NHS Resolution

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

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

31 July 2026

REF: SHA/26947

APPEAL AGAINST HEREFORDSHIRE AND WORCESTERSHIRE ICB DECISION TO REFUSE AN APPLICATION BY WATERFALL HEALTHCARE LIMITED FOR INCLUSION IN THE PHARMACEUTICAL LIST OFFERING UNFORESEEN BENEFITS UNDER REGULATION 18 AT UNIT N004, WYASTONE BUSINESS PARK, WYASTONE LEYS, GANAREW, MONMOUTH, NP25 3SR

1 Outcome

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

1.2 The Committee determined that the application should be refused.

A copy of this decision is being sent to:
Waterfall Healthcare Limited
PCSE on behalf of Herefordshire and Worcestershire ICB
Community Pharmacy Herefordshire & Worcestershire

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1 The Application

By application received 16 June 2025, Waterfall Healthcare Limited ("the Applicant") applied to Herefordshire and Worcestershire ICB ("the Commissioner") for inclusion in the pharmaceutical list offering unforeseen benefits under Regulation 18 at Unit N004, Wyastone Business Park, Wyastone Leys, Ganarew, Monmouth, NP25 3SR. In support of the application it was stated:

1.1 Proposed core opening hours

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	Total
9:00 – 17:00	9:00 – 17:00	09:00 – 17:00	09:00 – 17:00	09:00 – 17:00	Closed	Closed	40

1.2 Total Proposed opening hours

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	Total
9:00 – 17:00	9:00 – 17:00	09:00 – 17:00	09:00 – 17:00	09:00 – 17:00	Closed	Closed	40

1.3 Pharmaceutical services to be provided at these premises

1.3.1 Terms of service (paragraphs 3 to 12, Schedule 5 – DACs)

1.4 In response to "if you are undertaking to provide appliances, specify the appliances that you undertake to provide" the Applicant stated:

1.4.1 "All appliances as specified in Drug Tariff Part IX".

1.5 In response to why this application should not be refused to Regulation 31 the Applicant left this blank.

1.6 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.

1.7 "Within the terms of Reg. 18(2) (b) of the NHS (Pharmaceutical Services) Regulations 2013 the HWB, in determining the application, has to consider-'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

(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 or

(iii) There being innovative approaches taken with regard to the delivery of pharmaceutical services granting the application would confer significant benefits on persons in its area which were not foreseen when it published its pharmaceutical needs assessment'

1.8 Although it is necessary only to fulfil one of these criteria, we feel that our application satisfies all three for the reasons given below:

1.9 (1) Reasonable Choice – Currently, within the Herefordshire HWB, the PNA confirms in Statement 1 on pages 8 & 9 that there is currently no Dispensing Appliance Contractor (DAC) listed there.

1.10 Granting this application would therefore immediately provide an additional choice of service for patients within the confines of their own HWB that does not exist today.

1.11 Whilst we do not dispute the fact that appliances are available for dispensing from pharmacy contractors and dispensing GP practices, and as such there may be choice of pharmacy providers, there is a difference between dispensing a prescription and offering the services and professional advice of a trained, registered stoma and continence nurse based within the specific location of Herefordshire HWB.

1.12 In granting this application, those patients with the shared characteristic of either a continence related condition and/or stoma condition would have local access to a specialist DAC nurse who can visit in the comfort of their own home.

1.13 Page 57 of the PNA details the challenges of physical access to services. Granting this application would now ensure ALL patients across the HWB having access to a specialist nurse who can visit and provide support in their own homes, ensuring that the physical inability to access services does not marginalize this patient group's access to care.

1.14 This unforeseen benefit is further reinforced by the PNA's classification in Part B (page 51) of 'over half of Herefordshire's population live in areas defined as rural'.

1.15 All of the above benefits that this application would deliver to the local population help to comply with the ICS' objectives detailed on page 7 of the PNA to deliver 'targeted support to reduce health inequalities and inequities'.

1.16 In addition to a specialist nursing service, all personnel based in our Herefordshire DAC office would be trained to answer urgent problems associated with stoma and continence care.

1.17 This specialist knowledge can be used as per NICE guidelines: community pharmacies, promoting health and wellbeing (2018) 'encouraging partners to signpost' to specialist providers when specialist advice might be required.

1.18 Granting our application would certainly raise the level, quality and range of specialist services available from within Herefordshire HWB for stoma and continence patients that is not available today. This is also supported by reference to page 15 of the PNA detailing the 'Pharmaceutical service population coverage by Primary Care Network' noting the 'South and West' regions of Herefordshire having the worst population per contractor ratio.

1.19 Our confirmed DAC location sits firmly within this 'South and West' locality, which will ensure improved choice of services and concurrently help to improve the 'population per contractor' coverage for local residents. This in turn will help to further reduce the current gap for Herefordians located within this specific, Southern part of the county with their English counterparts.

1.20 (2) Shared Characteristics – Unlike the vast majority of people on medication for acute or chronic ailments, stoma and continence patients have a unique shared characteristic in that they are required to walk around with an attachment to their body (either a urine drainage bag, male external catheter, stoma bag or additional body worn appliances) in order to get rid of unwanted metabolic by-products.

1.21 This often causes considerable psychological distress coupled with such acute embarrassment that they are reluctant to leave their own homes. Our specialist nurse would be able to offer advice and encouragement in the comfort of the patient's home/care setting thereby improving the existing access to pharmaceutical services currently being offered within the HWB.

1.22 This is evidenced within the PNA's pharmacy survey results on page 37, which details only 2 pharmacies currently providing appliance use review services, but only 1 doing so in the next 12 months, and no pharmacy being able to provide service provision for stoma customization within the HWB.

1.23 Across the UK, there is a predominance of people in the 60+ age range that typically present with stoma and/or continence conditions. Taking into account the county of Herefordshire's demographic concentration of 65+ age groups, which is detailed within the PNA as above the national average and the projected growth of 65+ and 85+ age categories by 2031 (page 55), pressure on existing services will be even more stretched.

1.24 Taking this into account it becomes even more important to provide a local specialized stoma and continence service for this category of people.

1.25 The improved access to a specialist continence and stoma DAC service, situated within the HWB, will ensure that this cohort of patients, with protected characteristics, will be given the best opportunity to 'remain independent and in control of their own lives' (Point 3 of the 'Joint Strategic Needs Assessment 2021').

1.26 (3) Innovative Approach to Pharmaceutical Services Delivery:

1.27 If our application is successful we will employ a local specialist continence and stoma nurse based within the Herefordshire HWB providing unbiased advice for all stoma and continence patients across the HWB.

1.28 This specialist nurse will help their local Healthcare Professionals, providing support to stretched community nursing teams.

1.29 This local resource will help identify patients who need support and such timely interventions will help reduce further pressure on stretched hospital flow and bed capacity ('NHS Long Term Plan' focus area) within Herefordshire HWB.

1.30 Our accredited DAC Nurse would carry out Appliance Use Reviews (AURs) in the comfort of the patient's own home/care setting.

1.31 If there is the need, we will look to add further specialist nurses to help those most in need.

1.32 All nurses are fully funded by Waterfall Healthcare and cost NHS Herefordshire nothing.

1.33 Nurses are available for domiciliary visits on request. This will support the Government's ambition of putting prevention at the heart of the NHS, as set out in the NHS Long Term Plan.

1.34 Our Herefordshire DAC Centre will have a 24 hour freephone line and online ordering platform that will enable orders to be placed at any time of the day or night and not restricted to our core 9am-5pm opening times.

1.35 Part B of the PNA details survey data and table 11 (page 76) highlights that 0 pharmacies currently provide a stoma appliance customization service. As a DAC located locally, we would provide this service for all patients within the HWB to ensure they are not dependent upon another 'out of area', remote provider.

1.36 The above customization would involve customising stoma pouches to specific sizes to ensure best fit for patients, a key requisite for their ongoing healthcare needs.

1.37 Our local DAC nurse would be trained and proficient on all Part IX appliances, ensuring that the patient receives the most suitable product more quickly, leading to a higher quality of life for the patient and greater cost effectiveness for the NHS with less wastage. This would enable greater patient choice across the entire Herefordshire HWB.

1.38 Waterfall Healthcare would provide local patients with samples of all manufacturers' products free of charge until the correct suitable products are identified. This helps reduce prescribing costs and ties in to page 7 of the PNA to ensure 'taxpayers' investment to be used to maximum effect'.

1.39 Linked to the above is that our DAC team will work to a 'Customer Usage Chart' that identifies any prescription requests that are outside of typical usage. This immediately flags patients that may not be using the product correctly and require either a visit from our nurse or referred back to their GP accordingly. This avoids excessive stock being supplied to patients thus reducing the HWB's overall prescribing costs.

1.40 In addition to all of the above, Waterfall Healthcare will offer a prescription collection service, free discreet delivery to everyone to either the home or specified address and free disposal bags and wipes with stoma and continence goods.

1.41 This entire range of services is both innovative – in that it exceeds anything currently on offer within the HWB – and importantly fulfils yet another requirement of the PNA as detailed on page 7's local strategies and priorities to 'make the best use of resources, being exemplar employers and strengthening the local economy by employing local people, and investing in local business wherever possible'. General Practitioners benefit from our service since there are fewer prescription requests made in person thus reducing patient visits. Also, we are able to monitor patient usage thus reducing over-prescribing of expensive items.

