mischaracterises both the scope of our service and the nature of current provision for compression hosiery within the Somerset Health and Wellbeing Board (HWB) area.

2.3 **Unique and Targeted Service for Compression Hosiery and Lymphoedema Garments**

2.4 Patient Choice Direct (PCD) is the only (applicant) DAC in the UK whose sole focus is the safe, accurate, and timely supply of compression hosiery and lymphoedema garments. This is a highly specialised area of appliance provision requiring detailed clinical understanding and robust validation of prescriptions—significantly more complex than the dispensing of general appliances such as stoma or continence products.

2.5 Daylong (Credenhill Ltd) is the only other DAC significantly involved in compression hosiery. However, it does not offer a prescription request service and operates as a conventional dispenser—fulfilling prescriptions exactly as received, regardless of clinical accuracy. This approach contributes to the persistent inaccuracies and delays documented in multiple professional audits.

2.6 Other DACs either do not supply compression hosiery at all or do so in negligible volumes. For example, Nightingale Home Delivery Service in Bridgwater is a specialist in urology and continence products, owned by a major continence supplier, and has no operational interest in supplying compression garments—neither in Somerset nor elsewhere in the UK.

2.7 **Our Service Enhances, Not Competes With, Local Provision**

2.8 Contrary to the representation's suggestion, DACs do not compete with or displace community pharmacy provision. In practice, most community pharmacies routinely forward Part IX appliance prescriptions to agency DACs such as NWOS or Wardles, reflecting their preference not to handle complex appliance dispensing directly due to low reimbursement and product complexity.

2.9 Introducing a dedicated DAC specialising in compression hosiery supports, rather than undermines, community pharmacy. It alleviates their workload in an area they typically opt not to serve, while improving outcomes for a patient group with very specific needs.

2.10 **A Unique Local Benefit for Somerset**

2.11 While our service is available nationally, establishing a DAC base in Wellington, Somerset additionally provides a direct, local benefit:

2.11.1 For the first time, patients in the area will have access to same-day pick-up or local delivery of compression garments.

2.11.2 This service is not currently offered by DACs anywhere else in the UK. A few isolated examples exist in the North West where DACs provide

local delivery for their ostomy and urology products, but nowhere offers this for hosiery.

2.12 Patients in Somerset currently rely on a fragmented system that does not routinely stock or clinically validate compression garment prescriptions. Our proposal fills this gap with a responsive, locally integrated service, and aligns directly with the Somerset HWB's PNA commitment to improving access and reducing delays for vulnerable patient groups.

2.13 **Protected Characteristics and Health Inequalities**

2.14 The Somerset PNA 2022–25 highlights a growing number of patients with long-term conditions.

2.15 Compression therapy is increasingly prescribed for chronic oedema, venous disease, and lymphoedema—conditions that disproportionately affect:

2.15.1 Older adults, especially those living alone or with mobility restrictions.

2.15.2 People in rural communities, who face difficulty accessing face-to-face pharmacy services.

2.15.3 Patients with obesity or disabilities, for whom compression therapy is clinically necessary but challenging to obtain consistently under current systems.

2.16 Our service directly supports these groups—many of whom fall under the Equality Act 2010's protected characteristics—by offering:

2.16.1 Validated prescription handling to avoid clinical harm,

2.16.2 Home or local delivery to eliminate travel requirements,

2.16.3 Simplified, patient-led repeat ordering and clinician collaboration.

2.17 These interventions help reduce access inequalities and support NHS England's duties under Section 13G (duty to reduce inequalities in access and outcomes) and 13P (variation in provision).

2.18 **Unforeseen Need – Not Anticipated in the PNA**

2.19 The Somerset PNA does not identify compression hosiery or lymphoedema supply as a service gap, nor does it reference prescription validation or appliance dispensing accuracy. In fact, the PNA makes no mention of compression garment provision at all beyond general appliance categories—despite compression prescribing and dispensing being well-documented across the NHS as complicated, wasteful, and error-prone.

2.20 Multiple national audits and peer-reviewed studies have consistently highlighted high rates of dispensing inaccuracy, prescription rejection, and long delays in patients receiving their garments—often resulting in clinical harm, wasted NHS expenditure, or abandoned therapy.

2.21 This omission reflects that the needs our application addresses were not foreseen when the PNA was published—specifically:

2.21.1 The high error rates in prescriptions for compression therapy.

2.21.2 Delays of multiple weeks (sometimes months) in receiving clinically essential garments.

2.21.3 The opportunity for same-day fulfilment of validated prescriptions locally.

2.22 Our model addresses all three, and therefore qualifies fully as an "unforeseen benefit" under Regulation 18(2)(b).

2.23 **Alignment with Regulation 18 Criteria**

2.24 Our application meets all the requirements of Regulation 18(2)(b), providing:

2.24.1 Better access – through validated prescriptions, direct NHS integration, and local delivery in Somerset.

2.24.2 Improved patient safety – by eliminating widespread prescription and dispensing errors.

2.24.3 Service innovation – via a unique, clinically-led validation process for compression not offered by any other DAC.

2.24.4 Support for protected groups – particularly patients with mobility issues and long-term conditions such as lymphoedema.

2.24.5 Improved patient choice – through a specialised alternative not currently available from any other provider within the HWB area, or beyond.

2.25 **Conclusion**

2.26 Patient Choice Direct does not duplicate existing services. It introduces a novel, evidence-based service model that addresses an unmet need within both Somerset and the wider NHS system, with additional benefits specifically for the Somerset region.

2.27 The representation from Orange Private Ltd does not address the specific nature of appliance provision in this category and presents no valid grounds for refusing our application.

2.28 We would welcome the opportunity to present further evidence at an oral hearing, or to host you—or any interested respondents—at our premises in Somerset to demonstrate first-hand the clinical, logistical, and operational efficiencies our service offers."

3 The Decision

The Commissioner considered and decided to refuse the application. The decision letter dated 11 August 2025 states:

3.1 “NHS England 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 NHS England’s decision. Should you choose to appeal then either complete the online form available on the NHS Resolution website or send a concise and reasoned statement of the grounds for your appeal within 30 days of the date of this letter to nhsr.appeals@nhs.net or:

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

South West Pharmaceutical Services Regulations Committee (PSRC) Decision Report

3.4 “**The SW Committee noted:**

3.5 Wellington is a market town in Somerset, situated 7 miles southwest of Taunton, near the border with Devon. The town had a population of 16,669, which includes the residents of the parish of Wellington Without and the villages of Tone and Tonedale Population, 2021 Census.

3.6 The application is for Unforeseen Benefits (Regulation 18) with a premises known address of Unit 1 Block B, Westpark, Chelston, Wellington, TA21 9FN.

3.7 An application for a new Distance Selling Premises (DSP) in the Westpark26 business park, Wellington, Taunton, TA21 9AD, was approved by the SW PSRC in March 2025 and is currently under appeal. The SW Committee recently considered and refused an application for a standard pharmacy at the Wellington Medical Centre. This later application is currently in the 30-day appeal period.

3.8 **PRELIMINARY ISSUES**

3.9 Summary of the application

3.10 The applicant is proposing to open Monday to Friday 0900 – 1700. These are all described as core hours. Dispensing Appliance Contractors are only obliged to provide 30 core hours. The hours proposed are indicated below from section 3.1 and 3.2 of the application form:

“3.1 Proposed core opening hours

Core opening hours must total 40 hours per week for pharmacies or not less than 30 hours for DACs, unless the applicant is proposing more core opening hours to secure unforeseen benefits in which case NHS England or the relevant delegated integrated care board will need to agree with you when these additional core hours would be.

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	Total

09:00 – 17:00	09:00 – 17:00	09:00 – 17:00	09:00 – 17:00	09:00 – 17:00	Closed	Closed	40:00

3.2 Total proposed opening hours

The total opening hours includes the core hours and any supplementary opening hours"

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	Total
09:00 – 17:00	09:00 – 17:00	09:00 – 17:00	09:00 – 17:00	09:00 – 17:00	Closed	Closed	40:00

3.11 The applicant proposes to provide appliances including Elastic Hosiery Lymphodema [sic] Garments, Dressings and Wound care and any other appliances requested, and specified advanced services at section 4 of the application form.

