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REF: SHA/26879

APPEAL AGAINST HAMPSHIRE AND ISLE OF WIGHT ICB DECISION TO REFUSE AN APPLICATION BY WILLINGSFORD LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST OFFERING UNFORESEEN BENEFITS UNDER REGULATION 18 AT NEW FOREST ENTERPRISE CENTRE, UNIT 35C, CHAPEL LANE, TOTTON, SOUTHAMPTON, SO40 9LA

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:

Willingsford Ltd
PCSE on behalf of Hampshire and Isle of Wight ICB

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1 The Application

By application dated 6 May 2025, Willingsford Ltd ("the Applicant") applied to Hampshire and Isle of Wight ICB ("the Commissioner") for inclusion in the pharmaceutical list offering unforeseen benefits under Regulation 18 at New Forest Enterprise Centre, Unit 35C, Chapel Lane, Totton, Southampton, SO40 9LA. In support of the application it was stated:

1.1 Proposed core opening hours

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	Total
9:30 – 16:30	9:30 – 16:30	10:00 – 16:00	10:00 – 16:00	10:00 – 14:00			30

1.2 Total proposed opening hours

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	Total
9:30 – 16:30	9:30 – 16:30	10:00 – 16:00	10:00 – 16:00	10:00 – 14:00			30

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 "Wound care products and associated products, including cold chain products."

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

1.5.1 "Not applicable. No dispensing appliance contractor within 1.6km."

Information in support of the application

1.6 "Amicapsil is an innovative new type of wound treatment that currently is being evaluated by NHSBSA for inclusion on the Drug Tariff Part IX (appliances). However, Amicapsil requires cold-chain procedures, which are currently not in place for the distribution of appliances, and this presents a barrier for its implementation.

1.7 Furthermore, while Amicapsil is very easy to use, it is also very different to existing wound products and, due to its novelty, existing DACs will not be able to provide the required guidance to healthcare professionals and patients on its use to secure the intended improvements in treatment.

1.8 The aim of this application is to address these issues by seeking approval of Willingsford as a DAC. First, the burden of wound care in the NHS and Amicapsil will be described; second, the issues related to the implementation of Amicapsil and what the barriers are will be discussed, and third, in the subsequent "Unforeseen Benefits" section, will be outlined how Willingsford can address these issues.

Wound care

1.9 Burden of wound care on the NHS

1.10 The prevalence of wounds requiring NHS involvement is growing by 11% annually (Guest et al. 2020) and are placing an ever-growing burden on the NHS, e.g. NHS data indicate that community nursing spends over 50% of their time on wound dressing changes. The majority of wounds requiring care are infected and standard care is mostly based on antimicrobials, but Hussey et al. (2019) concluded following a review of the use of antimicrobials in wound care in the UK: "*This paper suggests that in the last 20 years there has been a large increase in the use of antimicrobial wound dressings [in the UK] despite a lack of research evidence to support their routine use.*" The US FDA concluded in 2016 and reiterated in 2022 (Verma et al. 2022) that dressings with antibiotics and antiseptics are ineffective in removing wound infections and in supporting healing.

1.11 Pressure injuries constitute a subgroup of wounds that respond poorly to standard care treatment approaches, particularly if they are infected (critically colonised). NICE (2014) concluded that systemic and topical antibiotics, antiseptics and negative pressure wound therapy should not be used routinely for the treatment of pressure injuries. Nevertheless, these continue to be the standard care approaches offered to patients due to the lack of proper alternatives. Many individuals, particularly if affected by spinal cord injury (SCI), develop osteomyelitis (bone infection) if a pressure injury is not treated effectively and in a timely manner to prevent infection from reaching the bone. Osteomyelitis is a life-changing event, and 10-12% of SCI persons die as a consequence of pressure injuries, typically sepsis caused by osteomyelitis.

Novel innovative treatment for wounds

1.12 Amicapsil (technical name micropore particle technology or MPPT) is a novel first-in class treatment for wounds, which removes wound infection and supports tissue regeneration by supporting the immune system via the wound microbiome; it does not involve any use of antimicrobials. Amicapsil is effective in immunocompetent and immunocompromised individuals and on antimicrobial resistant wound infections. Amicapsil is a class IIb medical device developed and manufactured by the British company Willingsford Ltd. Amicapsil is accompanied by a series of clinical evaluations, including a 266-patient randomised controlled trial (RCT).

1.13 Two studies conducted in community care have shown that Amicapsil is effective in treating pressure injuries and in controlling and removing soft tissue infection caused by an underlying osteomyelitis:

1.13.1 https://www.frontiersin.org/articles/10.3389/fmed.2023.1279100/full.

1.13.2 https://www.frontiersin.org/journals/rehabilitationsciences/articles/10.3389/fresc.2024.1386518/full

1.14 The first is a clinical study in collaboration between the spinal cord units at Stoke Mandeville, Aylesbury and Salisbury District Hospital, Salisbury, and Willingsford; and the second a patient-reported outcome study by the British Spinal Injuries Association (SIA). Both studies found a 100% closure rate for acute and chronic grade 1-4 pressure injuries in SCI-persons, a patient group who is immunocompromised. On average, for acute grade 1-4 pressure injuries, per wound savings were 85% the first year compared to standard care and 100% the following years as the Amicapsil wounds had closed. Amicapsil was also shown effective on antimicrobial resistant wound infections. Amicapsil was also able to remove soft tissue infection caused by an underlying osteomyelitis and to induce tissue regeneration. This allowed better control of the condition until surgery could be performed. In patients with inoperable osteomyelitis, it was successfully used for palliative care. For example, in many a strong reduction in the frequency of septicaemia with subsequent hospitalisation was seen.

1.15 An increasing body of data indicate that antimicrobials contribute strongly to climate change as they increase CO_2-levels in the atmosphere by damaging Earth microbial environments. Using recent data, it was found that a standard course of antibiotic released an amount of CO_2 corresponding to a car driving around Earth 1.47 times. Amicapsil does not involve the use of antimicrobials, they are specifically contraindicated for use in wound treatment when using Amicapsil, and, since Amicapsil replaces the use of antimicrobials in wound care, it will contribute with a corresponding reduction in CO_2-release. Additionally, all packaging is recyclable and Amicapsil itself only contains natural, non-toxic ingredients.

1.16 Amicapsil has recently been accepted on NHS Supply Chain on the Advanced Wound Care tender (Project 1126).

Innovation in the NHS

1.17 There are two key regulations that strongly support the approval of Willingsford Ltd. as a DAC:

1.18 The Health and Social Care Act 2012, section 23, 1 state under "*General duties of the Board"* that*:*

"*The Board must, in the exercise of its functions, promote innovation in the provision of health services (including innovation in the arrangements made for their provision)*."

1.19 Furthermore, the Pharmaceutical and Local Pharmaceutical Services Regulations (2013/349) state in section 18, paragraph 2,b in relation to Unforeseen benefits applications that the NHS must have regard to the following matters:

"*(ii) people who share a protected characteristic having access to services that meet specific needs for pharmaceutical services*"

"*(iii) there being innovative approaches taken with regard to the delivery of pharmaceutical services*;"

1.20 and whether

"*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*".

1.21 Amicapsil is an innovative technology as it currently is the only wound product globally that is effective in removing wound infections and in supporting tissue regeneration and that can demonstrate 100% closure rates for acute and chronic pressure injuries. It has the potential to provide billions of pounds of savings to the NHS annually and its CO_2 profile is excellent compared to current standard care, which is detrimental to the environment. Its implementation is, therefore, important in order to secure these benefits to the NHS and patients across the UK, including NI as Amicapsil is CE-marked.