1.42 Furthermore, we are able to offer the practices individual product usage and dispensed items data on request."

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

1.44 "Our previous answer has detailed how our application meets each of the three stipulations set out in the 2013 NHS (Pharmaceutical Services) Regulations. 18(2). Waterfall Healthcare would secure the unforeseen benefits detailed in the above answer as follows:

1.45 Employment of Specialist DAC Nurse – we would recruit a specialist stoma and continence clinician from within the locality of the Herefordshire HWB boundary to provide all of the requisite patient support and care previously detailed above. As well as visiting patients in the comfort of their own home, our DAC centre would also provide a consultation room should this be the patient's preferred option (please see floorplan previously provided). Patients would then have the choice of a home visit or if preferred come to our DAC site for a discreet assessment with our nurse.

1.46 There would also be scope for the DAC Nurse to work in conjunction with the local pharmacy on 'The New Medicine' initiative (pg. 38) that specifically identifies a gap in patient need for Urinary incontinence/retention conditions. Whilst the DAC nurse would only focus on the appliances, there would be scope to help signpost the patient to the pharmacist for any medicine related support.

1.47 Appliance Use Review provision – in line with the above service provision, our nurse will submit the necessary AUR documentation for all meaningful patient interactions. A copy of this will be kept on file for our records, a copy will be sent to the registered GP for their records and finally the referrer (e.g. District Nurse) for their records. All AURs to be conducted in line with Part 3 'Advanced Services: Appliances' Directions. Clearly if the anticipated growth rates in the 65+ (33%) and 85+ (55%) are accurate then we will ensure greater nurse presence to accommodate the increasing pressure across the HWB.

1.48 Stoma Customization – patients requesting stoma pouch customization will have this performed at our DAC site either by our DAC nurse or alternatively our trained customer service team. This can be performed in our consultation room when not in use.

1.49 Premises – The premises will be user friendly, clean, have a consulting room, free parking, storage and be accessible for all customers. Please note our DAC site and consultation room are all on ground floor level, ensuring ease of access for all users.

1.50 Product Sampling – Our DAC site comes equipped with 530 sq. ft. of designated storage space. This will enable us to store comprehensive product ranges and offer patients a variety of products to try should they need to determine what best suits their unique needs. In addition to this enhanced patient choice, the storage space also has the benefit of holding adequate stock provision should any appliance manufacturer have supply issues that could consequently seriously compromise a patient's quality of life. Holding plentiful stock will help alleviate this risk factor to patients across the Herefordshire HWB. It should be noted that continence and stoma appliances tend to be large, bulky items that are difficult for pharmacies to store. Having our own designated storage facility within our Herefordshire address will alleviate this challenge.

1.51 Discreet Deliveries - As part of the home delivery service, all parcels will be made to patients via discreet courier deliveries ensuring neighbours will have no insight into the types of delivery being made.

1.52 Workforce – In keeping with the requirements on page 7 of the PNA (ICS Objective 3), Waterfall Healthcare will have the most highly trained, local workforce possible, with far more relevant skills in dealing with the patients who require continence and stoma products than any existing dispensing outlets. All colleagues will undergo continual professional development in the relevant field and have regular peer appraisals.

1.53 Environment - The local presence of a DAC will help meet the ongoing demands for Herefordshire county to achieve 'net zero carbon by 2030' (www.herefordshire.gov.uk/business).

1.54 Pharmacies from across the county would now be able to signpost to their local DAC, employing local people, and delivering from a local location, as opposed to relying on an alternative provider based further afield in the UK. This again helps meet the key ICS objectives detailed on page 7 of the PNA.

1.55 For all of the above reasons, we believe that in granting this application Herefordshire HWB will save money, reduce wastage, offer a better range and choice of service to a particular group of disadvantaged patients. All of these benefits have not been foreseen within the PNA."

2 The Decision

The Commissioner considered and decided to refuse the application. The decision letter dated 3 March states:

2.1 **"Re: Application offering unforeseen benefits at Unit N004, Wyastone Business Park, Wyastone Leys, Ganarew, Monmouth, NP25 3SR.**

2.2 Herefordshire and Worcestershire ICB has considered the above application and I am writing to confirm that it has been refused. Please see the enclosed report for the full reasoning.

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

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

Decision report

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

2.5 "The Committee have **Refused** the following application for Unforeseen Benefits within Herefordshire HWB.

2.6 **Waterfall Healthcare Limited - ME3421 - CAS-369599-X4M7K7**

2.7 **Address/best estimate of the proposed premises:** Unit N004, Wyastone Business Park, Wyastone Leys, Ganarew, Monmouth, NP25 3SR

2.8 **Determination:**

2.9 The Committee reviewed the services offered, in general, from a dispensing appliance contractor and that the services are offered nationally. Most services offered by a DAC are provided within the patients home by a specialist nurse, patients also have the choice to attend the DAC premises for measurements and fitting.

2.10 PSRC Determination Regulation 18 - Unforeseen benefits applications

2.11 18.—(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

2.12 The Committee considered that this was an application for unforeseen benefits under the provisions Regulation 18(1)(a) and was satisfied in that it was 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 Herefordshire HWB

2.13 (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(a) (regulations as to pharmaceutical services), NHS England must have regard to the matters set out in paragraph (2).

2.14 (2) Those matters are— (a)whether it is satisfied that granting the application would cause significant detriment to—

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

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

2.17 This Regulation is deemed to have been not met.

2.18 Granting the application will cause significant detriment to the proper planning and provision of pharmaceutical services in the HWB area (i) and (ii)

2.19 (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—

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

2.21 The PNA states "There are 27 Pharmacies and 10 Dispensing GP Practices.

2.22 The PNA does not include the need for improvement or better access. The applicant has not provided any evidence that any persons within the area of the proposed premises are having difficulty accessing pharmaceutical services, or pharmaceutical services of a specified type.

2.23 Therefore, this Regulation is deemed not to have been met.

2.24 (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)

2.25 The applicant has not provided evidence that people who share a protected characteristic have either difficulty accessing pharmaceutical services or are unable to access pharmaceutical services.

2.26 This Regulation is deemed not to have been met.

2.27 (iii) there being innovative approaches taken with regard to the delivery of pharmaceutical services (taking into account also the NHSCB's duties under section 13K of the 2006 Act(a) (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.

2.28 Innovative approaches to the delivery of pharmaceutical services were not demonstrated by the applicant. There is no innovative approach offered within the application.

2.29 This Regulation is deemed to have not been met.

2.30 This application is not being consider alongside with any other application under paragraph 22 (3), Schedule 2 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013

2.31 (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;

2.32 This application is not being consider alongside with any other application under paragraph 22 (3), Schedule 2 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013

2.33 (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;

2.34 Currently there are no appeals relating to another application offering to secure the same improvements or better access pending however committee. (f) whether the application needs to be deferred or refused by virtue of any provision of Part 5 to 7. No deferral was required.

2.35 (3) The NHSCB 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).

2.36 Regulation 65: The applicant has applied to provide a total of forty core hours.

2.37 Regulation 65 (4) therefore applies if the application is to be granted, Dispensing Appliance contractors are only required to open for thirty core opening hours, the additional ten opening hours will need to be directed subject to the conditions set out in Regulation 65(4).

2.38 Regulation 66: The applicant has undertaken to provide the following directed services if the application is granted: Appliance use reviews (AURs) and Stoma appliance customisation.

2.39 Regulation 66(4) therefore applies if the application is to be granted, and the inclusion of the applicant and the pharmacy premises in the pharmaceutical list for the area of Herefordshire HWB would be subject to the condition set out in Regulation 66(5).

2.40 The Committee refused the application.

2.41 Regulation 18 (1) a, b is not met. Regulation 18 (2) b(ii), (iii) is not met. The Committee determined that appeal rights are to be granted to the applicant.

2.42 Application is refused, appeal rights to the applicant."

3 The Appeal

In a letter dated 13 March 2026 addressed to NHS Resolution, the Applicant appealed against the Commissioner's decision. The grounds of appeal are:

3.1 "This document sets out the grounds of appeal against the refusal of application ME3421-CAS369599-X4M7K7 for Unforeseen Benefits within Herefordshire Health and Wellbeing Board (HWB).

3.2 The application sought inclusion in the pharmaceutical list as a local Dispensing Appliance Contractor to provide dispensing services and directed service including:

3.2.1 Appliance Use Reviews (AURs)

3.2.2 Stoma Appliance Customisation

3.3 The decision of the committee concluded that the application did not satisfy any of the key determinants within Regulation 18 of the 2013 NHS Regulations.

3.4 The appellant respectfully judges the committee's decision to be flawed in reasoning and application of the statutory test.

3.5 In particular, the committee:

3.5.1 Failed to provide evidence of significant detriment.

3.5.2 Placed determinative weight on the PNA.

3.5.3 Failed to properly assess unforeseen benefits.

3.5.4 Failed to assess access to specialist DAC services.

3.5.5 Dismissed service delivery innovation.

3.6 **Significant Detriment**

3.7 The committee stated that granting the application would:

3.8 'cause significant detriment to the proper planning and provision of pharmaceutical services in the HWB area (i) and (ii)',

3.9 There is NO evidence to support this decision, and the appellant would strongly reject this statement based on the following grounds:

3.9.1 The statutory threshold is ‘significant detriment' and the absence of any reasoning or supporting analysis means that the committee has NOT demonstrated that the statutory threshold has been met.