3.12 The applicant does not provide a floor plan of the proposed premises claiming it does not apply to appliance contractors.

3.13 The applicant provides supporting information describing the unforeseen benefit they are offering to secure, summarising: [see paragraph 1.26]

3.14 **PUBLIC INVOLVEMENT / REPRESENTATIONS**

3.15 Full details of the applicant's proposals were notified to various parties in accordance with the Regulations. Representations have been received from:

3.15.1 Boots UK Ltd acknowledge the application and state they have no comments to make so do not support or oppose the application.

3.15.2 PSC on behalf of Orange Private Ltd object to the application providing a detailed response they suggest that information provided by the applicant in this case is not sufficient to satisfy the ICB that the requirements of Regulation 18 have been met. There is no information contained within the application to illustrate the specific needs of Wellington that this applicant would meet.

3.16 There were no responses to the representations received.

3.17 When comments are circulated to the applicant and interest [sic] parties the covering letter states:

3.18 *Please note that any new information that you submit at this stage will have little or no weight placed upon it unless it can be demonstrated that you are presenting it in response to representations submitted by another party that you believe are not true or are incorrect.*

3.19 The SW Committee was satisfied it is not necessary to hold an oral hearing to determine the application.

3.20 Regulation 31 (same or adjacent premises) [quotes regulation in full]

3.21 There are no other contractors currently providing pharmaceutical services at the address provided or adjacent premises. The nearest existing pharmacy is 0.3 miles away in Wellington. If the application for a new pharmacy in the Wellington medical centre is granted on appeal that pharmacy would be more than 2 miles away. ***The SW Committee was satisfied it is not required to refuse the application by virtue of Regulation 31.***

3.22 **CONTROLLED LOCALITY ISSUES**

3.23 The application does not relate to a controlled locality.

3.24 **UNFORESEEN BENEFITS**

3.25 Reg 18(1)(b) – Improvements or better access not included in the Pharmaceutical Needs Assessment

3.26 Regulation 18 concerns 'Unforeseen Benefits' applications, which are applications where the improvements or better access that would be secured were or was not included in the relevant PNA. The current Somerset PNA can be found here: Somerset PNA 2022-25 County Report.pdf Wellington is included in the Taunton Deane West Primary Care Network area. The locality summary, Page 71, notes there is some expected house building in Wellington which is the largest settlement in the PCN and notes the four pharmacies that were available at the time of writing the PNA would be expected to meet the growth in demand. No supplementary statements have been issued.

3.27 ***The SW Committee was satisfied that as the improvements or better access which the applicant is proposing to secure were not identified in the PNA, an 'unforeseen benefits' application is the correct type of application.***

3.28 Reg 18(2)(a) – Would granting the application cause significant detriment to the proper planning or arrangements in place for provision of pharmaceutical services in this area

3.29 The ICB has no particular plans regarding pharmaceutical services in the area, so there can no detriment to such plans. There has not been any suggestion that there would be significant detriment to the arrangements already in place.

3.30 ***The SW Committee was satisfied that granting the application would not cause significant detriment to the proper planning or arrangements in place for provision of pharmaceutical services.***

3.31 Regulation 18(2)(g) – Whether the application presupposes that a gap in pharmaceutical services provision has been or is to be created as a result of a consolidation application

3.32 As no consolidation applications have been made relating to this part of Wellington **the SW Committee is not required to refuse the application under regulation 18(2)(g)**.

3.33 Reg 18(2)(b)(i) – Significant benefit: Reasonable choice with regard to obtaining pharmaceutical services

3.34 The SW Committee had a map showing the location of existing pharmacies in the area and noted there is an existing dispensing appliance contractor at 1st Floor, Mallard Court, Express Park, Bristol Road, Bridgwater which is approximately 22 miles from the proposed premises.

3.35 The SW Committee had confirmation of the local pharmacies opening hours.

3.36 The applicant comments that it is already an online retailer of compression hosiery and lymphoedema garments via its website. It suggests that dispensing of these items by pharmacies and other DACs is plagued with high error rates, delays and inefficiencies that have a negative effect on the patient care. They suggest the benefit they will provide is the elimination of errors, timely access to therapy, cost saving, improved patient safety an enhanced experience for clinicians and patients and states it is a superior alternative to previous projects.

3.37 The applicant comments do not appear to directly deal with the matter of choice beyond suggesting they would be “better” than existing pharmacies and DACs.

3.38 PSC suggest that there is no information contained within the application to illustrate the specific needs of Wellington that this applicant would meet. They also note the existing DAC in Bridgwater.

3.39 The SW Committee could not identify within the application evidence of the need that the applicant is going to meet. The application has presented the company’s business model and approach but not detailed why a Dispensing Appliance Contractor is needed in Wellington.

3.40 The SW Committee did not find evidence that the existing pharmacy providers are not already providing an adequate level of service provision and are not meeting demand. There is no evidence that patients are not already able to access the specialist services a DAC provides.

3.41 The applicant suggests their presence will improve the standard of access to services in the area and seeks to reduce the number of errors made, however, this is not the test for an Unforeseen Benefits application, and any issues with standards of services are operational issues and would be addressed through the contract monitoring route with existing providers.

3.42 ***The SW Committee was satisfied that because of the choice and accessibility of the existing pharmacies that granting the application would not confer a significant benefit by way of access to, or choice of, pharmaceutical services.***

3.43 Reg 18(2)(b)(ii) – Significant Benefit: Patients with a protected characteristic

3.44 The applicant does not appear to address this matter and PSC raise this point. The SW Committee agreed there is no evidence of benefit in relation to patients with protected characteristics.

3.45 ***The SW Committee was satisfied that granting the application would not confer significant benefits on people sharing a protected characteristic.***

3.46 Reg 18(2)(b)(iii) – Significant Benefit: Innovative approaches to delivery of pharmaceutical services

3.47 No information has been provided by any party on this matter.

3.48 The SW Committee did not identify anything innovative in the application; there is nothing offered over and above what is the expected service standard from a provider.

3.49 ***The SW Committee was satisfied that granting the application would not lead to significant benefits by virtue of innovation.***

3.50 **Decision**

3.51 **The SW Committee determined that the application SHOULD NOT be GRANTED because:**

3.51.1 Granting the application would not confer a significant benefit by way of access to, or choice of, pharmaceutical services.

3.51.2 Granting the application would not confer significant benefits on people sharing a protected characteristic.

3.51.3 Granting the application would not lead to significant benefits by virtue of innovation

3.52 Appeal Rights

3.53 The application is refused, therefore, the applicant has appeal rights."

4 The Appeal

In an email dated 10 September 2025 addressed to NHS Resolution, the Applicant appealed against the Commissioner's decision. The grounds of appeal are:

4.1 "**Appeal Submission: Response to PCSE Rejection of Application ME3687 Grounds for Appeal:** Procedural errors, factual misinterpretations, and failure to consider material evidence

4.2 **Attachment:** Copy of Representation Response (15 May 2025)

4.3 **Summary**

4.4 We respectfully submit that the PCSE decision contains fundamental procedural and substantive errors that require the application to be reconsidered. The committee failed to consider material evidence,

misinterpreted the regulatory test for unforeseen benefits, and reached conclusions unsupported by objective data.

4.5 **Critical Procedural Error: Omission of Representation Response**

4.6 The committee's report incorrectly states that no response was received to representations. This is factually wrong:

4.6.1 **15 May 2025**: We submitted a comprehensive rebuttal to Orange Private Ltd's representation

4.6.2 **PCSE acknowledged receipt**, yet this material evidence is neither referenced nor considered in the decision

4.6.3 The rebuttal directly addressed key assertions repeated in the decision report regarding local choice and compression hosiery services

4.7 This represents a significant procedural flaw and a failure to consider relevant and material evidence.

4.8 **Objective Evidence of Unmet Need**

4.9 The decision ignores concrete dispensing data that demonstrates clear gaps in compression hosiery provision:

4.10 **FOI Data (April 2024) - Wellington Area:**

4.10.1 Jhoots Wellington: 1 item (elastic hosiery)

4.10.2 Boots Wellington High Street: 2 items (1 lymphoedema, 1 elastic hosiery)

4.10.3 Superdrug Wellington: 2 items (elastic hosiery)

4.11 **Great Bear/Nightingale DAC (Bridgwater):**

4.11.1 0 items of compression hosiery or lymphoedema garments

4.11.2 Does not accept hosiery prescriptions

4.12 These figures provide clear, objective evidence contradicting the committee's assumption that existing providers meet demand.