1.22 Furthermore, Amicapsil requires cold chain delivery. Cold chain delivery service is currently not available for medical devices and Willingsford is, therefore, proposing an innovative approach with regards to its delivery which ensures unbroken cold chain as well as equal access to the innovation by patients, including delivery to people who share protected characteristics.

Factors preventing implementation of Amicapsil

1.23 Cold chain requirements

1.24 Amicapsil requires cold chain from the manufacture until delivery to the patient. The issue was discussed with the NHSBSA:

1.25 Question: "Given that Amicapsil needs cold-chain delivery, does this mean it will be placed in the "Discount Not Deducted" (DND) category? Do we need to apply separately for this, or will you at your end make sure to indicate that Amicapsil requires this?"

1.26 Answer: "*This is a process that is currently carried out for all cold chain storage products, providing they are to be stored between 2°C and 8°C.* ***However, as far as we are aware, there are currently no Part IX appliances that require cold chain storage*** *and so this would be a decision that DHSC would make. We can't see this being an issue as there are already some Part IX appliances that are on the DND list. If Amicapsil was successful this would be raised with DHSC prior to the device being added to the Drug Tariff and we would envisage this being confirmed prior to the product being listed*."

1.27 The facilities for cold-chain distribution are, as stated by NHSBSA, not in place for appliances and this will prevent the implementation of Amicapsil. The MHRA and the ISO 13485 Quality Management System place the responsibility of ensuring safe delivery to the end-user with the medical device manufacturer. The manufacturer is therefore legally required to have validated procedures in place to protect the product during transit to the end-user. In relation to the recent inclusion of Amicapsil on NHS Supply Chain, Willingsford will be responsible for distribution, because the Supply Chain does, similarly, not have cold-chain facilities in place.

1.28 Willingsford has contacted a large number of existing DACs as well as pharmacies with the aim to establish a collaboration regarding home-delivery of Amicapsil to patients under cold-chain conditions. DACs do not have cold-chain process in place since none of the appliances on Part IX require cold-chain. Pharmacies do handle medicines requiring cold-chain, but generally do not have validated cold-chain procedures in place to cover the transport from the pharmacy to the home of the patient. Instead, we know that patients are asked to solve this problem themselves, but few will have a good solution and transporting a cold-chain device during the summer months from the pharmacy to their home is very likely to result in a damaged product, meaning that the patient is not receiving an effective treatment and is consequently at risk of developing complications. Community nurses will not be able to bring the treatment with them as they do not have cold-storage possibilities in the car, particularly not facilities that would allow a car to stand in the sun for several hours, while helping other patients on their route, and still be able to protect the product. Also, Amicapsil does not always require the presence of a community nurse and this way of bringing it to the patient would, therefore, not be exhaustive.

1.29 It will, therefore, be necessary to establish cold-chain processes covering the transport from the manufacturer to the end-user. An additional unforeseen benefit of direct delivery from the manufacturer to the end-user is that the transit route is reduced to a single step. This reduces the risk of errors and will reduce carbon emission.

Home delivery

1.30 Home-delivery is not required for wound products, but a large proportion of users will be disabled, which is a protected characteristic, and most of the patients requiring Amicapsil will be bed-bound, given that they have pressure injuries, and they will often be on forced bed rest to support healing. They will, consequently, have difficulty visiting the local pharmacy to obtain their prescription. An option could be family and friends helping, but not all would be

able to arrange this plus the issue of maintaining cold chain from the pharmacy to the home, which was mentioned above, will remain.

1.31 In relation to the Pharmaceutical and Local Pharmaceutical Services Regulations (2013/349), protected characteristics include people with disability such as spinal cord injury, who are particularly prone to developing pressure injuries. They will, due to their condition, have difficulty collecting the treatment from a pharmacy. They would therefore as an unforeseen benefit gain from the implementation of home delivery.

Advice and guidance on proper use

1.32 A requirement under Schedule 5, clause 9 of the Pharmaceutical and Local Pharmaceutical Services Regulations is that the DAC must be able to advise the patient on the general use of the product. Given that Amicapsil is novel and first-in class, DACs and pharmacies will not possess this knowledge, which means that they cannot fulfil the requirements of Schedule 5, clause 9. Approving this application would enable patients and healthcare professionals to receive guidance from the manufacturer, who has developed the instructions for Use, all training resources, has conducted clinical studies with the product, and who is currently daily supporting patient's use in other countries.

1.33 In summary, to enable the implementation of Amicapsil in community care, it is necessary first to solve the issues around cold-chain, home delivery and ensuring access to proper advice and guidance. Once addressed, the NHSBSA will be able to complete its evaluation of Amicapsil for inclusion on the Drug Tariff Part IX. This will be to the benefit of patients and the NHS across the UK in line with section 23,1 of the Health and Social Care Act. Without this license, there are currently no direct routes forward to enable the adoption of this new, and innovative technology in community care."

In response to "Please explain how you intend to secure the unforeseen benefit" the Applicant stated:

1.34 "The manner in which Willingsford intends to fulfil the unforeseen benefits are:

Cold-chain distribution

1.35 Willingsford is certified under the medical device ISO 13485:2016 Quality Management System, and it has validated transit procedures in place. Willingsford is currently successfully delivering Amicapsil across UK, USA, Canada, EU, and Asia, e.g. Singapore and Australia, during all seasons of the year. The inhouse knowledge covers both packing solutions to protect the product as well as establishing working relationships with reliable couriers to ensure safe delivery and that appropriate actions are taken in case of delays. Broad experience is therefore already established and continue to be developed.

Home delivery to end-user

1.36 Willingsford has considerable experience in delivering the product to both healthcare professionals and patients, including ensuring that the receiver, who may not always be the end-user, is aware that it is a cold-chain product that needs to be placed on refrigeration immediately upon arrival.

Advice and guidance on proper use

1.37 Willingsford has for Amicapsil developed the Instructions for Use; three training videos; published in peer-reviewed medical journals on its use and effects; has been and is regularly giving presentations to healthcare professionals as well as patient organisations; and is participating at scientific and medical conferences focusing on wound treatment. Since 2016, Willingsford has helped many, both healthcare professionals and patients, in the correct use of Amicapsil and has. through these interactions, developed a deep understanding of how best to guide and train people in the correct use of Amicapsil. Willingsford is, therefore, currently the institution with the broadest, most in depth, and most up-to-date knowledge about Amicapsil and its use.

1.38 In summary, Willingsford has validated cold-chain procedures in place, is already delivering to the end-user, and has a unique understanding of the product, its use and how to convey this to the end-user. Willingsford therefore fulfils the requirements needed to deliver Amicapsil across the UK, thereby ensuring equal access to these unforeseen benefits. Approving Willingsford Ltd. as a DAC would ,consequently, provide essential unforeseen benefits in relation to the Pharmaceutical and Local Pharmaceutical Services Regulations section 18, 2b, and will support the implementation of innovation as outlined in section 23,1 of the Health and Social Care Act."

2 Comments to the Commissioner

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

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

2.1 THE APPLICANT

2.1.1 "Thank you very much for sending the comments that have been made to our application.

2.1.2 In relation to the comment by the Community Pharmacy Hampshire & Isle of Wight: "*We would seek reassurance that all relevant regulations around offering unforeseen benefit application are considered*" we can confirm that to the best of our knowledge all relevant regulations have been considered as outlined in our application. Without reference to a specific regulation in the comments by the Community Pharmacy Hampshire & Isle of Wight , we are unable to provide a more specific response."