3.9.2 All relevant 'interested parties' across the HWB and surrounding localities were sent notification of the DAC application (15th August 2025) along with detailed explanatory notes outlining the proposal. Interested Parties were granted a 45-day time period to make any comments. The only notable feedback received during this notification period was a strong endorsement by the Chief Executive Officer for Community Pharmacy Herefordshire and Worcestershire citing, the application is well presented, and the proposal offers additional beneficial options for patients needing appliances and associated discreet services'. NO concerns from the existing pharmacy network or other ‘interested parties' were raised about detrimental impact to services.

3.9.3 The nearest pharmacy within Herefordshire HWB to the appellant's address is over 8 miles away. There is no DAC located within the HWB (nearest one is 35 miles away).

3.9.4 The appellant's address is located within the southern region of Herefordshire HWB. This region of the county has the worst pharmacy/ contractor density per head by some margin (ref. p.46 of 2025 PNA).

3.9.5 The Committee's decision does not identify any existing DAC providers who would be materially affected, any pharmaceutical services that would be undermined or any planning arrangements that would be disrupted,

3.10 All of the above points demonstrate that the committee's conclusion of 'significant detriment' is unsubstantiated and flawed.

3.11 The appellant believes that this further justification satisfies Regulation 18 (2) (a) (i) (ii).

3.12 **Placed determinative weight on the PNA**

3.13 The Committee rejects the appellant's case based on the following statements:

3.14 'The PNA does not include the need for improvement or better access',

3.15 This statement is used by the Committee to help to justify their rejection of the improved access to pharmaceutical services that the application would bring to residents within the HWB, Use of this statement by the Committee is flawed as the entire purpose of Regulation 18 is precisely to allow applications where

benefits were NOT foreseen when the PNA was prepared The Committee is using the absence of identified need within the PNA as the determining factor. The appellant submits that this represents a misapplication of the statutory test.

3.16 **Failed to properly assess unforeseen benefits**

3.17 The Committee states:

3.18 'The applicant has not provided any evidence that any persons within the area of the proposed premises are having difficulty accessing pharmaceutical services'.

3.19 This logic is flawed as Regulation 18 (unforeseen benefits) should focus on whether the granting of the application would secure improvements or better access that were not foreseen in the PNA.

3.20 The Committee requesting proof that patients are struggling or unable to access services is NOT the correct test to apply. Regulation 18 does NOT require evidence of current access failures. It instead allows applications where additional benefits would improve access or service quality. By requiring evidence of difficulty accessing services, the Committee appears to have applied a higher threshold than that required by Regulation 18.

3.21 The appellant believes that these further justifications satisfy Regulation 18 (2) (b) (i).

3.22 **Failed to assess access to specialist DAC services**

3.23 The Committee rejects the appellant's proposal that a new DAC service located within the HWB, will improve access to services for people who share a /protected characteristic'.

3.24 The appellant strongly refutes this position, and the following comparison table helps to underline the pharmaceutical services offered within the HWB today (as detailed in the 2025 PNA) and what would be available to patients if a DAC was located within Herefordshire HWB:

SERVICE TYPE	AVAILABLE FROM PHARMACIES IN THE HWB	AVAILABLE FROM APPELLANT'S PROPOSED DAC
Standard Appliance Dispensing	Yes	Yes
Stoma Appliance Fitting	No	Yes
Appliance Use Reviews	No	Yes
Appliance Customisation	No	Yes

Specialist Stoma Support	No	Yes

3.25 This visually shows that should the appellant's proposal be accepted then patients with challenging health conditions like continence and stoma complications (i.e. 'protected characteristics') would now have improved choice and better access to pharmaceutical services of a specified type, within the confines of their own HWB.

3.26 The appellant's case is further strengthened when an analysis of the proposed DAC premises and the nearest DAC providers is considered:

DAC PROVIDER	**LOCATION**	**DISTANCE FROM APPELLANT'S PROPOSED DAC ADDRESS**	**TRAVEL TIMES**
Provider A	Cardiff	45 miles	60 minutes
Provider B	Gloucestershire	35 miles	55 minutes
Provider C	Bristol	42 miles	50 minutes

3.27 The Committee relied on the national availability of DAC Services. However, analysis of local provision (see above) demonstrates that the nearest DAC premises are located significant distances from the proposed site.

3.28 For patients with complex, clinical conditions (i.e. 'protected characteristics') requiring appliance services, travel over such distances will represent a major barrier to accessing specialist support. The Committee has relied on general national service availability rather than analysing whether patients in the local area have reasonable and practical access to services, which is the key consideration under the Regulations.

3.29 The appellant would therefore argue against the Committee's rejection and instead attest that the proposed service would improve practical access to dispensing appliance services for patients within the Herefordshire HWB. The Committee has failed to appreciate the benefits of locally accessible support, including fitting services, appliance advice, local nurse support and appliance use reviews.

3.30 Continence and stoma conditions are typically complex and highly emotive health challenges. The potential that this application offers for patients within their own HWB to have ongoing access and continuity of care from the comfort of their own home is genuinely life changing. The existing pharmacy and dispensing practice offering within the Herefordshire HWB can't Offer this specialist, on going support. It is important to note that not all DAC providers have nursing 'teams, and those that do often have patchy coverage and will

never be able to offer the full patient support and continuity of care that this locally driven application will deliver.

3.31 The appellant believes that this further justification satisfies Regulation 18 (2) (b) (ii).

3.32 **Dismissal of service delivery innovation**

3.33 Regulation 18 (2) (b) (iii) states the following:

3.34 'Innovative approaches taken with regard to the delivery of pharmaceutical services' which would 'confer significant benefits on persons in the area of the relevant HWB'.

3.35 The Committee has simply stated,

3.36 ‘There is no innovative approach offered within this application’.

3.37 The Committee did not provide analysis explaining why the services proposed would not be innovative and represent improvements in service delivery.

3.38 The appellant rejects the Committee's statement and instead argues that innovation is clear/y demonstrated by:

INNOVATION	HOW IS IT DELIVERED	OUTCOME
Specialist, local Nurse support	Specialist, local DAC Nurse, will support all patients across the Herefordshire & Worcestershire Patients will be assessed quickly and provided with ongoing support either in the comfort of their own home or at the DAC licenced address.	Improved Clinical pathways / reduction of unnecessary hospital admissions and reduced waiting lists/bed blocking
Product Availability	Applicant's licence address has considerable storage space tor Part IX products. Pharmacies do not hold such stock. Items can either be collected from local premises or delivered direct to user.	Improved availability and speed of delivery to end user.

Emergency Supply	Applicant will hold samples of leading manufacturers' products. If a patient runs out and urgently requires emergency stock, samples can be provided.	Improved Patient Safety.
Ongoing Support	Local DAC Customer Service Team and Local DAC Nurse(s) will be experts on the needs of the local HWB e.g. prescribing formulary awareness, geography of the region, GP practices etc.	Patient Reassurance knowing they are supported by a local, in-area provider. Improved continuity of care and patient support. Reduced catheter associated infection risks.

3.39 The appellant contests that the Committee dismissed the potential for innovative approaches without assessing whether locally delivered appliance services could improve patient experience, clinical pathways and service delivery outcomes.

3.40 The appellant believes that this further justification satisfies Regulation 18 (2) (b) (iii).

3.41 **Conclusion**

3.42 The appellant respectfully submits that the Committee's decision was flawed for the following reasons:

3.42.1 Regulation 18 was misapplied through reliance on the absence of need in the PNA.

3.42.2 The Committee did not provide evidence supporting the conclusion of significant detriment.

3.42.3 The decision was predicated on the national availability of DAC services without proper assessment of practical access issues for patients in the Herefordshire HW8 area.

3.42.4 The specialist nature of DAC services was not adequately considered.

3.43 The appellant respectfully requests that the appeal body:

3.43.1 Allow the appeal.

3.43.2 Grant the application for inclusion in the pharmaceutical list as a dispensing appliance contractor.

3.43.3 Apply any conditions required under Regulations 65 and 66 regarding core hours and directed services."

4 Summary of Representations

On reviewing the paperwork provided by PCSE, it was noted that the 'Pharmaceutical Application Report for Committee' [Appendix A] provided further reasoning for the Commissioner's decision.

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

This is a summary of representations received on the appeal.

4.1 The Applicant

4.1.1 "The appellant respectfully invites the Committee to consider the lived reality of those managing long-term continence and/or stoma conditions, in order to provide important context to this appeal.

4.1.2 While this application must necessarily be considered within the relevant regulatory framework, the appellant believes it is equally important to recognise the real-world impact these conditions have on patients' daily lives, independence, dignity, and wider wellbeing.

4.1.3 Continence and stoma conditions are often life-changing, complex, and enduring. Although affected patients may represent a comparatively small proportion of the wider population, prevalence data alone does not fully capture the true burden of need. These conditions remain highly stigmatised, with many individuals delaying help-seeking or suffering in silence due to embarrassment, social isolation, and loss of dignity.

4.1.4 For many patients, bowel or urinary incontinence creates a persistent fear of accidents, leading to anxiety around leaving the home, reduced social participation, loss of confidence, and, in some cases, significant deterioration in both physical and mental wellbeing. The consequences therefore extend well beyond symptom management alone, often impacting mobility, employment, family life, and overall quality of life.