4.13 **Misapplication of the "Unforeseen Benefit" Test**

4.14 The committee fundamentally misunderstood what constitutes an unforeseen benefit by:

4.15 **A) Dismissing Genuine Innovation**

4.16 Our **zero-error prescription validation system** represents a transformative approach not offered by any other UK contractor. While other providers dispense what GPs prescribe (leading to 50% error rates), PCD prevents errors before dispensing occurs.

4.17 **Quantified Impact:**

4.17.1 Already monthly NHS savings: £90,000–£118,000 through error prevention

4.17.2 Annual savings exceeding £1 million

4.17.3 100% prescription accuracy achieved through clinical validation

4.18 **B) Conflating Systemic and Operational Issues**

4.19 The committee incorrectly concluded that prescription errors are "operational issues" addressable through contract monitoring. Independent studies demonstrate these are **systemic failings** inherent to traditional pharmacy infrastructure:

4.19.1 Only 17% of patients receive compression garments without problems (Wounds International, 2022)

4.19.2 Up to 50% of prescriptions dispensed incorrectly (JCN, 2021)

4.19.3 Pharmacies lack specialist knowledge and rarely stock these complex items

4.20 Contract monitoring cannot resolve structural inadequacies in the existing system.

4.21 **Geographic Access and Local Benefit**

4.22 **Enhanced Regional Access**

4.23 PCD's Wellington location near the M5 enables same-day delivery across Somerset and Devon, providing genuine regional benefit beyond narrow postcode boundaries. The Somerset PNA makes no requirement that unforeseen benefits be exclusively local.

4.24 **New Clinical Facility**

4.25 Since application submission, construction has begun on a **dedicated clinic room at B1 Westpark** for measuring clinics and patient assessments, enhancing face-to-face access and demonstrating commitment to the local area.

4.26 **Protected Characteristics**

4.27 Patients requiring compression therapy typically present with:

4.27.1 Advanced age and mobility limitations

4.27.2 Multiple comorbidities affecting access to services

4.27.3 Urgent clinical needs requiring timely intervention

4.28 Our direct-to-patient delivery model specifically supports these vulnerable groups by removing access barriers and ensuring rapid, accurate supply.

4.29 **Innovation Beyond Standard Service**

4.30 The committee's conclusion that we offer "nothing over and above the expected service standard" demonstrates complete misunderstanding of our model:

4.31 **Standard dispensing Practice:**

4.31.1 Dispense exactly what GP prescribes

4.31.2 No clinical validation

4.31.3 Accept inevitable error rates

4.32 **PCD Innovation:**

4.32.1 All prescriptions clinically validated against the original referral before dispensing

4.32.2 Direct liaison with clinicians and manufacturers

4.32.3 Proactive error prevention and correction

4.32.4 Zero-error delivery achieved

4.33 This is not only innovative — it is transformative. It eliminates waste, prevents patient harm, and ensures that NHS resources are used efficiently and safely. We believe the committee's assertion that this service offers nothing beyond the standard is wholly inaccurate and unsupported by the record.

4.34 **Current Market Failure**

4.35 The committee noted existing pharmacy provision without investigating adequacy. The **closure of Boots Pharmacy at Wellington Medical Centre** and visible pressure on remaining pharmacies (delays, queues, patients turned away) demonstrates system strain ignored in the decision.

4.36 The committee declined a recent application to re-establish a pharmacy at the Wellington Medical Centre site, and the closure of Luson Surgery precipitating the likely closure of the already failing Jhoots will further increase this pressure.

4.37 The inconsistency of approving a Distance Selling Pharmacy (unable to serve local walk-in patients) while rejecting a DAC that improves local access is particularly notable.

4.38 **Precedent and Regulatory Support**

4.39 Similar applications have succeeded where applicants demonstrated:

4.39.1 Operational inefficiencies in agency arrangements (Ward Mobility)

4.39.2 Need for direct NHS integration (Nightingale Home Delivery)

4.39.3 Service improvements for specialist populations (Manfred Sauer UK)

4.40 PCD meets all these criteria with additional quantified benefits.

4.41 **Summary**

4.42 We respectfully submit that the PCSE decision should be overturned for the following reasons:

4.42.1 Acknowledged written representations were not considered

4.42.2 The committee failed to understand or investigate current local provision

4.42.3 Material inaccuracies in dispensing data and DAC services were accepted uncritically

4.42.4 The committee misapplied the test for "unforeseen benefit"

4.42.5 The scope of "access" was interpreted far too narrowly

4.42.6 The innovation of the proposed service model was entirely overlooked

4.42.7 Systemic problems were mistaken as operational ones

4.43 **Request for Oral Hearing:** Given the complexity of issues and extent of misinterpretation identified, we respectfully request this appeal be considered at an oral hearing to enable comprehensive examination of our innovative service model and the clear access gaps in Somerset's compression hosiery services.

4.44 Without DAC recognition, nearly 70,000 patients face potential service disruption, the NHS loses proven cost savings exceeding £1 million annually, and a demonstrably successful innovation in pharmaceutical care may be forced to withdraw from NHS service provision."

4.45 ['14 day comments' provided – see section 2]

5 Summary of Representations

After reviewing the paperwork to the Commissioner, it was noted that the comments made by the Applicant in response to the representations on the application [see 2.1 to 2.28 above] had not been circulated or seen by parties. NHS Resolution therefore applied its discretion under Schedule 3, Part 3, paragraph 7 and allowed parties the opportunity to make comments on these. This is a summary of representations received on the appeal.

5.1 The Commissioner

5.1.1 "Thank you for your letter, received 26 September 2025, addressed to […] at Primary Care Support England (PCSE) enclosing a copy of the above appeal. The South West Pharmaceutical Services Regulations Committee (SW Committee) wishes to make the following comments on the appeal.

5.1.2 The SW Committee notes it was not presented with the applicant's response to the 45-day notification responses. This was due to an administrative error that has been identified by the team at Primary Care Support England who did not forward the response to the SW Committee.

5.1.3 The appeal focuses on innovation, and the applicants view on the error rates of other providers and a declaration that they have a zero-error validation system. The SW Committee would respectfully suggest that working toward eradicating errors is not innovative, it is something all providers are expected to continually work toward achieving.

5.1.4 As NHS Resolution will be aware Paragraph 3 of Schedule 5 states that appliance contractors must "*provide proper and sufficient appliances to persons presenting prescriptions for appliances ordered by health care professionals in pursuance of their functions in the health service*". There is a claim that other DACs do not supply hosiery or do so in small volumes, but this is a service that many community pharmacies can, and do, offer. There is no evidence that patients are having difficulty in obtaining elastic hosiery.

5.1.5 In the response to the 45-day notification process the appellant makes claims about dispensing errors but even if that is the case granting an application for a new appliance contractor is not an appropriate way of managing poor performance in existing contractors. The ICB is not aware of any complaints regarding obtaining elastic hosiery or lymphoedema garments.

5.1.6 The SW Committee could not identify within the application evidence of the gap or need that the applicant is going to meet. The application has presented the company's business model and approach but not detailed why a Dispensing Appliance Contractor is needed in Wellington or evidenced that patients are currently facing difficulties accessing services from existing providers.

5.1.7 The SW Committee was satisfied that because of the choice and accessibility of the existing providers that granting the application would not confer a significant benefit by way of access to, or choice of, services and there is no evidence that granting the application would confer significant benefits on people sharing a protected characteristic.

5.1.8 The SW Committee looks forward to receiving the Primary Care Appeals' decision in due course."

6 Observations and Regulation 22

Regulation 22 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 ("the Regulations") states that the relevant Pharmaceutical Needs Assessment ("PNA") for the purpose of determining a pharmacy application is the PNA that is current at the time NHS Resolution makes the determination unless the only way to determine the application justly is with regard to an earlier PNA. Regulations 5 and 6 envisage there will be a revised PNA published by each Health and Wellbeing Board regularly. NHS Resolution noted that the original decision of the Commissioner in this matter was taken in relation to an earlier PNA. 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 to add an additional round of observations on this matter. The following comments were received, together with observations on the representations.