2.2 THE APPLICANT

2.2.1 "Thank you for your letter of November 18, 2025 regarding the feedback on our DAC application offering unforeseen benefits.

2.2.2 In relation to the representations made by the Community Pharmacy Hampshire & Isle of Wight, regarding the fulfilment of all relevant regulation involving offering unforeseen benefits, it is difficult to address the representation when no specifics are provided. We do, however, know that there are five key unforeseen benefits, which are obtained by approving the DAC application:

2.2.2.1 Promotion of Innovation, as required by the Health and Social Care Act 2012, section 23, 1 and the Pharmaceutical and the Local Pharmaceutical Services Regulations (2013/349), section 18, paragraph 2,b.

2.2.2.2 Enabling access to Amicapsil as its distribution requires cold-chain, a service that currently does not exist in community as none of the appliances currently on the Drug Tariff require cold-chain.

2.2.2.3 Support of individuals with protected characteristic such as disability as they will find it difficult to collect a cold-chain product from the local pharmacy and to bring it home while maintaining the required environmental conditions.

2.2.2.4 Advising patients on the use of the product as required of the DAC by Schedule 5, clause 9 of the Pharmaceutical and Local Pharmaceutical Services Regulations. Given that the product in question represents a completely new class of wound treatment, existing DACs will not have the required background to fulfil this requirement of the Regulation. Willingsford is currently advising both healthcare professionals and patients.

2.2.3 Furthermore, the NHS, including pharmacies, have statutory obligations under the Climate Change Act 2008 and the Health and Care Act 2022 to take action to support sustainability in their activities. Current standard care for infected wounds is based on the use of antibiotics and antiseptics, but they have never been shown clinically effective, they cause long-term adverse reactions, and they contribute substantially to climate change. A new publication focusing on the environmental impact of antimicrobials found that a single course of antibiotic resulted in the release of 9.84 tonnes CO2 into the atmosphere from soil depots, the equivalent of a car driving around the Earth 1.47 times (https://www.frontiersin.org/journals/publichealth/articles/10.3389/fpubh.2025.1644086/full). In contrast, the product Amicapsil lacks antimicrobial properties and will not contribute to the release of carbon from soil storage. Amicapsil itself has a very low carbon footprint, meaning that essentially the full benefits of avoiding antimicrobials will be realised. Newly approved carbon certification practice (https://www.naturalcarbonsolutions.com/certifications/organisation-footprintcertification/organisation-avoided-carbon-emissions-certification/) will make it possible for the NHS to benefit from “avoided carbon emission”, when using Amicapsil, thereby benefitting its sustainability status.

2.2.4 In case any specific representation is made by Community Pharmacy Hampshire & Isle of Wight in relation to our application, we will of course be happy to address this."

3 The Decision

The Commissioner considered and decided to refuse the application. The decision letter dated 2 January 2026 states:

3.1 "Hampshire and the Isle of Wight 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."

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

Extract from the Pharmaceutical Services Regulations Committees meeting in common for: Buckinghamshire, Oxfordshire and Berkshire West ICB, Hampshire & IoW & Frimley ICB

"Introduction and background

3.2 An unforeseen benefits application to open a Dispensing Appliance Contractor pharmacy had been received from Willingsford Ltd, on 8 May 2025 at New Forest Enterprise Centre, Unit 35C, Chapel Lane, Totton, Southampton, Hampshire, SO40 9LA. The Committee was now required to consider the application in accordance with Regulations 18 and 19 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended.

3.3 Full details of the applicant's proposal had been notified to the various interested parties in accordance with the regulations on 19 May 2025 and 2 October 2025. The interested parties were notified twice as the publication of the Hampshire PNA 2025- 2028 took place after the 45-day notification period, but before the application was determined. Comments had been received from the following parties – Community Pharmacy HIOW LPC. There were also follow up comments from the applicant.

Consideration by the Committee

3.4 The Committee had before it:

3.4.1 The NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended.

3.4.2 Department of Health guidelines on market entry by means of pharmaceutical needs assessment – Chapter 8 – Unforeseen Benefits.

3.4.3 The Report which included:

3.4.3.1 the application form,

3.4.3.2 letters from interested parties and a response to those comments from the Applicant,

3.4.3.3 maps of the location,

3.4.3.4 opening times and distances to surrounding pharmacies and GP Practices,

3.4.3.5 a site visit report,

3.4.3.6 Hampshire PNA extracts and a link to the full PNA,

3.4.3.7 demographic information including population density,

3.4.3.8 public transport information,

3.4.3.9 prescription information,

3.4.3.10 the relevant Regulations (18, 19, and 31).

3.5 In relation to the application, the Committee noted the following:

3.5.1 the applicant's fitness information was approved on 27 May 2025

3.5.2 The Committee noted that the applicant was proposing to provide Terms of service (paragraphs 3 to 12, Schedule 5 – DACs)

3.5.3 The applicant also proposed core opening of 30 hours per week and total proposed opening of 30 hours per week.

3.6 The Committee considered the applicant's statement as to the unforeseen benefits it is offering. The Applicant has stated that "*Amicapsil is an innovative new type of wound treatment that currently is being evaluated by NHSBSA for inclusion on the Drug Tariff Part IX (appliances). However, Amicapsil requires cold-chain procedures, which are currently not in place for the distribution of appliances, and this presents a barrier for its implementation. Furthermore, while Amicapsil is very easy to use, it is also very different to existing wound products and, due to its novelty, existing DACs will not be able to provide the required guidance to healthcare professionals and patients on its use to secure the intended improvements in treatment*."

3.7 The Committee considered information from a virtual site visit of the Totton area that had been undertaken by a Pharmacy Commissioning Hub representative.

3.8 Totton is a town in the New Forest district of Hampshire, located across the estuary to the West of Southampton. The M27 is to the North of Totton running East to Portsmouth and to the West is becomes the A31 heading towards Bournemouth & Poole.

3.9 The Committee considered the representations made by Community Pharmacy HIOW LPC and noted that they made no comments regarding the application.

3.10 The applicant's response to the representations received during the consultation period was also considered.

Regulation 31 – Refusal: same or adjacent premises

3.11 The Committee first considered Regulation 31(2)(a)(i) and was of the view that Regulation 31(2)(a)(i) is not met as there is currently no person on the pharmaceutical list at the premises to which the application relates.

3.12 The Committee went on to consider paragraph (a)(ii) of Regulation 31(2); whether there is a person on the pharmaceutical list providing pharmaceutical services from adjacent premises.

3.13 The Committee was satisfied that there is no pharmacy providing pharmaceutical services within the area of the proposed premises. The application did not therefore need to be refused in accordance with Regulation 31.

Regulations 40,41 and 44

3.14 The Committee noted that the proposed pharmacy location was not in a controlled locality, and therefore Part 7 of the Regulations (in particular Regulations 40, 41 and 44) did not have to be considered.

Oral Hearing

3.15 The Committee decided that it was not necessary to hold an oral hearing before determining the application.

Regulation 18 – Unforeseen benefits application

3.16 The Committee noted that this was an application for "unforeseen benefits" and fell to be considered under the provisions of Regulation 18 which states: [quoted in full]

3.17 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 HWB

3.18 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 (the 'PNA') in accordance with paragraph 4 of Schedule 1 of the Regulations.

3.19 The Committee had regard to the Hampshire PNA 2025-2028 (issue date 1st August 2025) (the 'PNA') and noted that supplementary statements had not been issued.