4.1.5 It is the appellant's position that access to a high-quality, responsive local Dispensing Appliance Contractor (DAC) service has the potential to deliver meaningful and unforeseen benefit to this patient group through improved access, enhanced support, greater convenience, and preservation of dignity for vulnerable individuals managing highly sensitive conditions.

4.1.6 The Committee is therefore respectfully asked to consider not only the regulatory and commissioning criteria applicable to this application, but also the practical and human consequences of service accessibility for this often overlooked patient cohort.

4.1.7 **The central question for consideration is whether approval of this application would provide substantial incremental benefit to Herefordshire patients and the wider NHS, without introducing financial risk to the Commissioner. The appellant submits that the evidence presented demonstrates that this threshold is met.**

4.1.8 **Response to refusal ground: Regulation 18(1)(a) and (b)**

4.1.9 The Commissioner relies upon the October 2025 PNA, which states that there is currently sufficient provision of pharmacies and dispensing GP practices within Herefordshire delivering essential pharmaceutical and dispensing services.

4.1.10 The PNA further concludes that no gaps were identified in the provision of necessary services within the area.

4.1.11 The appellant submits that this conclusion is based predominantly on an assessment of essential dispensing services, rather than the full scope of pharmaceutical services relevant to patients requiring specialist appliance support.

4.1.12 The proposed DAC service does not relate solely to essential dispensing activity, but instead focuses on the delivery of specialist appliance-related support services, including:

4.1.12.1 Appliance Use Reviews

4.1.12.2 Stoma Customisation services

4.1.13 These services fall within the category of advanced pharmaceutical services, which are distinct in nature from standard dispensing provision and are designed to meet the specific clinical and practical needs of patients requiring ongoing appliance support.

4.1.14 The appellant submits that the conclusions reached within the October PNA may be limited by the methodological approach used to assess service sufficiency. In particular, the assessment appears to rely predominantly on the presence of general pharmaceutical and dispensing provision, without clearly distinguishing or separately evaluating the availability, visibility, and accessibility of specialist appliance dispensing and associated advanced services within the Herefordshire HWB.

4.1.15 As a result, there is a risk that conclusions regarding ‘no gaps in provision’ may reflect the adequacy of general pharmacy infrastructure rather than a granular assessment of specialist continence and stoma related service provision. This may have the effect of under-representing or not fully evidencing variations in access to dedicated

appliance focused services, which are materially different in nature from standard dispensing activity.

4.1.16 Patients requiring stoma or continence appliances typically present with ongoing and highly individualised needs, which differ materially from general dispensing users. These needs commonly include:

4.1.16.1 specialist product knowledge and ongoing support

4.1.16.2 requirement for discreet and reliable supply arrangements

4.1.16.3 continuity of supply for essential medical appliances

4.1.16.4 personalised adjustment of products through specialist review and customisation

4.1.17 Such requirements are most effectively met through dedicated appliance-focused services, rather than general dispensing arrangements alone.

4.1.18 At present, there is no identifiable DAC service located within the geographical area of the Herefordshire HWB.

4.1.19 As a result, patients requiring specialist appliance support are reliant on non-local or dispersed provision pathways, which may limit accessibility and continuity of care.

4.1.20 In light of the above, the appellant submits that:

4.1.20.1 the current assessment of service sufficiency is primarily based on general dispensing provision; and

4.1.20.2 the specific requirements of patients requiring specialist appliance dispensing and associated advanced services are not fully reflected in the PNA conclusions.

4.1.21 **Accordingly, the appellant submits that the introduction of a locally based DAC service would address a currently unrecognised gap in specialist appliance service provision within the Herefordshire HWB, and that it is therefore reasonable and appropriate to grant the application under Regulation 18(1)(a) and (b).**

4.1.22 **Response to refusal ground: Regulation 18(2)(a)(i) and (ii)**

4.1.23 Granting the application does not prejudice existing arrangements; it supplements them.

4.1.24 Granting the application would not see existing services replaced or removed, would not require NHS England to fund new infrastructure and all existing providers would remain unaffected operationally.

4.1.25 Beyond the above points, the appellant has no further comment than previously detailed within the initial appeal response statement.

4.1.26 **Response to refusal ground: Regulation 18(2) (b)**

4.1.27 **Overview**

4.1.28 This section addresses Regulation 18(2)(b), namely whether, notwithstanding that the proposed improvements and better access were not included within the relevant PNA, the Committee is nevertheless satisfied that granting the application is desirable having regard in particular to:

4.1.29 (i) the desirability of there being reasonable choice in obtaining pharmaceutical services; and

4.1.30 (ii) the desirability of ensuring equitable access for persons with protected characteristics who experience barriers accessing pharmaceutical services.

4.1.31 **Reasonable Choice in obtaining pharmaceutical services in the HWB - 18(2)(b)(i)**

4.1.32 The October 2025 PNA identifies nine advanced services currently associated with community pharmacies within the Herefordshire HWB, including Appliance Use Reviews and Stoma Customisation services. However, the PNA further confirms that information regarding which specific pharmacies within Herefordshire currently provide these services was not available at time of publication.

4.1.33 In the absence of clearly identifiable local providers delivering these advanced services, patients are unable to readily determine where specialist appliance-related support is available within their local area. This creates a practical limitation on the exercise of meaningful choice, as patients cannot make informed decisions between locally accessible providers where service availability is not transparent or clearly delineated.

4.1.34 In addition, there is currently NO locally based dedicated DAC service within the HWB area. As a result, patients requiring stoma or continence-related pharmaceutical support are required to access services through non-local or fragmented provision routes, which may reduce the extent to which choice is both accessible and practically exercisable.

4.1.35 Accordingly, whilst services may exist within the wider system, the current configuration does not provide patients within the HWB with a clearly identifiable or locally accessible range of specialist options from which to exercise meaningful choice in relation to appliance dispensing and specialist, associated support services.

4.1.36 It is this shortfall in specific, localised, advanced service provision for residents within the Herefordshire HWB that the appellant is seeking to secure improvements and better access to.

4.1.37 **Access for persons with protected characteristics and reduction of inequalities in the HWB – 18(2)(b)(ii)**

4.1.38 NHS Health Data demonstrates that the Herefordshire & Worcestershire ICB has a higher-than-national average prevalence of both intermittent catheter and stoma patients. In addition, the October 2025 PNA identifies a significant ageing population, including substantial growth in both the 65+ and 85+ age cohorts between 2013 and 2023. These demographic factors are strongly associated with increased prevalence of continence-related conditions and stoma care needs.

4.1.39 A significant proportion of this patient population is therefore likely to include individuals with protected characteristics under the Equality Act 2010, particularly age and disability. These characteristics are commonly associated with reduced mobility, increased reliance on carers, and greater difficulty accessing dispersed or non-local healthcare services.

4.1.40 Patients within this cohort may also experience additional barriers to accessing pharmaceutical services, including embarrassment associated with continence conditions, reduced confidence in seeking help, and heightened sensitivity to delays or lack of specialist support. These factors can contribute to under-utilisation of services and disproportionate difficulty in accessing timely and appropriate appliance-related care.

4.1.41 Taken together, the evidence supports the conclusion that individuals with protected characteristics within the HWB are more likely to experience barriers to accessing specialist pharmaceutical services where provision is not locally based, clearly visible, or designed around their specific needs. This engages the duties under section 13G of the NHS Act 2006 in relation to reducing health inequalities.

4.1.42 Policy Context

4.1.43 National policy direction, including the Department of Health and Social Care's 'Fit for the Future: 10 Year Health Plan', supports an expanded role for community pharmacy in the delivery of care for patients with long-term conditions. This provides relevant contextual support for service models that enhance local access to specialist pharmaceutical services, particularly for vulnerable patient groups.

4.1.44 The appellant therefore concludes that when considered collectively, the evidence demonstrates that:

4.1.44.1 **Current service provision does not provide clearly identifiable or locally accessible choice in specialist appliance dispensing services within the HWB; and**

4.1.44.2 **Patients with protected characteristics, particularly older adults and individuals living with disability, are more likely to experience barriers in accessing such services**.

4.1.45 The appellant respectfully rejects the Commissioner's reference to the lack of complaints in the last 12 months to justify their decision making. The absence of formal complaints over a 12-month period cannot reasonably be treated as evidence that current service provision fully meets patient needs, particularly in a patient cohort characterised by vulnerability, low complaint propensity, and dependence on third-party carers. Regulation 18 does not require proof of service failure or complaint history as a precondition for grant. The absence of complaints would have more merit had there already been a DAC provider located within the HWB and offering all of the advanced services detailed within the application. As there is currently no DAC provider located within the HWB then patients do not have an equivalent service to benchmark against.

4.1.46 The appellant therefore submits that the introduction of a locally based DAC service would materially improve both reasonable choice and equitable access within the HWB.

4.1.47 These benefits were not explicitly identified within the relevant PNA and therefore constitute material considerations under Regulation 18 (2) (b).