6.1 The Applicant

6.1.1 “Thank you for providing the representations submitted by the South West Pharmaceutical Services Regulations Committee (“SW Committee”) dated 24 October 2025.

6.1.2 We submit the following final observations, rebutting a number of inaccurate or misleading assertions in the SW Committee's comments and reinforcing the strong case for granting our application.

6.1.3 **Omission of Our Response: Not Just Procedural – Material**

6.1.4 The SW Committee claims it “was not presented with the applicant’s response to the 45-day notification responses” due to an administrative error. This response was submitted and acknowledged by PCSE on 15 May 2025.

6.1.5 This was not a trivial omission. Our representation directly rebutted multiple claims now repeated in the SW Committee’s position, particularly concerning:

6.1.5.1 The supposed adequacy of existing provision for compression hosiery

6.1.5.2 Misunderstandings about how our service operates

6.1.5.3 The systemic nature of the problem we solve

6.1.6 It is disappointing that, despite now having sight of that response, the ICB’s feedback continues to reiterate the same incorrect statements and misunderstandings we already addressed. This demonstrates not only a procedural failure, but also a lack of meaningful engagement with the evidence we provided. We reiterate that this failure materially undermines the fairness and validity of the original determination and should alone justify the appeal being upheld.

6.1.7 **Mischaracterisation of Our Innovation**

6.1.8 The SW Committee states that we claim innovation on the basis of error rates and asserts that “eradicating errors is not innovative.” This is a mischaracterisation of our application.

6.1.9 We are not claiming that other providers are careless or that they make dispensing errors. Our application makes clear: the source of error is not in dispensing but in prescribing. Specifically:

6.1.9.1 Complex compression prescriptions are typically initiated by a specialist nurse, passed to a GP, then issued via EPS without sufficient product understanding or validation.

6.1.9.2 These systemic gaps lead to incorrect prescriptions, which will be dispensed correctly - but inaccurately - by any provider.

6.1.10 What Patient Choice Direct (PCD) does differently is intervene before the prescription is written. We:

6.1.10.1 Initiate the prescription process, typically on the instructions of the specialist nurse

6.1.10.2 Validate prescriptions before submission

6.1.10.3 Liaise directly with the nurse, the patient, the manufacturer, and the GP

6.1.10.4 Ensure accuracy of the items before the prescription is generated and dispensed

6.1.11 This pre-dispensing clinical validation is not part of standard DAC or pharmacy service specifications, and no other contractor offers it for this therapy area. It is not just innovative - it is demonstrably effective, with error rates reduced to near zero and more than £1 million of NHS waste prevented annually.

6.1.12 **Misuse of Schedule 5, Paragraph 3**

6.1.13 The SW Committee quotes paragraph 3 of Schedule 5 of the Pharmaceutical Regulations, asserting that appliance contractors must provide "proper and sufficient appliances." However, the Committee omits the crucial part of that sentence: *"to the extent that paragraphs 4 to 8 require..."*

6.1.14 In practice:

6.1.14.1 DACs routinely turn away prescriptions that are not part of their normal business e.g. not ostomy or urology products, or not their own manufactured products

6.1.14.2 Hosiery and lymphoedema prescriptions are typically refused by DACs, as they require more clinical oversight, complex customisation, or offer poor commercial return

6.1.14.3 Pharmacies also struggle to supply these items due to complex prescription specifications, long supply chains, and frequent specials fees that make them unviable

6.1.15 Our own data and FOI responses confirm that the DAC in Bridgwater (Great Bear) dispensed zero hosiery items in the most recent months available, and local pharmacies dispensed only five compression items between them. This reinforces that supply is limited or unavailable, regardless of what the regulations expect.

6.1.16 **Dismissing NHS Wide Waste as "Contractor Performance"**

6.1.17 The Committee states:

6.1.18 “Granting an application for a new appliance contractor is not an appropriate way of managing poor performance in existing contractors.”

6.1.19 We are not suggesting that existing contractors are underperforming. Rather, we assert that the system is not designed to handle these types of prescriptions effectively. The fragmentation between nurse, GP, prescriber, and dispenser introduces errors at the structural level.

6.1.20 PCD offers a tested, integrated solution to a structural problem. Our application was not seeking to penalise others, but to offer a complementary model that fixes a well documented NHSwide issue.

6.1.21 The Committee also states:

6.1.22 “There is no evidence that patients are having difficulty in obtaining elastic hosiery.”

6.1.23 To directly refute this statement, we are submitting additional testimonial evidence from nurses, clinicians, and patients, including those in Wellington, that clearly shows the extent of the difficulties experienced under existing systems and the value of the PCD model. We enclose a selection of these testimonials and direct quotes in **Appendix A**.

6.1.24 **Lack of Understanding of the “Gap” We Fill**

6.1.25 The Committee states:

6.1.26 “The SW Committee could not identify within the application evidence of the gap or need...”

6.1.27 This is difficult to accept given the clear evidence we provided:

6.1.28 **a) Peer-Reviewed Evidence of Systemic Problems**

6.1.29 *Wounds International (2022):* Only 17 % of patients received compression garments without issues.

6.1.30 *JCN (2021):* Up to 50 % of prescriptions were incorrect or problematic.

6.1.31 **b) Local Dispensing Data**

6.1.32 Combined hosiery and lymphoedema items dispensed in Wellington (April 2024): 5 items total.

6.1.33 Great Bear DAC: 0 items - does not accept hosiery prescriptions.

6.1.34 **c) 3,300+ Somerset Patients Requiring Garments**

6.1.35 NHS ePACT data shows over 3,300 patients in Somerset ICB require compression hosiery or lymphoedema garments on prescription - yet Wellington pharmacies and local DACs are demonstrably not meeting this demand.

6.1.36 **d) £1 million+ NHS Waste Prevented**

6.1.37 Our system is already delivering verified NHS savings of approximately £100,000 per month simply by ensuring prescriptions are accurate before dispensing.

6.1.38 **e) New Evidence Submitted**

6.1.39 Additional nurse and patient testimonials (Appendix A)

6.1.40 Two clinician authored conference posters (Appendix B):

6.1.40.1 *Implementation and Evaluation of a Virtual Care Pathway for Early-Stage and Low-Risk Lymphoedema Management* (Accelerate CIC)

6.1.40.1.1 Discharges increased 44 %

6.1.40.1.2 Issues obtaining garments fell 86 %

6.1.40.1.3 100% of clinicians reported high satisfaction.

6.1.40.2 *Reducing Delays in Lymphoedema Garment Supply* (James Paget Hospital)

6.1.40.2.1 All issues reported related to the pharmacy/GP pathway, not to PCD;

6.1.40.2.2 Recommendation: use specialist DACs instead.

6.1.41 **f) St Margaret's Hospice Lymphoedema Clinic, Taunton**

6.1.42 The main lymphoedema service in Taunton, supporting a large number of Somerset patients, has contacted us regarding their patients' current inability to access PCD. The clinicians there have identified the same problems obtaining prescription garments seen nationally.

6.1.43 Their approach reflects growing local demand for our model, and we are in active discussions to explore a solution. This interest further illustrates a clear local need for the service, which cannot currently be met under existing arrangements.

6.1.44 If this is not a gap in need of solution, we question what level of evidence would be required.

6.1.45 **Relevance to Wellington and Protected Groups**

6.1.46 While our model brings national benefit, the local advantages are equally significant:

6.1.46.1 Our Wellington base enables same-day personalised delivery or collection for patients in Somerset and Devon - faster than postal DACs.

6.1.46.2 A new clinic room at B1 Westpark (since the application) is now available for NHS and private nurses and hosiery manufacturers to conduct local measurements, patient checks, and training.

6.1.46.3 Compression patients are disproportionately elderly, less mobile, and living with multiple comorbidities - i.e. within protected groups under the Equality Act.

6.1.47 **Addressing Somerset's Own PNA**

6.1.48 The *Somerset Pharmaceutical Needs Assessment (2025 – 2028)* states:

6.1.49 "There is good provision generally of the advanced services across Somerset... except appliance use review (AUR) and stoma appliance customisation... which could be seen as an area for improvement."