3.20 The Committee also noted that, having considered the entire Hampshire locality including the area of Totton, the HWB had reached the conclusion that "*The conclusion of this assessment is that the number, distribution, and choice of pharmaceutical services meets the current and future population, with no gaps in necessary services within the lifetime of this PNA. There are no identified gaps for additional pharmaceutical services or improvements to current arrangements across the county*." [Page 3, Hampshire PNA 2025-2028].

3.21 The Committee noted that the HWB had considered access (distance, travelling times and opening hours') to assess how current service provisions will meet the needs of the population within the lifetime of the PNA.

3.22 The Committee noted that the Applicant had not mentioned the PNA in their application.

3.23 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 pharmaceutical needs' assessment in accordance with paragraph 4 of Schedule 1.

3.24 The Committee was satisfied that the unforeseen benefits claimed in the application were not identified in the PNA.

3.25 In order to be satisfied in accordance with Regulation 18(1), the Committee went on to consider those matters set out at Regulation 18(2).

3.26 Regulation 18(2)(a)(i) - whether or not granting the application would cause significant detriment to the proper planning in respect of the provision of pharmaceutical services.

3.27 The Committee was not aware of any plans that would be affected and concluded that granting the application would not have an adverse effect on any future plans. None of the submissions included any comment or evidence in regard to this matter. Therefore, the Committee concluded that granting the application would not cause significant detriment in this regard.

3.28 Regulation 18(2)(a)(ii) - whether or not granting the application would cause significant detriment to the arrangements in place for the provision of pharmaceutical services.

3.29 None of the submissions included any evidence on this question and the Committee found no proof to support the suggestion that if the application was to be granted, it would cause significant detriment to the arrangements in place for pharmaceutical services in the area.

3.30 The Committee did not find any significant detriment to proper planning or to the arrangements in place for the provision of pharmaceutical services and therefore was not obliged to refuse the application under Regulation 18(2)(a).

3.31 Regulation 18(2)(b)(i) – whether notwithstanding that the improvements or better access were not included in the relevant PNA, it is satisfied that, having regard in particular to the desirability of – there being a reasonable choice with regard to obtaining pharmaceutical services in the area of the relevant HWB – granting the application would confer significant benefits on persons in the area of the relevant HWB which were not foreseen when the relevant PNA was published.

3.32 On this point the Applicant stated; "*Amicapsil is an innovative new type of wound treatment that currently is being evaluated by NHSBSA for inclusion on the Drug Tariff Part IX (appliances). However, Amicapsil requires cold-chain procedures, which are currently not in place for the distribution of appliances, and this presents a barrier for its implementation. Furthermore, while Amicapsil*

is very easy to use, it is also very different to existing wound products and, due to its novelty, existing DACs will not be able to provide the required guidance to healthcare professionals and patients on its use to secure the intended improvements in treatment."

"Willingsford has contacted a large number of existing DACs as well as pharmacies with the aim to establish a collaboration regarding home-delivery of Amicapsil to patients under cold-chain conditions. DACs do not have cold-chain process in place since none of the appliances on Part IX require cold-chain. Pharmacies do handle medicines requiring cold-chain, but generally do not have validated cold-chain procedures in place to cover the transport from the pharmacy to the home of the patient."

3.33 The representations from Community Pharmacy HIOW LPC did not include comments relating to choice.

3.34 In order to determine if patients in the area already had a reasonable choice, the Committee considered access (distance, travelling times and opening hours) as an important factor in determining the extent to which the current pharmaceutical service provision meets the needs of the population in the Totten area.

3.35 The Committee had regard to the current service provision in the immediate area of Totton and noted that there are 10 pharmacies within 3-mile radius of the proposed address, some of which offer Advanced services.

3.36 The Committee noted that there are 2 Dispensing Appliance Contractors (DAC) within the Hampshire HWB area, and one further DAC in Portsmouth HWB area.

3.37 The Committee noted that the Applicant had not provided any information to demonstrate that patients were experiencing any difficulties in accessing DAC services either on foot or via public or private transport or why a DAC located at the proposed site would improve access for patients. The Committee was of the view that there was nothing provided with regard to physical access in the area of the HWB which demonstrated that those who require the services of a DAC were not having their prescriptions fulfilled.

3.38 The Committee noted that appliances can be delivered to patients across the country from any specific DAC as well as through other pharmacies, both have the choice to use a cold chain delivery service. All distance selling pharmacies provide assurance as part of the application process that they have arrangements for maintaining the cold chain as part of their delivery services.

3.39 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 area or from DACs in other HWB areas.

3.40 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.

3.41 Regulation 18(2)(b)(ii) - whether notwithstanding that the improvements or better access were not included in the relevant PNA, it is satisfied that, having regard in particular to the desirability of – 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 - granting the application would confer significant benefits on persons in the area of the relevant HWB which were not foreseen when the relevant PNA was published.

3.42 The Committee reminded itself that it was required to address itself to people who share a protected characteristic having access to services that meet specific needs for pharmaceutical services that are difficult for them to access. The Committee was also aware of its duties under the Equality Act 2010 which include considering the elimination of discrimination and advancement of equality between patients who share protected characteristics and those within such characteristics.

3.43 The Applicant stated that "*In relation to the Pharmaceutical and Local Pharmaceutical Services Regulations (2013/349), protected characteristics include people with disability such as spinal cord injury, who are particularly prone to developing pressure injuries. They will, due to their condition, have difficulty collecting the treatment from a pharmacy. They would therefore as an unforeseen benefit gain from the implementation of home delivery*.

Cold chain delivery service is currently not available for medical devices and Willingsford is, therefore, proposing an innovative approach with regards to its delivery which ensures unbroken cold chain as well as equal access to the innovation by patients, including delivery to people who share protected characteristics."

3.44 The Committee noted that whilst these statements had been included by the Applicant there was no evidence provided that identified a group of patients in the Totton area, sharing a protected characteristic who were having difficulty accessing services that meet a specific need.

3.45 The representations from Community Pharmacy HIOW LPC did not include comments relating to groups of patients having difficulty accessing pharmaceutical services.

3.46 The Committee therefore concluded that the application did not satisfy the test in this part of the Regulation.

3.47 Regulation 18(2)(b)(iii) - whether notwithstanding that the improvements or better access were not included in the relevant PNA, it is satisfied that, having regard in particular to the desirability of – there being innovative approaches taken with regard to the delivery of pharmaceutical services - granting the application would confer significant benefits on persons in the area of the relevant HWB which were not foreseen when the relevant PNA was published.

3.48 In relation to innovative approaches the Applicant had stated that "*Amicapsil is an innovative technology as it currently is the only wound product globally that*

is effective in removing wound infections and in supporting tissue regeneration and that can demonstrate 100% closure rates for acute and chronic pressure injuries. It has the potential to provide billions of pounds of savings to the NHS annually and its CO2 profile is excellent compared to current standard care, which is detrimental to the environment. Its implementation is, therefore, important in order to secure these benefits to the NHS and patients across the UK, including NI as Amicapsil is CE-marked. Furthermore, Amicapsil requires cold chain delivery. Cold chain delivery service is currently not available for medical devices and Willingsford is, therefore, proposing an innovative approach with regards to its delivery which ensures unbroken cold chain as well as equal access to the innovation by patients, including delivery to people who share protected characteristics".