4.1.48 The appellant accordingly submits that approval of the application is justified.

4.1.49 **Response to refusal ground: Regulation 18(2)(b)(iii) – Innovative approaches to delivery of pharmaceutical services**

4.1.50 The Committee states:

4.1.51 "*Innovative approaches to the delivery of pharmaceutical services were not demonstrated by the applicant. There is no innovative approach offered within the application."*

4.1.52 Waterfall Healthcare respectfully disagrees with this conclusion.

4.1.53 This statement does not appear to engage with multiple specific service innovations expressly detailed within the application, nor explain why those proposals were discounted.

4.1.54 The appellant's proposal contained a number of innovative, cohesive service features (expanded further in points 1-5 below) which, both individually and cumulatively, constitute innovative approaches to the delivery of pharmaceutical services within Herefordshire.

4.1.55 **1. Introduction of a clinically integrated DAC model not currently available within Herefordshire**

4.1.56 Waterfall Healthcare proposed to fund and deploy a specialist continence and stoma nurse(s) based locally within the Herefordshire Health and Wellbeing Board area.

4.1.57 This service model integrates dispensing appliance provision with:

4.1.57.1 specialist continence and stoma clinical support;

4.1.57.2 domiciliary assessments;

4.1.57.3 appliance optimisation;

4.1.57.4 early intervention where patients are experiencing difficulties with appliance use;

4.1.57.5 support for local community nursing teams and other healthcare professionals.

4.1.58 This represents a materially different pharmaceutical service delivery model from traditional remote DAC provision, which is generally limited to order processing and supply.

4.1.59 The proposed service therefore links pharmaceutical appliance provision directly with cohesive, proactive clinical review and intervention.

4.1.60 This is an innovative approach to pharmaceutical service delivery.

4.1.61 **2. Introduction of local stoma appliance customisation service where none currently exists**

4.1.62 The appellant referenced the 2025 PNA that could not evidence the pharmacies providing a stoma customisation service.

4.1.63 Waterfall Healthcare proposed to establish a local stoma appliance customisation service for all eligible patients within the HWB.

4.1.64 This is not an enhancement of an existing service, but the introduction of a pharmaceutical service capability currently absent from the local market.

4.1.65 It is therefore difficult to reconcile the Committee's conclusion that "there is no innovative approach offered" with the objective PNA evidence confirming this service is currently unavailable from any service provider within the specific HWB.

4.1.66 **3. Data-led prescribing and appliance utilisation monitoring**

4.1.67 The application described use of a "Customer Usage Chart" to identify prescription requests outside expected usage parameters.

4.1.68 This system enables:

4.1.68.1 early identification of possible over-ordering;

4.1.68.2 under-utilisation;

4.1.68.3 incorrect appliance use;

4.1.68.4 changes in patient clinical need;

4.1.68.5 referral for nurse review or onward GP intervention where appropriate.

4.1.69 This introduces a proactive, cohesive appliance stewardship and prescribing efficiency mechanism into the DAC pathway.

4.1.70 This is materially different from reactive dispensing and represents an innovative data-driven pharmaceutical service model designed to improve outcomes and reduce NHS waste.

4.1.71 **4. Integrated locally accountable community support pathway**

4.1.72 The application also proposed a combined service model including:

4.1.72.1 locally based DAC premises (equipped with patient consultation room);

4.1.72.2 domiciliary Appliance Use Reviews;

4.1.72.3 24-hour freephone ordering;

4.1.72.4 online ordering access;

4.1.72.5 free product sampling across all manufacturers;

4.1.72.6 local nurse-led domiciliary support;

4.1.72.7 discreet delivery and prescription collection.

4.1.73 Whilst certain individual components may exist elsewhere in isolation, innovation should not be assessed solely by reference to whether each isolated component exists in another context.

4.1.74 The relevant issue is whether the appellant has proposed an innovative approach to service delivery.

4.1.75 Waterfall Healthcare proposed an integrated, locally embedded DAC model combining pharmaceutical supply, clinical support, appliance customisation and prescribing stewardship into a single pathway not currently available within Herefordshire.

4.1.76 The cumulative model is itself innovative.

4.1.77 **5. Apparent failure to provide reasons**

4.1.78 The refusal provides no reasoning as to:

4.1.78.1 which elements of the appellant's proposals were considered;

4.1.78.2 why the specialist nurse model was not regarded as innovative;

4.1.78.3 why introduction of a currently absent stoma customisation service was not regarded as innovative;

4.1.78.4 why the data-led monitoring system was not regarded as innovative**.**

4.1.79 A bare assertion that no innovation exists is insufficient where detailed proposals were submitted.

4.1.80 Without reasons explaining why these proposals were rejected, the appellant is unable to understand how Regulation 18(2)(b)(iii) was properly applied.

4.1.81 For the reasons above, Waterfall Healthcare submits that the Committee's conclusion under Regulation 18(2)(b)(iii) is unsustainable.

4.1.82 The application clearly proposed multiple innovative approaches to pharmaceutical service delivery, including:

4.1.82.1 a locally funded specialist continence/stoma nurse model;

4.1.82.2 introduction of currently absent local stoma customisation services;

4.1.82.3 proactive appliance utilisation monitoring and prescribing stewardship;

4.1.82.4 an integrated, cohesive community-based DAC pathway exceeding the current

4.1.82.5 service model available within the HWB.

4.1.83 Accordingly, the finding that "there is no innovative approach offered within the application" is not supported by the evidence before the Committee and should be reconsidered.

4.1.84 The appellant respectfully cites that until an individual experiences the life changing challenges of managing a long-term stoma or continence condition, it is very difficult to understand and define innovation. The innovations in service delivery detailed above are not currently available from within the local HWB. What the appellant is proposing needs to be seen through the eyes of a potential catheter, stoma bag, drainage bag, faecal bag, etc. user and appreciate the qualitative enhancements that granting this application will deliver.

4.1.85 **Conclusion: Public benefit and proportionality of granting the application**

4.1.86 Granting the application would create substantial incremental benefit for Herefordshire patients and the NHS at no financial risk to the commissioner.

4.1.87 **Approval would introduce:**

4.1.87.1 a new locally based DAC provider not currently present within the HWB;

4.1.87.2 greater patient choice;

4.1.87.3 local stoma appliance customisation currently absent from the area; specialist continence and stoma nursing support funded entirely by the appellant;

4.1.87.4 domiciliary appliance support for vulnerable and housebound patients;

4.1.87.5 proactive appliance utilisation monitoring to reduce waste and improve prescribing efficiency.

4.1.88 These benefits are particularly relevant to vulnerable patient groups, including elderly, disabled, post-operative and housebound individuals who may face greater barriers accessing fragmented or remote appliance services.

4.1.89 By contrast, refusal of the application produces **NO** equivalent patient or NHS benefit.

4.1.90 It simply preserves the current position, including the continued absence of the above locally available services.

4.1.91 The Committee is therefore invited to consider that approval offers material patient, system and service benefits at no commissioning cost or financial exposure to NHS Herefordshire.

4.1.92 Stoma and continence patients often represent a clinically vulnerable and under-recognised cohort whose needs are highly personal, dignity-sensitive and frequently managed within the home.

4.1.93 For these patients, responsive local support, correct appliance fitting and timely clinical intervention can have a disproportionate impact on dignity, independence and quality of life.

4.1.94 **The appellant respectfully requests that the appeal body:**

4.1.94.1 Grant the application for inclusion in the pharmaceutical list as a dispensing appliance contractor.

4.1.94.2 Apply any conditions required under Regulations 65 and 66 regarding core hours and directed services.

4.1.95 **Appendix: Waterfall Healthcare Ltd**

4.1.96 The appellant (Waterfall Healthcare) notes that on Page 1 of the Commissioner's Pharmacy Application Report (CPAR) it states the 'best estimate' of the proposed premises. Please note this is incorrect. The appellant provided a confirmed, exact address and NOT a 'best estimate'. This was clearly stated in the appellant's 'Annex 1' application form that was submitted on 16th June 2025.

4.1.97 The appellant notes that the previously submitted action report document circulated with the refusal letter on 3rd March 2026, states a meeting date of 7th January 2026 on the header of each page of the 7 page report. In the 'meeting date' column, however, the meeting date is detailed as '07/02/26'. The appellant would welcome clarity on this date conflict.

4.1.98 The appellant notes a typing error on page 2 of the CPAR. At no point in the application did the appellant make reference to 'the county of 6 of 10'. What is the Commissioner stating here? It did not feature in the appellant's original application. The appellant can only assume this is a typing error."

4.2 Community Pharmacy Herefordshire and Worcestershire

4.2.1 "Thank you for your letter dater 28th April 2026.

4.2.2 Further to our correspondence in August 2025, Community Pharmacy Herefordshire & Worcestershire (LPC) would like to make the following observations. We consider this to be a routine application under Regulation 18 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as it offers unforeseen benefits.

4.2.3 The application is clearly presented and outlines a proposal that would provide valuable additional options for patients requiring appliances, including access to associated discreet services. We also note that the nearest pharmacies are located more than three miles away.

4.2.4 The LPC has no further comments at this stage; however, we would appreciate being kept informed of any developments, particularly if an oral hearing is scheduled.

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

5 Observations

This is a summary of observations received by NHS Resolution in response to the representations received on appeal.

5.1 The Applicant

5.1.1 "**FINAL OBSERVATIONS**

5.1.2 The Appellant notes that no further representations have been submitted by the Commissioner in response to the appeal.