6.1.50 While we did not present AURs or customisation services as unforeseen benefits, they were included in our original application as part of our standard DAC model. We already operate an ultrasonic cutting machine at our Wellington site, demonstrating readiness to meet these identified needs.

6.1.51 We would welcome the opportunity to demonstrate to Somerset ICB the speed, efficiency, and quality of our stoma customisation service.

6.1.52 **Final Summary**

6.1.53 In addition to meeting an urgent local need, this application offers a scalable blueprint for resolving a persistent national issue - benefitting patients, clinicians, and NHS finances.

6.1.54 The SW Committee's submission is based on:

6.1.54.1 A fundamental misunderstanding of the innovation in our model and its proven results

6.1.54.2 Repetition of claims already addressed in our May 2025 response (which was not considered)

6.1.54.3 Dismissal of substantial clinical, operational, and testimonial evidence

6.1.55 We believe our service offers a genuine unforeseen benefit, consistent with both the letter and spirit of the Regulations, and aligns directly with the unmet needs set out in the Somerset PNA 2025 – 28.

6.1.56 We do not simply propose to do the same thing more efficiently - we fundamentally change how the system works, at no cost to the NHS.

6.1.57 We respectfully request that our appeal be upheld, or failing that, that the matter proceed to an oral hearing so that the model, the data, and the widespread system problems can be properly examined and understood, as they should have been from the outset.

6.1.58 **Appendix A – Selected Quotes**

6.1.59 **From clinical specialists:**

6.1.60 "Before we used PCD, we were constantly chasing prescriptions. It would take hours—sometimes days—to get the correct garments issued. Now, it's seamless. I just send the request through, and they handle the rest. It's taken so much stress off our team and, more importantly, our patients." - CNS, Lymphoedema Specialist – National Lymphoedema Conference 2024

6.1.61 "Prescriptions were frequently wrong from the outset. We spent so much time chasing hosiery, and patients were stuck in the middle. Now it's slick and efficient. The patient gets the right product quickly, and we get our clinic time back." - Douglas Macmillan Hospice Lymphoedema Clinic CNS

6.1.62 "Our receptionists and GPs were dealing with constant queries, what to prescribe, which code, what size. It was messy and time-consuming. Now, it's efficient. Patient Choice ensures everything is accurate before it even gets to us, which reduces errors and saves valuable GP time." - Practice Manager, GP Surgery – National Lymphoedema Conference 2024

6.1.63 "PCD delivers to their house, which is amazing for patients." – Salford Royal Lymphoedema Clinic CNS

6.1.64 "Before, we were always having prescriptions rejected or sent back. We'd get confused over codes or descriptions, and then the patient would be stuck waiting. PCD have taken that stress away. They just get it right." - GP Surgery Receptionist

6.1.65 "PCD tell our patients when their garments are ready, so they stay on track." – Ashgate Hospice Lymphoedema Clinic CNS

6.1.66 "I can send all of my prescription requests to PCD, and they deal with the rest for me." – BLS Clinician Interview 1

6.1.67 "I would definitely recommend Patient Choice to any health provider, they have saved my service time and money and improved patient experience during what sometimes can be very worrying for them. This is for both palliative and non-palliative patients. Neil's team in Somerset are very professional and efficient. They offer suggestions to help us improve our working with them so that processes are streamlined." - St Luke's Hospice Lymphoedema Specialist CNS

6.1.68 "Garments were taking months. We were bandaging a patient for four extra weeks while waiting for the correct set. Now, we know with Patient Choice the garments will arrive correctly and on time — it's a massive relief." - Florence Nightingale Hospice Lymphoedema Clinic CNS

6.1.69 "PCD will keep in contact with our patients to see what they need." – BLS Clinician Interview 2

6.1.70 "We used to spend hours sorting prescription errors. Now we just send our recommendations to Patient Choice and they take care of it. That means we get more time to see patients — which is what we should be doing." - East of England Lymphoedema Clinic CNS 1

6.1.71 "It used to take hours trying to get through to surgeries, to chase prescriptions. Now it's all by email — traceable, easy to manage, and accurate. That admin time is gone, and we can use that time to actually care for patients." - East of England Lymphoedema Clinic CNS 2

6.1.72 "Pharmacists often didn't understand lymphoedema prescriptions. Patients were given the wrong class or size, the wrong colour, or missing accessories. It wasted clinical time, cost patients money, and left us trying to explain why their garments were unusable. With Patient Choice, these errors are picked up early, and we know garments will be delivered correctly." - East of England Lymphoedema Clinic CNS 3

6.1.73 "We're seeing better adherence. When the right garment is sent first time, patients wear it—and that means better outcomes. There's less frustration. If something's wrong, the patient might just give up. Now, they're supported properly, and that makes a big difference." – Community lymphoedema Team

6.1.74 "We are loving PCD. It is brilliant. Stock getting through to us really quickly. Thank you PCD Team." Simon, Team Leader/Charge Nurse, Professional Nurse Advocate

6.1.75 "One of our main issues was wait times — five or six weeks or longer. Patients often received the wrong garments or something was missing. One patient waited four months and when the garments finally arrived, they didn't fit and had to be thrown away." – Bowthorpe Surgery

6.1.76 "Our patients have been using PCD for a year and a half. Prior to that, they had great difficulty getting their garments… patients would tell us they had not got their garments or that they were wrong. It's really made a difference to us in the practice and allowed more time in clinic with our patients. Patients are in control now and happy." Dorset County Hospital Lymphoedema Clinic CNS

6.1.77 "PCD has made such a difference to our service, the time we've got and to our patients. Before PCD, we had so much time wasted and potential harm from patients not getting the compression they needed. Our old issues are hardly there at all, and it's allowed us to discharge our stable patients." – Salford Royal Hospital Lymphoedema Clinic CNS

6.1.78 **From Wellington residents (Facebook survey, September 2025 – "What are the most common challenges you have faced when collecting or receiving your compression prescriptions?"):**

6.1.79 I was told by the nurse at the surgery to order off Amazon, the pharmacy said they have trouble getting them."

6.1.80 "A lot of stressful backwards and forwards between clinic, doctor, and pharmacy three or four times."

6.1.81 “Short stock of stockings.”

6.1.82 “Never seem to be available.”

6.1.83 “If the items are in stock there’s not a problem delivering… it’s the availability that’s the problem.”

6.1.84 “Length of time to get the stockings; wrong colour received.”

6.1.85 **From other patients recently:**

6.1.86 “PCD have been a godsend with my compression garments - no more hassle with the pharmacy getting them ordered in.”

6.1.87 “Using PCD was the best thing I ever did for the lymphoedema in my arm post breast cancer.”

6.1.88 “You provide a great service for my lymphoedema prescriptions, thank you!”

6.1.89 "I used to get the wrong garments all the time, either the wrong size, wrong compression, or just something I didn’t ask for. Since switching to Patient Choice, I get exactly what I need, when I need it."

6.1.90 "I used to have to collect my prescription, post it, and wait weeks. Now I don’t have to do anything. It just arrives. It’s so much better, and I know it’s right."

6.1.91 "I remember breaking down in the pharmacy once because they ordered the wrong thing - for the third time. With PCD, there’s a human being who understands my needs. I get my garments without hassle.""

6.1.92 [Supporting documents provided – ‘Evaluation of a District General Hospital Lymphoedema Service Procurement Process’ and ‘Implementation and evaluation of a Virtual Care Pathway for early-stage and low-risk lymphoedema Management’]

7 Observations on the Regulation 22 comments

No observations on the Regulation 22 comments were received.

8 Consideration

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

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

8.3 The Committee noted the Applicant’s request that the appeal be considered by means of an Oral Hearing. On the basis of this information, the Committee considered it was not necessary to hold an Oral Hearing.