3.49 The Applicant went on further to say that "*The facilities for cold-chain distribution are, as stated by NHSBSA, not in place for appliances and this will prevent the implementation of Amicapsil. The MHRA and the ISO 13485 Quality Management System place the responsibility of ensuring safe delivery to the end-user with the medical device manufacturer. The manufacturer is therefore legally required to have validated procedures in place to protect the product during transit to the end-user. In relation to the recent inclusion of Amicapsil on NHS Supply Chain, Willingsford will be responsible for distribution, because the Supply Chain does, similarly, not have cold-chain facilities in place.*

Willingsford has contacted a large number of existing DACs as well as pharmacies with the aim to establish a collaboration regarding home-delivery of Amicapsil to patients under cold-chain conditions. DACs do not have cold-chain process in place since none of the appliances on Part IX require cold-chain. Pharmacies do handle medicines requiring cold-chain, but generally do not have validated cold-chain procedures in place to cover the transport from the pharmacy to the home of the patient. Instead, we know that patients are asked to solve this problem themselves, but few will have a good solution and transporting a cold-chain device during the summer months from the pharmacy to their home is very likely to result in a damaged product, meaning that the patient is not receiving an effective treatment and is consequently at risk of developing complications. Community nurses will not be able to bring the treatment with them as they do not have cold-storage possibilities in the car, particularly not facilities that would allow a car to stand in the sun for several hours, while helping other patients on their route, and still be able to protect the product. Also, Amicapsil does not always require the presence of a community nurse and this way of bringing it to the patient would, therefore, not be exhaustive."

3.50 The Committee noted that other Pharmacies such as Distance Selling Pharmacies have arrangements in play for maintaining the cold chain for deliveries and any pharmacy or DAC could use a cold chain delivery service if they chose to.

3.51 The Committee noted that no evidence was provided by the Applicant to demonstrate that there was an unmet need for wound care treatment in the Totton area or further afield.

3.52 The Committee agreed that the applicant had not provided evidence that an innovative approach would be taken with regard to the delivery of pharmaceutical services.

3.53 Therefore, the Committee concluded that there is no evidence that innovative approaches would be taken with regard to the delivery of pharmaceutical services.

3.54 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 relevant area of the HWB which were not foreseen when the PNA was published.

Other Considerations

3.55 Regulation 18(2)(c)-(f) - The Committee had previously determined that there was no need to defer the application under Regulation 18(2)(c) to (f).

Decision

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

3.57 The Committee had 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 was not satisfied that it would.

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

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

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

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

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

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

Rights of appeal

3.61 The application is refused so the applicant has the right to appeal.

3.62 The Committee decided not to grant third party rights of appeal to the decision to any of the parties that responded during the consultation period because the application had been refused."

4 The Appeal

In a letter dated 29 January 2026 addressed to NHS Resolution, the Applicant appealed against the Commissioner's decision. The grounds of appeal are:

4.1 "Enclosed please find our appeal towards the decision by the Hampshire and Isle of Wight Integrated Care Board's decision to refuse our application for a Dispensing Appliance Contractor license.

4.2 The refusal was received January 2nd, 2026 and our response was therefore submitted within the 30 days."

Supporting information

"Preamble to DAC application appeal

4.3 The NHS had estimated direct costs of £45 billion in 2025 for the treatment of wounds in the UK and wounds demand over 50% of all community nursing capacity due to lack of efficacy of all current standard wound care. Amicapsil is a new wound treatment shown to offer 100% healing rates and first-year per wound savings of 86% for acute and 50% for chronic pressure ulcers and it has high patient satisfaction scores. Willingsford Ltd., the manufacturer, aims to establish a DAC to rapidly and effectively deliver Amicapsil across England and to provide accurate advice on its use, as it is fundamentally different from existing approaches. Amicapsil requires cold-chain, which existing DACs do not offer. Immediate start and correct use of treatment are essential to contain costs and long-term morbidity issues. Home-delivery is important because pressure ulcers mainly affect persons who are bed-bound or have disabilities, e.g. spinal cord injury. Willingsford already carries out the deliveries on behalf of NHS Supply Chain, who do not have cold-chain, and therefore has all facilities and approved procedures in place.

4.4 Please note: The ICB Committee seems to have erroneously assessed the application as if it were for a local pharmacy in the town of Totton in Hampshire and repeatedly emphasised the local conditions. However, the application is for a DAC licence with national reach and no face-to-face contact.

Introduction and background

4.5 Willingsford Ltd., a UK medical device company, has developed an innovative, first-in-class treatment for wounds, which was recently included on NHS Supply Chain. It is CE-marked and classified as a Class IIb medical device. Advanced discussions are ongoing with NHSBSA regarding inclusion on the Drug Tariff (FP10) for the treatment of pressure ulcers as Amicapsil in a study performed as a collaboration between The National Spinal Injuries Centre at Stoke Mandeville Hospital and The Duke of Cornwall Spinal Treatment Centre at Salisbury District Hospital and Willingsford, as well as in a study performed by the Spinal Injuries Association has shown 100% closure rates and savings of 86% and 50% in the treatment of acute and chronic pressure ulcers, respectively, in persons with spinal cord injury in community care (1,2). In

comparison, using standard care, the closure rate for an acute stage 3 pressure ulcer (the most common type) is only 15% the first year (3). Amicapsil has proved to save lives, as demonstrated in the clinical studies performed with Amicapsil, https://willingsford.com/technology/mppt-micropore-particle-technology/#overview, and across England, Wales, Scotland and Northern Ireland many patients are actively calling for Amicapsil to be included on the Drug Tariff, including via the patient organisation for spinal cord injury, Spinal Injuries Association (SIA): https://www.spinal.co.uk/news/amicapsil-sci-petition/.

4.6 Amicapsil is approved as a treatment for wounds, i.e. with a clinical treatment effect. This is unusual for a medical device. Medical devices are usually approved as aids that can be useful in the treatment of a condition, but not as treatments in their own right as if they were a pharmaceutical. The reason is that the classification as a medical device versus pharmaceutical is based on the mode of action and not on efficacy. This means that dispensers and commissioners are used to having a range of devices with a similar mode-of-action available for the patient to choose from. In the case of Amicapsil treatment, Amicapsil is the only one available, has shown efficacy in an area considered an unmet medical need – meaning that none of the current devices or drugs are effective - and it needs to reach the patients and healthcare professionals urgently.

4.7 Amicapsil needs to be stored, handled and transported under refrigeration. As mentioned, Amicapsil is available via NHS Supply Chain, but Supply Chain does not have cold-chain distribution and Willingsford is, therefore, responsible for delivering the product directly to the NHS Trusts. Similarly, Willingsford is responsible for providing advice and training to healthcare professionals on behalf of Supply Chain. This is essential since Amicapsil is a new class of wound products and, whilst simple to use, the requirements to its use differ fundamentally from existing approaches. The discussions with NHSBSA for inclusion on the Drug Tariff necessarily involve a similar focus on cold-chain delivery as well as the obligatory provision of advice and guidance to patients and healthcare professionals.

4.8 NHSBSA has informed Willingsford that currently no appliance on the Drug Tariff requires cold-chain, meaning that none of the existing DACs would readily be able to be responsible for delivery to patients. Cold-chain procedures - from the manufacturer to the end user - constitute an integral part of the requirements to the quality management system of the manufacturer as set out by the MHRA (ISO13485:2016) and form part of the annual regulatory audit. This means that the manufacturer has the ultimate responsibility for ensuring that the cold-chain is as low-risk as possible, which includes as few handling steps as possible and evidence of compliance at all steps. The manufacturer does not have the right to abdicate its responsibility, e.g. by handing that over to a dispenser without that dispenser having similar or more rigorous procedures in place accredited by MHRA recognised certification bodies.