5.1.3 Accordingly, the Appellant does not seek to repeat the detailed submissions already before the Pharmacy Appeals Committee and relies upon the application, appeal grounds and supporting evidence previously submitted.

5.1.4 The Appellant respectfully maintains that the appeal should be allowed for the reasons already advanced, namely that:

5.1.5 The proposed service would introduce a locally based Dispensing Appliance Contractor within the Herefordshire Health & Wellbeing Board area, where NO such provider currently exists;

5.1.6 The application would improve access to specialist appliance services, including Appliance Use Reviews and Stoma Customisation;

5.1.7 The proposed service model offers benefits beyond routine dispensing through specialist continence and stoma support, domiciliary services and proactive patient engagement;

5.1.8 Granting the application would supplement existing arrangements, increase patient choice and create NO material detriment to existing providers;

5.1.9 The benefits arising from the proposal were not identified within the Pharmaceutical Needs Assessment and are therefore capable of satisfying the Regulation 18 unforeseen benefits test.

5.1.10 The Appellant also notes the support received during the application and appeal process from Community Pharmacy Herefordshire & Worcestershire, which considered that the proposal would provide unforeseen benefits and valuable additional options for patients requiring appliances and associated services.

5.1.11 In the absence of any further substantive representations from the Commissioner, the Appellant respectfully points out that the grounds of appeal remain unanswered. The evidence before the Committee supports the conclusion that granting the application would secure improvements and better access to pharmaceutical services of a specified type within the Herefordshire Health and Wellbeing Board area.

5.1.12 The Appellant therefore respectfully invites the Pharmacy Appeals Committee to quash the Commissioner's decision and direct that the application be granted."

6 Consideration

6.1 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.

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

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

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

6.5 There is no dispute that the application site of Ganarew, Monmouth is in a controlled locality, and the application was based on securing improvements or better access to pharmaceutical services in that controlled locality.

6.6 The Committee considered that the correct course was to first consider if the application must be refused pursuant to Regulation 31. The Committee will then consider if the application must be refused pursuant to Regulation 40. If the Committee is not so required to refuse the application, it will consider the issue of reserved location pursuant to Regulation 41. The Committee will then consider the application under Regulation 18. If the Committee has determined that the Applicant is seeking the listing of pharmacy premises which are in a part of a controlled locality that is not in a reserved location, it will consider the issue of prejudice under Regulation 44 last. The reason for this staged approach and in particular for dealing with prejudice last is that if the application does not meet the requirements of Regulation 18 the Committee is required to refuse it and prejudice cannot arise. The potential for prejudice only arises if the Committee has concluded that the application meets the requirements of Regulation 18 and may be granted. Depending on the determinations of the Committee in respect of the above as well as taking into consideration of whether the Commissioner has considered Regulation 50(1), the Committee will then consider Regulation 50(1) Discontinuance of arrangements for the provision of pharmaceutical services by doctors.

Regulation 31

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

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

(2) This paragraph applies where -

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

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

(ii) adjacent premises; and

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

6.8 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.

6.9 The Committee noted in the 'Pharmacy Application Report for Committee' the Commissioner stated that Regulation 31 is "*not applicable as the proposed location of the pharmacy is not adjacent or in close proximity to another pharmacy*" which had not been disputed on appeal.

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

Regulation 40

6.11 In those circumstances, the application (which is made under Regulation 18 of the Regulations) must be assessed against the provisions of Part 7 of the Regulations and, in particular Regulation 40 which reads:

(1) This paragraph applies to all routine applications—

(a) for inclusion in a pharmaceutical list as an NHS pharmacist; or

(b) from an NHS pharmacist included in such a list—

(i) to relocate to different pharmacy premises in the area of the relevant HWB, or

(ii) to open, within the area of the relevant HWB, additional pharmacy premises at or from which to provide pharmaceutical services,

where the applicant is seeking the listing of pharmacy premises which are in a controlled locality.

(2) If NHS England receives an application (A1) to which paragraph (1) applies, it must refuse A1 (without needing to make any notification of that application under Part 3 of Schedule 2), where the applicant is seeking the listing of premises at a location which is—

(a) in an area in relation to which outline consent has been granted under these Regulations, the 2012 Regulations or under the 2005 Regulations within the 5 year period—

(i) starting on the date on which the proceedings relating to the grant of outline consent reached their final outcome, and

(ii) ending on the date on which A1 is made; or

(b) within 1.6 kilometres of the location of proposed pharmacy premises (other than proposed distance selling premises), in respect of which—

(i) a routine application under these Regulations or the 2012 Regulations, or

(ii) an application to which regulation 22(1) or (3) of the 2005 Regulations (relevant procedures for applications) applied,

was refused within the 5 year period starting on the date on which the proceedings relating to the refusal reached their final outcome and ending on the date on which A1 is made,

unless NHS England is satisfied that since the date on which the 5 year period started, there has been a substantial and relevant change of circumstances affecting the controlled locality.

(3) For the purposes of paragraphs (1) and (2), if no particular premises are proposed for listing in A1, the applicant is to be treated as seeking the listing of pharmacy premises at the location which is the best estimate that NHS England is able to make of where the proposed listed pharmacy premises would be, having regard to the best estimate given by the applicant under paragraph 1(7)(a)(ii) of Schedule 2.

(4) Paragraph (2)(b) does not apply where NHS England is satisfied that there are reasonable grounds for believing the person making the refused application was motivated (wholly or partly) by a desire for that application to be refused.

(5) The refusal of an application pursuant to paragraph (2)(b), or regulation 40(2)(b) of the 2012 Regulations (applications for new pharmacy premises in controlled localities: refusals because of preliminary matters), is to be ignored for the purposes of the calculation of a 5 year period pursuant to paragraph (2)(b).

6.12 The Committee noted that there was no information to suggest that the instant application was in respect of a location where outline consent had been granted or there had been a refusal for a previous application within the last 5 years.

Regulation 41

6.13 Based on its conclusion above, the Committee went on to consider the application in light of the remainder of Part 7 of the Regulations and, in particular, Regulation 41 which reads:

(1) This paragraph applies to any routine application—

(a) for inclusion in a pharmaceutical list as an NHS pharmacist; or

(b) from an NHS pharmacist included in such a list—

(i) to relocate to different pharmacy premises in the area of the relevant HWB, or

(ii) to open, within the area of the relevant HWB, additional pharmacy premises at or from which to provide pharmaceutical services,

where the applicant is seeking the listing of pharmacy premises which are in a controlled locality and NHS England is required to notify the application under Part 3 of Schedule 2.

(2) If paragraph (1) applies to an application (referred to i0 n this regulation and regulation 42 as "A1"), subject to paragraph (5), NHS England must determine whether or not the "relevant location", that is—

(a) the location of the premises for which the applicant is seeking the listing; or

(b) if no particular premises are proposed for listing in A1, the location which is the best estimate that NHS England is able to make of where the proposed pharmacy premises would be, having regard to the best estimate given by the applicant under paragraph 1(7)(a)(ii) of Schedule 2,

is, on basis of the circumstances that pertained on the day on which A1 was received by NHS England, in a reserved location.

(3) Subject to regulation 43(2), the area within a 1.6 kilometre radius of a relevant location is a "reserved location" if—

(a) the number of individuals residing in that area who are on a patient list (which may be an aggregate number of patients on more than one patient list) is less than 2,750; and

(b) NHS England is not satisfied that if pharmaceutical services were provided at or from the relevant location, the use of those services would be similar to, or greater than, the use that might be expected if the number of individuals residing in that area who are on a patient list were 2,750 or more.

(4) Before making a determination under paragraph (2) (referred to in this regulation and regulation 42 as "D1"), NHS England must—

(a) notify the persons notified under Part 3 of Schedule 2 about A1 that NHS England is required to make D1 (and it may make this notification at the same time as it notifies those persons about A1); and

(b) invite them, within a specified period of not less than 30 days, to make representations to NHS England with regard to D1 (and the period specified must end no earlier than the date by which the person notified needs to make any representations that they have with regard to A1).

(5) NHS England must not make a determination under paragraph (2) in respect of A1 in circumstances where an earlier application which was in respect of the relevant premises and to which paragraph (1), regulation 44 of the 2012 Regulations (prejudice test in respect of routine applications for new pharmacy premises in a part of a controlled locality that is not a reserved

location) or regulation 18ZA of the 2005 Regulations (refusal: premises which are in a controlled locality but not a reserved location) applied was refused—

(a) for the reasons relating to prejudice in—

(i) regulation 44(3),

(ii) regulation 44(3) of the 2012 Regulations, or

(iii) regulation 18ZA(2) of the 2005 Regulations; and

(b) within the 5 year period starting on the date on which the proceedings relating to the refusal reached their final outcome and ending on the date on which A1 is made,

unless NHS England is satisfied that since the date on which the 5 year period started, there has been a substantial and relevant change of circumstances affecting the controlled locality.

(6) For the purposes of paragraph (5), the "relevant premises" are—

(a) the premises which are proposed for listing; or

(b) if no particular premises are proposed for listing in A1, premises at the location which is the best estimate that NHS England is able to make of where the proposed listed pharmacy premises would be, having regard to the best estimate given by the applicant under paragraph 1(7)(a)(ii) of Schedule 2.

6.14 The Committee noted that, although the application in this case is within the terms of Regulation 41(1), the correspondence from the Commissioner gives no indication that a notification was sent regarding the question of reserved location or that the question was considered. The correspondence gives no indication that any of the circumstances in which that process must not be undertaken applied to this case.