8.4 The Committee noted the Applicant had raised a preliminary point regarding its 14 day comments to the Commissioner, stating in the appeal that "*The committee's report incorrectly states that no response was received to representations. This is factually wrong…*". The Committee noted the Commissioner's response that "*…it was not presented with the applicant's response to the 45-day notification responses. This was due to an administrative error that has been identified by the team at Primary Care Support England who did not forward the response to the SW Committee.*" The Committee noted that a copy of the 14 day comments had been provided with the appeal and a copy had been circulated to interested parties. Whilst it was unfortunate that the comments were not considered by the Commissioner, the Committee considered that the matter would now be rectified as the comments would be considered together with the appeal, representations and observations received as part of the Committee's reconsideration of the application.

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

Regulation 31

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

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

(2) This paragraph applies where -

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

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

(ii) adjacent premises; and

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

8.7 The Committee noted that the Applicant had not provided any information in the application form on this point but the Committee noted that the wording of the application form only required the Applicant to include information in the relevant section if the proposed premises were adjacent to, or in close proximity to, another pharmacy or dispensing appliance contractor premises. The Committee considered it reasonable to determine that the lack of information in the application form on this point when read with the wording of the application form allowed it to be reasonably satisfied that the Applicant considered that the proposed premises were not adjacent to, or in close proximity to, another pharmacy or dispensing appliance contractor premises. The Committee noted that in the decision letter the Commissioner had stated "*There are no other contractors currently providing pharmaceutical services at*

the address provided or adjacent premises. The nearest existing pharmacy is 0.3 miles away in Wellington" and there was no dispute on the matter.

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

Regulation 18

8.9 The Committee noted that this was an application for "unforeseen benefits" and fell to be considered under the provisions of Regulation 18 which states:

"(1) If—

(a) NHS England receives a routine application and is required to determine whether it is satisfied that granting the application, or granting it in respect of some only of the services specified in it, would secure improvements, or better access, to pharmaceutical services, or pharmaceutical services of a specified type, in the area of the relevant HWB; and

(b) the improvements or better access that would be secured were or was not included in the relevant pharmaceutical needs assessment in accordance with paragraph 4 of Schedule 1,

in determining whether it is satisfied as mentioned in section 129(2A) of the 2006 Act (regulations as to pharmaceutical services), NHS England must have regard to the matters set out in paragraph (2).

(2) Those matters are—

(a) whether it is satisfied that granting the application would cause significant detriment to—

(i) proper planning in respect of the provision of pharmaceutical services in the area of the relevant HWB, or

(ii) the arrangements NHS England has in place for the provision of pharmaceutical services in that area;

(b) whether, notwithstanding that the improvements or better access were not included in the relevant pharmaceutical needs assessment, it is satisfied that, having regard in particular to the desirability of—

(i) there being a reasonable choice with regard to obtaining pharmaceutical services in the area of the relevant HWB (taking into account also NHS England's duties under sections 13I and 13P of the 2006 Act (duty as to patient choice and duty as respects variation in provision of health services)),

(ii) people who share a protected characteristic having access to services that meet specific needs for pharmaceutical services that, in the area of the relevant HWB, are difficult for them to access (taking into account also NHS England's duties under section 13G of the 2006 Act (duty as to reducing inequalities)), or

(iii) there being innovative approaches taken with regard to the delivery of pharmaceutical services (taking into account also NHS England's duties under section 13K of the 2006 Act (duty to promote innovation)),

granting the application would confer significant benefits on persons in the area of the relevant HWB which were not foreseen when the relevant pharmaceutical needs assessment was published;

(c) whether it is satisfied that it would be desirable to consider, at the same time as the applicant's application, applications from other persons offering to secure the improvements or better access that the applicant is offering to secure;

(d) whether it is satisfied that another application offering to secure the improvements or better access has been submitted to it, and it would be desirable to consider, at the same time as the applicant's application, that other application;

(e) whether it is satisfied that an appeal relating to another application offering to secure the improvements or better access is pending, and it would be desirable to await the outcome of that appeal before considering the applicant's application;

(f) whether the application needs to be deferred or refused by virtue of any provision of Part 5 to 7.

(g) whether it is satisfied that the application presupposes that a gap in pharmaceutical services provision has been or is to be created—

(i) by the removal of chemist premises from a pharmaceutical list as a consequence of the grant of a consolidation application, and

(ii) since the last revision of the relevant HWB's pharmaceutical needs assessment other than by way of a supplementary statement.

(3) NHS England need only consider whether it is satisfied in accordance with paragraphs (2)(c) to (e) if it has reached at least a preliminary view (although this may change) that it is satisfied in accordance with paragraph (2)(b)."

8.10 The Committee considered that Regulation 18(1)(a) was satisfied in that it was required to determine whether it was satisfied that granting the application, or

granting it in respect of some only of the services specified in it, would secure improvements, or better access, to pharmaceutical services, or pharmaceutical services of a specified type, in the area of the relevant Health and Wellbeing Board ("HWB").

8.11 The Committee went on to consider whether Regulation 18(1)(b) was satisfied, i.e. whether the improvements or better access that would be secured if the application was granted were or was included in the Pharmaceutical Needs Assessment ("the PNA") in accordance with paragraph 4 of Schedule 1 of the Regulations.

8.12 Paragraph 4 of Schedule 1 requires the PNA to include: "a *statement of the pharmaceutical services that the HWB had identified (if it has) as services that are not provided in the area of the HWB but which the HWB is satisfied (a)* ***would*** *if they were provided….secure improvements or better access, to pharmaceutical services… (b)* ***would*** *if in specified future circumstances they were provided…secure future improvements or better access to pharmaceutical services…"* (emphasis added).

8.13 The Committee noted that the application had been considered on the basis of the Somerset 2022-2025 PNA, but that the HWB had since issued the Somerset 2025-2028 PNA.

8.14 The Committee considered that there were two related issues that it needed to determine in relation to the PNA. It needed to determine which PNA was the relevant PNA for the purposes of Regulation 22 and whether the relevant PNA had identified the improvements or better access that the application was looking to secure.

8.15 In considering these issues, the Committee would have regard to any comments made by the parties.

8.16 The Committee considered that the starting point as set out in Regulation 22 was that the relevant PNA was the PNA of the relevant HWB that is current at the time that the decision is taken. There is no dispute that the 2025-2028 PNA is the current PNA.

8.17 The Committee considered the 2025-2028 PNA prepared by the Somerset HWB, conscious that the document provides an analysis of the situation as it was assessed at the date of publication. The Committee bears in mind that, under Regulation 6(2), the body responsible for the PNA must make a revised assessment as soon as reasonably practicable unless to do so appears to be a disproportionate response to those changes. Where it appears disproportionate, the responsible body may, but is not obliged to, issue a supplementary statement under Regulation 6(3). Such a statement then forms part of the PNA. The Committee noted that the PNA was dated 2025-2028 and that no supplementary statements had been issued.

8.18 The Committee noted that Wellington falls within the Taunton Deane West locality in the PNA and that section 3.1.2, 'Index of Multiple Deprivation' states:

8.18.1 "*the most deprived LSOAs in the county are in the urban areas, notably in Taunton, Yeovil and Bridgwater. This greater need is close to town centres – and thus generally close to community pharmacies. Large*

areas of west Somerset however are also in the more deprived deciles; these areas tend to be further from services, but are more sparsely populated."

8.19 The Committee also noted that the map indicates pockets of deprivation in Wellington.

8.20 The Committee noted that the Executive Summary at section 1 states:

8.20.1 "*There is good provision generally of the advanced services across Somerset, with all being available in every locality; except appliance use review (AUR) and stoma appliance customisation, which are only available in some localities. These services are however available via different means such as dispensing appliance contractors (DAC) but could be seen as an area for improvement within pharmaceutical provision.*"

8.21 The Committee noted section 5.2 'Pharmaceutical Services' states "*As of January 2025, there were 91 community pharmacies in Somerset, 23 dispensing GP, and 1 DAC*" and also had regard to section 5.6 'Current provision outside the area' which states:

8.21.1 "*DACs generally supply appliances by home delivery and are required to do so for certain types of appliance and tend to operate remotely; thus services are available to residents of the HWB's area. As of 2023/24 there were 112 DAC in England, including one in Somerset.*"

8.22 The Committee had regard to section 6 'Locality summaries', in particular Table 9: Locality Summary, adequacy of provision at page 37 and 38 of the PNA which states, with regard to the Taunton Deane West locality:

8.22.1 "*Improvements and better access*

8.22.1.1 *No gap, no Sunday Opening in the locality however this is mainly covered by other areas within the access criteria, areas outside the Sunday access criteria are rural and sparsely populated. AUR and Stoma Appliance Customisation not provided but is by DAC.*"

8.22.2 "*Future gaps*

8.22.2.1 *No gaps expected based on forecasted housebuilding or population change.*"

8.23 The Committee finally noted section 7 of the PNA titled 'Conclusion' states:

8.23.1 "*There is good provision generally of the advanced services across Somerset, with all being available in every locality; except appliance use review (AUR) and stoma appliance customisation, which are only available in some localities. These services are however available via different means such as DAC.*"

8.24 The Committee considered whether in this case it should have regard to the earlier PNA. The Committee was of the view that no need had been identified

for a pharmacy at this site either in the 2022-2025 PNA or 2025-2028 PNA. The Committee considered that whichever PNA it had regard to it would not materially affect its decision.