4.9 As Amicapsil is innovative and its mode-of-action is different from current standard wound approaches, it must be used fundamentally differently from what has been the usual approach to wounds. This means that any dispenser - pharmacy or DAC, walk-in or remote - must be able to provide advice on its

proper use to patients. This is an obligatory requirement to any dispenser among others for patient safety and for obtaining the expected level of efficacy.

4.10 Fulfilling the obligations of providing accurate advice would require all staff, that comes into contact with users at all pharmacies and/or DACs dispensing Amicapsil, to be thoroughly briefed in this fundamentally new approach to wounds and their care. Such undertaking would take considerable time, and thereby significantly delay the introduction of Amicapsil into community care. It would also constitute a financial investment by the pharmacies and/or DACs – an investment they would expect to add onto the price of Amicapsil to the NHS thereby increasing the cost to the NHS unnecessarily. Willingsford is currently the only authority on the use of Amicapsil and has over 10 years of experience in how to use it optimally and in instructing patients and healthcare professionals remotely.

4.11 In essence, the use of Amicapsil in NHS community care requires inclusion on the NHS Drug Tariff, and for this inclusion to be handled by the current dispensing community, would require the current dispensing community establishing validated cold-chain procedures as well as acquiring the knowledge to provide proper advice and guidance as well as the ability to provide these services across Britain. Fulfilling these three fundamental duties associated with the dispensing of Amicapsil would require investment of time and money from the dispensing community, who, when approached by Willingsford, was not forthcoming. Since Willingsford is already performing these tasks for NHS Supply Chain and has over 10 years of experience in performing them, including to end-users in the UK and abroad, it was decided to apply for a DAC licence for Willingsford as this was the safest, most secure, cost-effective, and fastest approach to providing NHS community patients access to Amicapsil. Until the outcome of this process has been determined, the FP10 application for inclusion on the Drug Tariff has had to be put on hold. As “wounds” or “wound care” constitutes an “unmet medical need”, and Amicapsil has been proved to be the only effective treatment for wounds, this delay is, without exaggeration, costing lives and loss of substantial, demonstrable potential savings to the NHS (1). The inclusion on the Drug Tariff is, consequently, a matter of urgency for the NHS and this inclusion is dependent on the granting of a DAC licence to Willingsford.

4.12 An application was in May 2025, submitted to the PCSE for a licence to establish a DAC with the specific purpose of providing NHS community care in England access to Amicapsil. On January 2, 2026, a response consisting of a refusal was received. However, on analysis of the refusal, referred to as the “Letter” going forward, it became clear that essential aspects of the Pharmaceutical Regulations Act of 2013 had not been considered. As a result of this, this appeal is being submitted.

4.13 The Letter states in 7.3.1 that the application should be refused based on the following:

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

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

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

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

4.14 Each of these points will be addressed below in order of importance together with the question of providing advice to patients, which was included in the application, but which was not addressed by the Committee in the Letter even though this is a clear statutory requirement.

4.15 A general comment to the Letter is that the analysis and responses focused on the requirement to a local pharmacy as it repeatedly included analysis of local access. This is irrelevant as a DAC will normally cover all of England and offer home delivery, as clearly stated by the UK Government as part of its Definition of Dispensing Appliance Contractors (https://www.gov.uk/government/publications/pharmaceutical-needs-assessments-information-pack/pharmaceutical-needs-assessments-information-pack-for-local-authority-health-and-wellbeing-boards). It is consequently neither relevant to analyse local distances to a pharmacy nor to demonstrate that a medical need, which has been shown to exist for all of England, also exists in the local area of Totton.

4.16 The Committee Letter paragraph 6.36 stated that "*no evidence was provided by the Applicant to demonstrate that there was an unmet need for wound care treatment in the Totton area or further afield*." This is incorrect given that the application in Section 6 cited several summaries by regulatory authorities (NICE and FDA) and specific medical publications demonstrating that all existing wound treatments are ineffective. Given that the PNA has not demonstrated a unique population demographic in the Totton area or further afield, it must be acceptable to conclude that disease conditions existing broadly in England and comparable Western countries will also be present "*in the Totton area and further afield*". The alternative would be that no generalisation is possible within England regarding conditions and their treatment which essentially would invalidate the use of statistical data. Consequently, all data on the lack of effective treatment of wounds apply to Totton, further afield, and the whole of England and are therefore relevant to the application.

4.17 The fact that the refusal Letter to a very large degree focuses on the missing need for opening a local pharmacy, and does not contemplate the need for a DAC that, as is customary, operates remotely, receiving prescriptions either by post or the electronic prescription service, and arranges for dispensed items to be delivered to the patients across the country, and does not handle pharmaceuticals, demonstrates a misunderstanding of the intended DAC application and renders the refusal out of scope.

4.18 Hampshire and Isle of Wight (HIOW) LPC provided comments on the application twice and, on both occasions, these were:

"The market entry sub-committee has given the matter careful consideration and can offer the following observations:

We would seek reassurance that all relevant regulations around offering unforeseen benefit application are considered."

4.19 We fully agreed to this statement as was indicated in our response. However, as will become clear in this letter, it turns out that the Committee actually failed to consider all relevant regulations, e.g. duty to promote innovation, and duty to provide advice to patients.

4.20 No other comments were provided at any point during the application process.

4.21 The response will address the points based on the UK Pharmaceutical Regulations of 2013. It will refer to other acts and regulations, when relevant.

NHS duty to promote innovation - Regulation 18 (2) b, iii

4.22 The regulation states: (iii) there being innovative approaches taken with regard to the delivery of pharmaceutical services (taking into account also [F2NHS England's] duties under section 13K of the 2006 Act M49 (duty to promote innovation)).

4.23 National Health Service Act 2006, section 13K (1) states: [F2NHS England] must, in the exercise of its functions, promote innovation in the provision of health services (including innovation in the arrangements made for their provision).

4.24 Letter 6.32 claims to be citing the regulation: "*whether notwithstanding that the improvements or better access were not included in the relevant PNA, it is satisfied that, having regard in particular to the desirability of – there being innovative approaches taken with regard to the delivery of pharmaceutical services - granting the application would confer significant benefits on persons in the area of the relevant HWB which were not foreseen when the relevant PNA was published*."

4.25 Comparing the regulation cited in 2.1 with the reference to the regulation provided in 6.32 of the Letter, shows that the citation in the Letter directly omits the reference to section 13K of the 2006 Act, which states a duty of the NHS to promote innovation. The Committee exclusively addresses the delivery of pharmaceutical services. The Committee did consequently not consider the legal obligation of the NHS to promote innovation to the benefit of patients, including the access of patients to innovative treatments, but instead chose to focus purely on the aspect of actual delivery which is only one of two components of Regulation 18(2)b,iii.

4.26 The author of the Letter is the NHS South East Commissioning Hub, Pharmacy Team representing between 4 and 7 NHS Integrated Care Boards (ICBs) and therefore falls under the obligation to promote innovation.

4.27 The aspect of innovation and the duty to promote it is essential for this application, since wounds not healing spontaneously by themselves, i.e. chronic wounds, are considered an unmet medical need. The medical and scientific literature addressing this is vast and consequently only a few examples are highlighted:

NICE 2014 (4) in its guidance on the treatment of pressure ulcers states that none of the following products should be used in the treatment of pressure ulcers with the consequence that no effective treatment is available for an infected pressure ulcer and no positive advice is offered regarding the treatment of an infected pressure ulcer:

"1.4.13 Do not routinely offer adults negative pressure wound therapy to treat a pressure ulcer, unless it is necessary to reduce the number of dressing changes (for example, in a wound with a large amount of exudate)."