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

6.15.1 confirm the Commissioner's decision;

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

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

6.16 In the absence of any reference to the question of reserved location, the Committee considered that it might need to quash the Commissioner's decision and remit the matter back to it. The Committee considered, however, that this would be an unnecessary exercise if the application would fail on its own merits against the criteria in Regulation 18.

6.17 The Committee considered that it would be able to assess the application and, if the application could succeed based on the criteria in Regulation 18, the matter should be remitted pursuant to paragraph 9(1)(a)(iii) so that the issue of reserved location could be dealt with. The application should also be remitted if there appeared to be a need to remit for reasons connected with the Regulation 18 criteria themselves.

6.18 If, on the other hand, it could be determined that the application would not succeed based on the Regulation 18 criteria, a decision to remit should not be made and the Committee could proceed under paragraph 9(1)(a)(i) or (ii).

Regulation 18

6.19 The Committee therefore considered the application 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)."

6.20 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").

6.21 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.

6.22 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).

6.23 The Committee noted that Regulation 22 states:

"Refusal of routine applications that are based on neither a pharmaceutical needs assessment nor unforeseen benefits

(1) If NHS England receives a routine application to which regulation 19(6) does not apply, NHS England must refuse it unless granting it, or granting it in respect of some only of the services specified in it, would–

(a) meet a current or future need for pharmaceutical services, or a pharmaceutical services of a specified type, in the area of the relevant HWB that has been included in the relevant pharmaceutical needs assessment in accordance with paragraph 2 of Schedule 1; or

(b) secure (including in the future) improvements, or better access, to pharmaceutical services, or pharmaceutical services of a specified type, in the area of the relevant HWB that have or has been included in the relevant pharmaceutical needs assessment in accordance with paragraph 4 of Schedule 1.

(2) For the purposes of paragraph (1), the relevant pharmaceutical needs assessment is–

(a) the pharmaceutical needs assessment of the relevant HWB that is current at the time that NHS England takes it decision to grant or refuse the application, unless in the opinion of NHS England (or on appeal the Secretary of State) the only way to determine the application justly is with regard to an earlier pharmaceutical needs assessment, in which case the relevant pharmaceutical needs assessment is that earlier assessment, or

(b) if the relevant HWB has not published a pharmaceutical needs assessment, the pharmaceutical needs assessment of a Primary Care Trust (as extended by regulation 7(1)) that relates to the locality in which the location or premises to which the application relates is or are situated."

6.24 The Committee noted that the Applicant had submitted its application in June 2025 but that the HWB had since published a 2025 version of the PNA (the "2025 PNA").

6.25 The Committee considered that there were two related issues that it needs 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.

6.26 The Committee noted that following the publishing of the 2025 PNA the Commissioner had sought representations from the Applicant on the PNA but did not circulate a copy of the Applicant's response to interested parties. The Commissioner did not contact the interested parties to seek their views in respect of the new PNA. In the interests of transparency and fairness, NHS Resolution sought to rely on the discretion afforded under Schedule 3, Part 3, paragraph 7 to allow parties the opportunity to make representations on this information.

6.27 The Applicant responded on 24 November 2025 to the Commissioner's request for comments on the 2025 PNA stating the following:

"As you correctly state our application was made whilst the earlier HWB PNA was in circulation – our justifications for this unforeseen benefits application are therefore detailed against this earlier PNA.
I have subsequently reviewed the more recent HWB PNA and believe there is nothing of material note within this updated PNA that contravenes any of the prior justifications made in our application."

6.28 The Committee considered the Herefordshire 2025 PNA prepared by Herefordshire Council, 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) explaining changes to the availability of pharmaceutical services since the publication of its PNA. Such a statement then forms part of the PNA. A supplementary statement must not provide a new analysis of service provision. The Committee noted that the PNA was dated 2025 and that no supplementary statements had been issued.

6.29 The Committee noted "Statement 2 Summary Findings" of the PNA which stated:

6.30 *"No gaps were found in provision of necessary services. Travel time analysis indicates good access to services by car. The entire population lives within a 20-minute journey by car to a Pharmacy or GP Dispensing Practice in*

weekdays up to 1800hrs. On Saturdays the entire population are within a 30-minute journey by car, and this only drops slightly to 97% on Sundays.

There is also good access by foot for most of the urban population during weekdays. However, access on foot is poorer out of hours and at weekends. Public Transport is also more limited, particularly in rural areas. 18 of the 27 Pharmacies in the county are open on Saturdays and 6 of the 27 are open on Sundays."

6.31 The Committee also noted 'Essential Services' in the PNA which states:

6.32 *"8. Stoma Appliance Customisation (SAC)*

The service involves the customisation of a quantity of more than one stoma appliance, based on the patient's measurements or a template. The aim of the service is to ensure proper use and comfortable fitting of the stoma appliance and to improve the duration of usage, thereby reducing waste.

If on the presentation of a prescription for such an appliance, a pharmacy owner is not able to provide the service, they are to be referred to another pharmacy owner or provider of appliances. Information on which Pharmacies in Herefordshire currently offer this service was not supplied by the NHS Business Service Authority. However, service level data shows no activity for any Herefordshire pharmacy over 2024/25."

6.33 The Committee finally noted the Conclusion of the 2025 PNA which states:

6.34 *"There are the same total number of Pharmacies (27) and Dispensing Practices (10) when compared to the last PNA in 2022.*

However, one 'bricks and mortar' Pharmacy has closed and has been replaced in the total figure by a Distance Selling Pharmacy (DSP).

There have been small reductions in out of hours provision, both during weekday evenings and weekends, particularly due to the change to the 100-hour pharmacy contract.

Weekday evening provision after 1900hrs is now reliant on a single pharmacy.

However, there are no gaps, as pre-defined by the PNA 2025 Working Group, identified in terms of access and travel times for essential services.

Overall, there is good coverage of Advanced Services. However, geographical variation remains, particularly between more deprived and affluent areas.

The exception is smoking cessation, where coverage is low. The locally commissioned service Stop Smoking Herefordshire is currently undergoing recommissioning, however, at the time of writing, uptake of the offer by pharmacies has been poor.

The projected health burden and demand on pharmacies in Herefordshire are likely to increase due to an ageing population and higher levels of disease management.

There are good overall levels of public satisfaction with Pharmaceutical Services.

However, awareness and public confidence may be limiting uptake of some services.

Some specific access and service provision issues were raised through engagement work. However, these may not be generalisable to the whole population.

Some recommendations from 2022 PNA have been addressed through CPCF 2025/26 contractual changes.

Others, including sharps disposal and equitable coverage of advanced services remain relevant issues and are incorporated into the current recommendations.

Many previous and proposed recommendations are reliant on partnership working with the ICB, local authority public health team and primary care. Therefore, these are not the sole responsibility of community pharmacy."

6.35 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 DAC either at this site or more generally within the area of the HWB either in the 2022 PNA or the 2025 PNA. The Committee considered that whichever PNA it had regard to it would not materially affect its decision. However, for the purposes of this application, the Committee considered that the relevant PNA was the 2025 PNA.

6.36 The Committee noted that the Applicant seeks to provide unforeseen benefits to those patients residing in Herefordshire who require appliances specifically those who require stoma care appliances and incontinence appliances. 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.

6.37 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)

6.38 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"

6.39 The Committee noted that the Commissioner had stated *"Granting the application will cause significant detriment to the proper planning and provision of pharmaceutical services in the HWB are (i) and (ii) a.*" However, no evidence had been provided to support this assertion.

6.40 In its appeal, the Applicant disputes the Commissioner's finding on this point by stating that "*The statutory threshold is significant detriment' and the absence of any reasoning or supporting analysis means that the committee has NOT demonstrated that the statutory threshold has been met.*

All relevant 'interested parties' across the HWB and surrounding localities were sent notification of the DAC application (15th August 2025) along with detailed explanatory notes outlining the proposal. Interested Parties were granted a 45-day time period to make any comments. The only notable feedback received during this notification period was a strong endorsement by the Chief Executive Officer for Community Pharmacy Herefordshire and Worcestershire citing, the application is well presented, and the proposal offers additional beneficial options for patients needing appliances and associated discreet services'. NO concerns from the existing pharmacy network or other 'interested parties' were raised about detrimental impact to services.

The nearest pharmacy within Herefordshire HWB to the appellant's address is over 8 miles away. There is no DAC located within the HWB (nearest one is 35 miles away).

The appellant's address is located within the southern region of Herefordshire HWB. This region of the county has the worst pharmacy/ contractor density per head by some margin (ref. p.46 of2025 PNA).

The Committee's decision does not identify any existing DAC providers who would be materially affected, any pharmaceutical services that would be undermined or any planning arrangements that would be disrupted".

6.41 The Committee considered that Regulation 18(2)(a)(i) relates to proper planning in respect of the provision of pharmaceutical services in the area of the relevant HWB if the application is granted. The reference to "proper planning in respect of the provision of pharmaceutical services" is very broad in scope.

6.42 The Committee therefore concluded that a finding that granting an application would cause significant detriment to proper planning in respect of the provision of pharmaceutical services can only be achieved after a consideration of all the consequences of granting an application, both positive and negative, benefits and detriment, provided that these consequences were all linked to the broad concept of proper planning in respect of the provision of pharmaceutical services.