8.25 The Committee noted that the Applicant seeks to provide unforeseen benefits to the patients of Somerset and Devon. The Committee noted that the improvements or better access that the Applicant was claiming would be secured by its application were not included in the relevant PNA in accordance with paragraph 4 of Schedule 1.

8.26 In order to be satisfied in accordance with Regulation 18(1), regard is to be had to those matters set out at 18(2). The Committee's consideration of the issues is set out below.

Regulation 18(2)(a)(i)

8.27 The Committee had regard to

> *"(a) whether it is satisfied that granting the application would cause significant detriment to—*
>
> *(i) proper planning in respect of the provision of pharmaceutical services in the area of the relevant HWB"*

8.28 The Committee noted that the Commissioner's decision report states "*The ICB has no particular plans regarding pharmaceutical services in the area, so there can no detriment to such plans*", concluding that "*The SW Committee was satisfied that granting the application would not cause significant detriment to the proper planning … of pharmaceutical services.*" The Committee noted that there was no dispute on the matter from other parties.

8.29 On the basis of the information available, the Committee was not satisfied that, if the application were to be granted and the pharmacy to open, the ability of the Commissioner thereafter to plan for the provision of services would be affected in a significant way.

8.30 The Committee was therefore not satisfied that significant detriment to the proper planning of pharmaceutical services would result from a grant of the application.

Regulation 18(2)(a)(ii)

8.31 The Committee had regard to

> *"(a) whether it is satisfied that granting the application would cause significant detriment to— …*
>
> *(ii) the arrangements NHS England has in place for the provision of pharmaceutical services in that area"*

8.32 The Committee noted that the Commissioner's decision report states "*There has not been any suggestion that there would be significant detriment to the arrangements already in place*", concluding that "*The SW Committee was satisfied that granting the application would not cause significant detriment to*

the … arrangements in place for provision of pharmaceutical services." The Committee noted that there was no dispute on the matter from other parties.

8.33 The Committee was therefore not satisfied that significant detriment to the arrangements currently in place for the provision of pharmaceutical services would result from a grant of the application.

8.34 In the absence of any significant detriment as described in Regulation 18(2)(a), the Committee was not obliged to refuse the application and went on to consider Regulation 18(2)(b).

Regulation 18(2)(b)

8.35 The Committee had regard to

> *"(b) whether, notwithstanding that the improvements or better access were not included in the relevant pharmaceutical needs assessment, it is satisfied that, having regard in particular to the desirability of—*
>
> *(i) there being a reasonable choice with regard to obtaining pharmaceutical services in the area of the relevant HWB (taking into account also NHS England's duties under sections 13I and 13P of the 2006 Act (duty as to patient choice and duty as respects variation in provision of health services)),*
>
> *(ii) people who share a protected characteristic having access to services that meet specific needs for pharmaceutical services that, in the area of the relevant HWB, are difficult for them to access (taking into account also NHS England's duties under section 13G of the 2006 Act (duty as to reducing inequalities)), or*
>
> *(iii) there being innovative approaches taken with regard to the delivery of pharmaceutical services (taking into account also NHS England's duties under section 13K of the 2006 Act (duty to promote innovation)),*
>
> *granting the application would confer significant benefits on persons in the area of the relevant HWB which were not foreseen when the relevant pharmaceutical needs assessment was published"*

Regulation 18(2)(b)(i) to (iii)

8.36 The Committee had regard to the location of existing pharmacies and GP surgeries as identified on a map provided by the Commissioner, which had not been disputed. The Committee noted that according to the decision report there is an existing DAC in Bridgwater approximately 22 miles from the proposed premises.

8.37 The Committee noted the Applicant's comment that "*PCD's Wellington location near the M5 enables same-day delivery across Somerset and Devon, providing genuine regional benefit beyond narrow postcode boundaries.*" The Committee was mindful that due to the nature of the service provided, appliances are able to be delivered to patients across the country from any specific DAC as well as

through other pharmacies. The Committee was aware that many existing DACs do not limit their services by local geography.

8.38 The Committee noted the Applicant's comments regarding the closure of Boots Pharmacy at Wellington Medical Centre and "*visible strain on remaining pharmacies (delays, queues, patients turned away)*". It also noted the Applicant states that the Commissioner "*..declined a recent application to re-establish a pharmacy at the Wellington Medical Centre site, and the closure of Luson Surgery precipitating the likely closure of the already failing Jhoots will further increase this pressure.*" The Committee was mindful that the closure of a pharmacy does not automatically lead to the conclusion that a new application should be granted. The Committee also noted the Applicant's comments regarding other applications, similar to its own, which have succeeded, but it was of the view that each application is considered on its own merits, rather than for its similarities with other applications.

8.39 The Committee noted that the Applicant is currently an online retailer of compression hosiery and lymphoedema garments and that "*As the existing model for dispensing compression garments through pharmacies and DACs is plagued by high prescription error rates, delays and inefficiencies that negatively impact patient care, PCD began incorporating NHS prescriptions into its service in 2016, delivering substantial benefits not anticipated in the HWB's Pharmaceutical Needs Assessment (PNA).*" The Applicant had provided statistics from a Wounds International study showing that "*only 17% of patients received their compression garments without problems*", amongst other issues. Similarly, a Journal of Community Nursing study from 2021 had been referenced, highlighting that "*…up to 50% of compression prescriptions were dispensed inaccurately due to complexities in product codes and prescription details, with over 70% of clinicians anticipating problems with their patients' compression prescriptions.*"

8.40 The Committee noted the Commissioner's representations that "*Paragraph 3 of Schedule 5 states that appliance contractors must "provide proper and sufficient appliances to persons presenting prescriptions for appliances ordered by health care professionals in pursuance of their functions in the health service". There is a claim that other DACs do not supply hosiery or do so in small volumes, but this is a service that many community pharmacies can, and do, offer. There is no evidence that patients are having difficulty in obtaining elastic hosiery.*"

8.41 The Committee noted the comments from the Applicant that "*dispensing data … demonstrates clear gaps in compression hosiery provision*" and "*Our own data and FOI responses confirm that the DAC in Bridgwater (Great Bear) dispensed zero hosiery items in the most recent months available, and local pharmacies dispensed only five compression items between them. This reinforces that supply is limited or unavailable, regardless of what the regulations expect.*" The Committee also noted the Applicant's comment that "*NHS ePACT data shows over 3,300 patients in Somerset ICB require compression hosiery or lymphoedema garments on prescription – yet Wellington pharmacies and local DACs are demonstrably not meeting this demand.*"

8.42 The Committee then had regard to the list of quotes provided by the Applicant from both clinical specialists and patients in Wellington, including:

8.42.1 "*From Clinical specialists*":

8.42.1.1 "*Before we used PCD, we were constantly chasing prescriptions. It would take hours—sometimes days—to get the correct garments issued. Now, it's seamless. I just send the request through, and they handle the rest. It's taken so much stress off our team and, more importantly, our patients.*" - CNS, Lymphoedema Specialist – National Lymphoedema Conference 2024

8.42.1.2 "*Our receptionists and GPs were dealing with constant queries, what to prescribe, which code, what size. It was messy and time-consuming. Now, it's efficient. Patient Choice ensures everything is accurate before it even gets to us, which reduces errors and saves valuable GP time.*" - Practice Manager, GP Surgery – National Lymphoedema Conference 2024