"1.4.14 Do not offer the following to adults to treat a pressure ulcer: electrotherapy or hyperbaric oxygen therapy."

"1.4.17 Do not routinely offer adults with a pressure ulcer: larval (maggot) therapy or enzymatic debridement."

"1.4.20 Do not offer systemic antibiotics specifically to heal a pressure ulcer in adults."

"1.4.22 Do not routinely use topical antiseptics or antimicrobials to treat a pressure ulcer in adults."

NICE 2016 (5) analysed the availability of treatments for chronic wounds and concluded: "*Overall, estimates of the effects of dressings are uncertain and not optimal in terms of informing clinical practice*."

Note: "dressings" typically refer to wound dressings laced with antimicrobials.

4.28 FDA 2016 (6) in a review on the use of wound dressings containing antibiotics and antiseptics, which is still the most used approach to infected wounds in the NHS, concluded: "*In summary, many experts in the wound care community have concluded that topical antimicrobials (including antimicrobial dressings) do not improve wound healing*."

4.29 Hussey et al. 2019 (7), a research group under the NHS concluded: "*This study quantifies the huge increase in the use of antimicrobial wound dressings over a 20-year period despite the lack of compelling evidence to support their routine use.*"

4.30 FDA 2022 (8) following a 2-year review of the wound area concluded that wounds not healing spontaneously constitute an unmet medical need and that the urgency of access to effective treatment is high: "*The US Food and Drug Administration (FDA) understands that innovative product development is essential to addressing the unmet medical need of non-healing chronic wounds.*"

4.31 Yang et al. 2025 (9) at one of the world's biggest and leading trauma and burn centres, after reviewing the area of wound healing, summarised: "*Antiseptics and antibiotics are extensively employed to manage infected or chronic wounds in clinical practice for a long time. However, the efficacy of conventional antibacterial therapies is poor. These antimicrobial agents not only kill pathogens but also eradicate commensal microbiota, which is crucial for wound*

healing [117]. The US FDA's evaluation of a 2020–2021 study revealed that current antibacterial therapies are inadequate in managing infected wounds. This insufficiency resulted in unmet medical needs for non-healing chronic wounds."

4.32 In summary, the consensus is, that existing treatments for infected wounds are ineffective and consequently wounds not healing spontaneously by themselves constitute an unmet medical need. Current standard care in the NHS is antiseptics and antibiotics (antimicrobials).

4.33 Amicapsil (technical name: micropore particle technology - MPPT) is a novel first-in-class wound treatment that uses physical forces to impact the microbiome-immune axis to support the immune system. It does not involve any antimicrobials, and the components are readily biologically recyclable. In terms of regulatory status, it is CE-marked as a class IIb medical device, and, unlike other wound products, it is approved as a treatment for wounds due to its clinical effects, i.e. comparable to a pharmaceutical, and not as an aid in the treatment of wounds, which is the norm for medical devices. It removes wound infections, including antimicrobial resistant infections, and its effectiveness extends to immunosuppressed patients. It also supports tissue regeneration. Amicapsil has been evaluated in several clinical studies and an overview of studies can be seen here: https://willingsford.com/technology/mppt-micropore-particle-technology/#overview.

4.34 In December 2025, Yang et al. (9) published a review on using the skin microbiome as a target for wound healing in Wound Repair and Regeneration, the official journal of The Wound Healing Society (USA), The European Tissue Repair Society, The Japanese Society for Wound Healing, and Wounds Australia. The review included a detailed discussion in section 7 of existing antimicrobial approaches, phage-therapy, pre and probiotic approaches and of Amicapsil. They summarised about Amicapsil:

"Amicapsil removes infections 60% faster than conventional treatments such as antibiotics and antiseptics in a spectrum of wounds, including acute wounds, venous leg ulcers, diabetic foot ulcers, and burns [145]. Studies have confirmed the efficacy of this method across various wound types, resulting in complete and stable wound closure."

"These findings suggest that wound management strategies targeting the microbiome–immune axis [which is the mode of action of Amicapsil] may offer superior efficacy compared to conventional antimicrobial approaches. This approach, which interacts with the microbiome without eradicating microorganisms or cells, offers a promising strategy to effectively address wound infections while supporting regenerative processes."

4.35 The summary of this independent analysis is, therefore, that Amicapsil is first-in-class and effective.

4.36 The lack of effective treatments obviously means that wounds, which demand approximately 20% of the total annual NHS budget (1), place a high burden on the NHS. Adderly (10), who is responsible for the National Wound Care Strategy Programme, reported that community nurses in England spend over 50% of their time on wound dressing changes, and, using a series of studies by Julian Guest and colleagues(3,11–15), it was estimated that in 2025 the

NHS would treat 8.6 million wounds at a total direct cost of £45.3 billion (1) to the NHS.

4.37 Amicapsil has been shown, in a clinical study in community care in England, to reduce the direct treatment costs associated with acute (see Table below) and chronic pressure ulcers by 86% and 50%, respectively (1), and comparable effects on other wound types have been seen in secondary care (16–18). All clinical findings therefore clearly show that substantial cost reductions can be achieved from the introduction of Amicapsil.

Table 3 Comparison study of outcomes of acute wounds to Guest et al. (51)

Acute wounds	Guest et al. (2018) Acute Wounds – Standard of care								Study Acute Wounds MPPT		
	No antimicrobials				Antimicrobials						
Grade	% of cohort	Closure	Time months	Cost	% of cohort	Closure	Time months	Cost	Closure	Time months	Cost
1	82%	100%	1.2	£801	18%	100%	4.0	£4,806	100%	<1	£328
2	53%	57%	4.9	£3,801	47%	0%	-	£13,084	100%	<1	£224
3	27%	23%	6.6	£5,219	73%	15%	8.2	£9,679	100%	1.8	£1,884
4	24%	0%	-	£8,226	76%	20%	7.36	£17,610	100%	1.3	£2,645

Percentage of cohort is the distribution of wounds receiving non-antimicrobial vs. antimicrobial treatment in the study by Guest et al. (51); Closure is the percentage of the group reaching closure; Time is the average number of months to closure for the ones that closed; Cost is mean costs first year (51) which in the case of MPPT also means cost to closure. Unstageable are not included as they represent a mix of grades. Adjusted to the beginning of 2022 prices (Supplementary material S1). *Source (1)*

4.38 Tabel 1 [sic] above compares the outcomes of treating acute pressure ulcers in community care, using non-antimicrobial and antimicrobial approaches or Amicapsil. The key parameters to compare are Closure rate, i.e. the number of wounds closing within 12 months of start of treatment; Time to closure; and Costs, covering materials used and staff time. Around 70% of pressure ulcers are infected. A grade 1 pressure ulcer is skin redness, but without actual skin breakage.

4.39 Smith & Ridler (2024)(2) from Spinal Injuries Association conducted a survey among confirmed Amicapsil users in the spinal cord injury community. The data on healing rate and time to healing were comparable to the study performed between Stoke Mandeville, Salisbury and Willingsford (1). The satisfaction score among users were: 84% (n = 31) highly positive; 11% (n = 4) positive; and 0% (n = 0) negative or very negative. 5% (n = 2) were uncertain whether the closure of their wounds was due to MPPT or to the use of water and access to air for treating the wound instead of standard care procedures. The comments of the Highly Positive group, which constituted 84% of respondents, are shown in Table 2 below.