6.43 The Committee was not persuaded by the Commissioner's statement that "*Granting the application will cause significant detriment to the proper planning and provision of pharmaceutical services in the HWB area"* without any reference to information regarding existing plans which would suffer significant detriment as a result of any grant.

6.44 On the basis of the information available, the Committee was not satisfied that should the application 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.

6.45 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)

6.46 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"*

6.47 The Commissioner had indicated in its decision that "*Granting the application will cause significant detriment to the proper planning provision of pharmaceutical services in the HWB area (1) and (ii)"* and concluded that this Regulation is deemed to have not been met. However, no further explanation or evidence had been provided to support this assertion.

6.48 The Committee noted the Applicant's comments above at paragraph 6.39.

6.49 The Committee considered that Regulation 18(2)(a)(ii) relates to significant detriment to arrangements in place for the provision of pharmaceutical services if an application is granted. The reference to "arrangements in place for provision of pharmaceutical services" is very broad in scope. It is not limited to detriment to a particular person, class of person, patient, patient group or provider of pharmaceutical services whether this is a dispensing practice or community pharmacy.

6.50 The Committee therefore concluded that a finding that granting an application would cause significant detriment to arrangements in place for the provision of pharmaceutical services can only be achieved after a consideration of all the consequences of granting the application, both positive and negative, benefits and detriment, provided that these consequences were all linked to the broad concept of arrangements in place for the provision of pharmaceutical services.

6.51 The Committee was not persuaded that the simple statement *"Granting the application will cause significant detriment to the proper planning provision of pharmaceutical services in the HWB area (1) and (ii*)" was a sufficient, detailed examination of the impact of any grant and how this would affect the arrangements in place.

6.52 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.

6.53 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)

6.54 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)

6.55 The Committee had regard to the location of existing pharmacies and GP surgeries as provided on a map by the Commissioner, which had not been disputed.

6.56 The Committee noted the Applicant's comments in relation to the 2022 PNA that *"within the Herefordshire HWB, … there is currently no Dispensing Appliance Contractor (DAC) listed there".* Further in its appeal, the Applicant states that the nearest DAC providers are located 35, 42 and 45 miles away, which had not been disputed.

6.57 The Committee had regard to the 2025 PNA which states:

"The PNA has assessed that there is currently sufficient provision of Pharmacies and Dispensing GP Practices in Herefordshire, delivering essential pharmaceutical and dispensing services. There are 27 Pharmacies and 10 Dispensing GP Practices."

6.58 The Committee noted within the supporting information on the application form, the Applicant stated that:

"Whilst we do not dispute the fact that appliances are available for dispensing from pharmacy contractors and dispensing GP practices, and as such there may be choice of pharmacy providers, there is a difference between dispensing a prescription and offering the services and professional advice of a trained, registered stoma and continence nurse based within the specific location of Herefordshire HWB. In granting this application, those patients with the shared

characteristic of either a continence related condition and/or stoma condition would have local access to a specialist DAC nurse who can visit in the comfort of their own home."

6.59 The Applicant believes that a DAC in the HWB area will enable it to provide services of a trained registered stoma and continence nurse and that a local service offering home visits and Appliance Use Reviews provides greater patient choice.

6.60 The Regulation speaks of there being "a reasonable choice with regard to obtaining pharmaceutical services in the area of the relevant HWB". The question is whether the words "in the area of the relevant HWB" precludes consideration of services available in a neighbouring HWB. In other words, must a Committee ignore the fact that patients may choose to use other DACs because they are across an administrative border? The Committee concluded that that was not the intent of the Regulation. It did not prevent the Committee from taking account of a patient choosing to go outside the HWB. The question is whether the choice available to patients including choosing to go across the HWB boundary is reasonable. To interpret the regulation otherwise had the capacity to create a considerable amount of mischief detrimental to the consideration of the provision of pharmaceutical services and potentially the public purse. It placed an arbitrary fetter on the assessment of the real 'on the ground' choices available to and made by patients and the reasons for such choices.

6.61 In this case, the Committee noted that the Applicant had provided no information to show that patients in the HWB area are currently having difficulty accessing either stoma care appliances or incontinence related appliances.

6.62 The Committee noted that due to the nature of the service provided, the appliances are able to be delivered to patients across the country from any specific DAC as well as through other pharmacies. The Committee was mindful that existing DACs do not limit their services by local geography. The Committee noted that no information had been provided by the Applicant to show that the existing pharmacies or DACs were not providing the relevant appliances or that patients were experiencing difficulties in accessing these services from the existing pharmacies in the HWB or from DACs in other HWBs.

6.63 The Committee noted the Applicant's comments in their appeal which stated that *"The Committee requesting proof that patients are struggling or unable to access services is NOT the correct test to apply. Regulation 18 does NOT require evidence of current access failures. It instead allows applications where additional benefits would improve access or service quality. By requiring evidence of difficulty accessing services, the Committee appears to have applied a higher threshold than that required by Regulation 18".*

6.64 The Committee does not accept the Applicant's submission that consideration of current access difficulties amounts to the application of an incorrect or higher test. Regulation 18 requires the Committee to consider whether granting the application would secure improvements or better access which would confer significant benefits. In doing so, the Committee has regard to there being reasonable choice in obtaining pharmaceutical services, and to whether

persons with protected characteristics have access to services meeting their specific needs where those services are difficult for them to access. Evidence as to whether patients can currently obtain the relevant services, and whether there is any difficulty in doing so, is therefore relevant to the consideration of Regulation 18. The Committee is not required to grant an application simply because an additional provider would create another option. It must be satisfied that the additional option would amount to a significant benefit, by improving access or choice. Where existing services are available and there is insufficient evidence of difficulty accessing those services, the Committee may conclude that the Regulation 18 test is not met.

6.65 Based on the lack of evidence regarding difficulty in accessing existing services, the Committee was of the view that there is already reasonable choice with regard to obtaining pharmaceutical services in the area of the relevant HWB, such that it was not satisfied that, having regard to the desirability of there being a reasonable choice with regard to obtaining services, granting the application would confer significant benefits on persons.

6.66 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 stoma care appliances and incontinence appliances may be difficult for people with protected characteristics based on age and disability, particularly due to the nature of the services that DACs offer.

6.67 The Committee noted the comments from the Applicant with regard to those who have protected characteristics and in particular those who are in the 60 plus age range which the Applicant states '*typically present with stoma and/or continence conditions'.*

6.68 Whilst the Committee accepted that there were always people in an area who share a protected characteristic, given that the Applicant was applying for a DAC and was not therefore restricted by local geography, the Committee was of the view that this area could be quite large. The Committee noted that apart from the general statements regarding those who may share a protected characteristic by way of age or disability, there was very little information provided regarding those who share a protected characteristic. The Committee was of the view that it was difficult to judge, given the lack of information, as to how many patients there may be, what their needs were and what the difficulties may be.

6.69 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.

6.70 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.

6.71 The Committee noted the Applicant's proposal that a *"specialist local DAC nurse will support all patients across the Herefordshire & Worcestershire HWB. Patients will be assessed quickly and provided with ongoing support either in the comfort of their own home or at the DAC licensed address".*

6.72 The Applicant also proposes innovation by way of product availability and that the *"Applicants licence address has considerable storage space for Part IX products. Pharmacies do not hold such stock. Items can be collected from local premises or delivered direct to user."*

6.73 The Committee noted the Applicant's assertions on emergency supply in that the *"Applicant will hold samples of leading manufactures' products. If a patient runs out and urgently requires emergency stock, samples can be provided".*

6.74 Further, the Applicant proposes to provide ongoing support and that a *"Local DAC Customer Service Team and Local DAC Nurse(s) will be experts on the needs of the local HWB e.g. prescribing formulary awareness, geography of the region, GP practices etc."*

6.75 However, the Committee was of the view that specialist nursing support with home visits, patient advice, product availability, emergency supply and ongoing support are services commonly associated with DAC provision and are not unique to the Applicant's proposal.

6.76 Whilst for some patients this may be convenient, these are characteristics of DAC provision generally rather than being an innovative approach to the delivery of pharmaceutical services.

6.77 The Committee was therefore 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

6.78 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.

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

Other considerations

6.80 Having determined that Regulation 18(2)(b) had not been satisfied, the Committee did not need to have regard to Regulation 18(2)(c) to (e).

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

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

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

6.84 The Committee was not 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.

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

6.85.1 confirm the Commissioner's decision;

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

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

6.86 As the Commissioner did not consider Regulation 41, the Committee determined that the decision of the Commissioner must be quashed.

6.87 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.

6.88 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.

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

7 DECISION

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

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

7.3 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;

7.4 The Committee determined that the application should be refused on the following basis:

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

7.4.1.1 there is already a reasonable choice with regard to obtaining pharmaceutical services;

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

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

7.4.2 Having taken these matters into account, the Committee not satisfied that granting the application would confer significant benefits as outlined above that would secure improvements or better access to pharmaceutical services.

7.4.3 Having determined that the application should be refused, it was unnecessary for the Committee to make a decision upon whether granting the application would prejudice the proper provision of relevant NHS services in the area of (a) the relevant HWB; or (b) a neighbouring HWB of the relevant HWB.

Case Manager
Primary Care Appeals