8.42.1.3 "*Our patients have been using PCD for a year and a half. Prior to that, they had great difficulty getting their garments… patients would tell us they had not got their garments or that they were wrong. It's really made a difference to us in the practice and allowed more time in clinic with our patients. Patients are in control now and happy.*" – Dorset County Hospital Lymphoedema Clinic CNS

8.42.2 "*From Wellington residents (Facebook survey, September 2025 – "What are the most common challenges you have faced when collecting or receiving your compression prescriptions?"):*"

8.42.2.1 "*I was told by the nurse at the surgery to order off Amazon, the pharmacy said they have trouble getting them.*"

8.42.2.2 "*A lot of stressful backwards-and-forwards between clinic, doctor, and pharmacy three or four times.*"

8.42.2.3 "*Short stock of stockings.*"

8.42.2.4 "*Never seem to be available.*"

8.42.2.5 "*If the items are in stock there's not a problem delivering… it's the availability that's the problem.*"

8.42.2.6 "*Length of time to get the stockings; wrong colour received.*"

8.42.3 "*From other patients recently:*"

8.42.3.1 "*PCD have been a godsend with my compression garments - no more hassle with the pharmacy getting them ordered in.*"

8.42.3.2 "*Using PCD was the best thing I ever did for the lymphoedema in my arm post-breast cancer.*"

8.42.3.3 "*You provide a great service for my lymphoedema prescriptions, thank you!*"

8.42.3.4 "*I used to get the wrong garments all the time, either the wrong size, wrong compression, or just something I didn't ask for. Since switching to Patient Choice, I get exactly what I need, when I need it.*"

8.42.3.5 "*I used to have to collect my prescription, post it, and wait weeks. Now I don't have to do anything. It just arrives. It's so much better, and I know it's right.*"

8.42.3.6 "*I remember breaking down in the pharmacy once because they ordered the wrong thing - for the third time. With PCD, there's a human being who understands my needs. I get my garments without hassle.*"

8.43 Taking all of the above into account, in particular the undisputed difficulties regarding obtaining hosiery and lymphoedema garments as identified by the Applicant and the difficulties in the system identified by both clinicians and local residents based on their experiences, the Committee was satisfied that, having regard to there being a reasonable choice with regard to obtaining services, granting the application would confer significant benefits on persons.

8.44 In considering Regulation 18(2)(b)(ii) the Committee reminded itself that it was required to address itself to people who share a protected characteristic under the Equality Act 2010 (age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex, sexual orientation) having access to services that meet specific needs for pharmaceutical services that, in the relevant area, are difficult for them to access. In considering 18(2)(b)(ii), the Committee identified that accessing a DAC and in particular accessing compression hosiery or lymphoedema garments might be difficult for people with protected characteristics, based on age and disability, particularly due to the nature of the services that DACs offer.

8.45 The Committee noted the Applicant's comments in the appeal that "*Patients requiring compression therapy typically present with: Advanced age and mobility limitations; Multiple comorbidities affecting access to services; Urgent clinical needs requiring timely intervention; Our direct-to-patient delivery model specifically supports these vulnerable groups by removing access barriers and ensuring rapid, accurate supply*" and also "*The Somerset PNA 2022–25 highlights a growing number of patients with long-term conditions.*" Whilst the Committee accepted that there were always people in an area who share a protected characteristic, there was very little information provided regarding those who may share a protected characteristic. The Committee was of the view that it was not sufficient to make speculative assumptions as to how many such patients there may be, what their needs were and what the difficulties might be. The Committee was therefore not satisfied that, having regard to the desirability of people who share a protected characteristic having access to services that meet specific needs for pharmaceutical services that are difficult

for them to access, granting the application would confer significant benefits on persons.

8.46 In considering Regulation 18(2)(b)(iii) the Committee had regard to the desirability of innovative approaches to the delivery of pharmaceutical services. In doing so, the Committee would consider whether there was something more over and above the usual delivery of pharmaceutical services that might be expected from all pharmacies, some 'added value' on offer at the location.

8.47 The Committee noted in the appeal the Applicant states that "*Our zero-error prescription validation system represents a transformative approach not offered by any other UK contractor. While other providers dispense what GPs prescribe (leading to 50% error rates), PCD prevents errors before dispensing occurs.*" Further in its observations, the Applicant states "*What Patient Choice Direct (PCD) does differently is intervene before the prescription is written. We:*

8.47.1 *Initiate the prescription process, typically on the instructions of the specialist nurse*

8.47.2 *Validate prescriptions before submission*

8.47.3 *Liaise directly with the nurse, the patient, the manufacturer, and the GP*

8.47.4 *Ensure accuracy of the items before the prescription is generated and dispensed*"

8.48 The Committee noted the Commissioner's comment in its representations that "*working toward eradicating errors is not innovative, it is something all providers are expected to continually work toward achieving.*" Whilst appreciating the Applicant's intentions, the Committee was of the view that any pharmacy or DAC that was supplying such appliances would already be working in conjunction with the prescriber and the patient and was of the view that this was not innovative. Further, it noted that the "*50% error rates*" referred to by the Applicant did not relate specifically to the area of the HWB.

8.49 The Committee was not satisfied that, having regard to the desirability of there being innovative approaches taken with regard to the deliverability of pharmaceutical services, granting the application would confer significant benefits on persons.

Regulation 18(2)(b) generally

8.50 The Committee has considered whether there are any other factors that would confer significant benefits including on patients who share protected characteristics. The Committee had regard to the need to eliminate discrimination and advance equality of opportunity and foster good relations between these patients and those who do not share their protected characteristics.

8.51 The Committee was of the view that in accordance with Regulation 18(2)(b) the granting of this application would confer significant benefits on persons in the area of the HWB which were not foreseen when the PNA was published.

Other considerations

8.52 Having determined that Regulation 18(2)(b) had been satisfied, the Committee needed to have regard to Regulation 18(2)(c) to (e) and found that these were not applicable.

8.53 No deferral or refusal under Regulation 18(2)(f) was required in this case.

8.54 The Committee had regard to Regulation 18(2)(g) and found that it was not applicable.

8.55 The Committee considered whether there were any further factors to be taken into account and concluded that there were not.

8.56 The Committee was satisfied that the information provided demonstrates that there is difficulty in accessing current pharmaceutical services such that a pharmacy at the proposed site would provide better access to pharmaceutical services.

8.57 The Committee had regard to Regulation 19(6) which states:

(6) If NHS England is satisfied as mentioned in regulation 18(2)(b), it may grant the application not withstanding that the improvements or better access were or was not included in the relevant pharmaceutical needs assessment.

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

8.58.1 confirm the Commissioner's decision;

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

8.58.3 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.

8.59 Given that it had reached a different decision to the Commissioner, the Committee determined that the decision of the Commissioner must be quashed.

8.60 The Committee went on to consider 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 remit the matter to the Commissioner) or whether it was preferable for the Committee to redetermine the application.

8.61 The Committee noted that representations on Regulation 18 had been sought from parties by the Commissioner and representations had already been made by parties to the Commissioner in response. 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 18.

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

9 DECISION

9.1 The Pharmacy Appeals Committee ("Committee"), appointed by NHS Resolution, quashes the decision of the Commissioner, for the reasons given above, and redetermines the application.

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

9.3 The Committee has considered whether the granting of the application would cause significant detriment to proper planning in respect of the provision of pharmaceutical services in the area covered by the HWB, or the arrangements in place for the provision of pharmaceutical services in that area and is not satisfied that it would;

9.4 The Committee determined that the application should be granted on the following basis:

9.4.1 In considering whether the granting of the application would confer significant benefits, the Committee determined that –

9.4.1.1 there is not already a reasonable choice with regard to obtaining pharmaceutical services;

9.4.1.2 there is no evidence of people sharing a protected characteristic having difficulty in accessing pharmaceutical services; and

9.4.1.3 there is no evidence that innovative approaches would be taken with regard to the delivery of pharmaceutical services;

9.4.2 Having taken these matters into account, the Committee is satisfied that granting the application would confer significant benefits as outlined above that would secure improvements or better access to pharmaceutical services.

Case Manager
Primary Care Appeals