Comments
GOD SEND …
Very effective. So easy to use and really works
Ite was so good I just can't speak highly enough when all else had failed
Excellent experience. So easy to use and extremely effective
It was really good
Very effective
Very. Saw faster progress compared to traditional dressings once started

I found Amicapsil to be very effective and healed the wound quickly
Extremely effective vs. all other treatments tried. It has absolutely changed my life.
Very effective
Amazing!!! This stuff is a game changer!!! I suffer regularly from pressure sores, I've finally found something which aids healing
The best dressing on the market. It is my "go to" treatment. I keep one in my fridge for emergencies.
Excellent, works much quicker than other products resulting in less time confined to bed.
Where I've used it on new wounds at the first sign of damage I'm very happy with its effectiveness.
It's the best product I have ever used. I have had a few pressure sores. One resulting in being in bed for 4 and a half months. I would not hesitate to recommend this product to other people
The Amicapsil along with detailed instructions were brilliant. The pressure ulcer has now healed properly and the skin has stayed intact for over 4 years now when it used to break down every few months.
I've used it several times and in the worst affected it halved my bed rest time which was incredible and the main thing that can affect mental health. I'm prone to skin breakdowns and now wouldn't use anything else even when I don't get the support from healthcare providers.
It did all the difference. Amicapsil together with the daily follow-up and relief made the wound heal. It was visible throughout the process, which had a positive effect on the mood, and action in relation to the tasks that had to be done from the bed during that period
I had a similar burn but on my R thigh in 2007 - pre menopause and before T2D. It was treated traditionally, got infected 3 times and broke down twice once healed. It wasn't as big or quite as deep as the one on my R thigh. I had no infections using Amicapsil & it didn't break down once healed. It was slow to heal initially because an esker had formed & local nurses would not remove it so that took almost 3 wks. Amicapsil also slowed when I had some ABs for a UTI band when I had a covid booster. Had it not been for these delays then the burn would have healed much quicker. I was advised beforehand by Willingsford Health that ABs, covid booster & esker would delay healing.
This was my fourth pressure ulcer. I've had two - one on each side near the ischium - that tunnelled and got infected and need flap surgeries to close. The third sore was more on the glute/buttock and that healed on its own, by cover with a hydrocolloid dressing. Amicapsil healed my 2021 left ischial pressure sore without necessitating surgery, antibiotics for infection, or using hydrocolloid dressings. I will say that I did immediately start spending more time on bed rest than I did with previous sores.

Table 2. User comments on their experience with Amicapsil (2). The highly positive comments, which constituted 84% of the respondents are show. There were 0% negative comments.

4.40 Standard care is typically based on antibiotics and antiseptics (antimicrobials), and they are both known to generally cause severe long-term side effects in patients such as diabetes, cancer, foetal malformations, asthma, obesity, and allergies (19–23).

4.41 In contrast, Amicapsil is safe and has not been associated with any side effects or allergies neither in studies nor in clinical use since approval, i.e. for a period of 10 years (1,2,16–18,24,25). It is non- toxic, consists of non-toxic ingredients, and is readily biologically recyclable.

4.42 NHS bodies, including Integrated Care Boards, are legally required under section 14Z34 of the NHS Act 2006 to work towards continuous improvement in service quality and safety, which includes considering adverse reactions from the use of treatments. ICBs, therefore, have an obligation to choose the most optimal option based on a risk benefit evaluation. Antimicrobials are harmful and ineffective and Amicapsil has been shown to be safe and effective, and ICBs consequently need to integrate this into their decision process.

4.43 Any use of antimicrobials contributes to the generation of antimicrobial resistance (AMR). The resistance is not limited to the person who is being treated with the antibiotics or the antiseptics but spreads rapidly and very effectively into the surroundings, including people's homes, clinics, hospitals and, to any public places, as well as wider into the environment (26–28). The most effective way to decrease the rise in antimicrobial resistance is to reduce, or preferably stop, the use of antimicrobials, i.e. both antibiotics and antiseptics. Given that wounds currently are primarily treated with antimicrobials and that wounds have a high prevalence, it means that wound care contributes substantially to the use of antimicrobials, but without achieving any documented clinical benefits.

4.44 Amicapsil does not contribute to the creation of AMR as it does not contain any antimicrobials, does not have any antimicrobial action, and bans the use of antimicrobials in the processes around its use. Studies show that Amicapsil can replace antimicrobials in wound care.

4.45 Under the Health and Social Care Act 2008 and 2022, NHS bodies, including Integrated Care Boards, in England have a legal obligation to ensure appropriate antimicrobial stewardship (AMS) and prudent antimicrobial prescribing, avoiding its use wherever possible.

4.46 Adopting Amicapsil will strongly contribute to the reduction in use of antimicrobials (1,25,26).

4.47 Antimicrobials contribute strongly to climate change (26). A standard course of antibiotic has been calculated to release 9.84 tonnes of CO2 from soil carbon storage, the equivalent of a standard car driving around the Earth 1.47 times (26). Amicapsil has no antimicrobial action, and no antimicrobials are used in the treatment processes. Amicapsil has proved clinically superior to antimicrobials and its adoption will consequently reduce the use of antimicrobials. Given that NHS organisations, including Integrated Care Boards such as the Commissioning Hub, have legal and strategic duties under the Health and Care Act (2022) and the Climate Change Act (2008) to reduce CO2 emissions, adapt to current and future climate risks, and consider health equity and environmental targets in decision making, the ICBs are required to support reductions in the use of antimicrobials.

4.48 The use of Amicapsil eliminates the use of antimicrobials in wound care and thereby avoids (saves) the contribution to climate change that these emissions would otherwise have produced.

4.49 In summary, from a financial (2.7), patient health (2.6), patient safety (2.8) and AMR & AMS (2.9) and environmental (2.10) perspective, it is of urgent and critical importance for the NHS to adopt solutions delivered via innovation. As Amicapsil is such a solution within the area of wound care, unjustifiably retarding its inclusion on the NHS Drug Tariff, e.g. by blocking its effective dispensing across the country, would counteract several of the NHS' legal obligations.

4.50 To illustrate the effect of Amicapsil, a typical example has been included below [see Appendix A]. The picture to the left shows a wound (pressure ulcer) that had been treated with NHS standard care for 7 months and which, during this period, had deteriorated significantly from being a small superficial wound to a grade 4 pressure ulcer associated with cellulitis (infection in the skin), which is a high-risk factor for sepsis and death. To the right is shown the results of using Amicapsil for 4 months, i.e. healing and closure.

4.51 A consequence of not treating a wound or pressure injury effectively is not only a non-healing wound but can result in severe life-changing complications, e.g. sepsis, or bone infection (osteomyelitis). The infection in the pressure injury in the picture was on the brink of invading the underlying bone and cause bone infection (osteomyelitis). Osteomyelitis is also associated with a high risk of sepsis.

4.52 Non-healing wounds are the main cause of osteomyelitis in the NHS. Osteomyelitis can only be treated by surgery to the bone but is generally regarded as an uncurable disease (29). Russell et al 2020 (30) performed a retrospective study at an NHS Trust of the outcome of surgery for osteomyelitis caused by a pelvic pressure ulcer. The surgical treatment *failure* rate was 71%; 64% of the wounds failed to heal; and in this group the median time to *death* was only 2 years.

4.53 In summary, wounds not treated effectively develop life-changing follow-on conditions with a high degree of life-changing, irreversible morbidity and death. Apart from improving patient safety and quality of life by closing the wounds and avoiding infection, osteomyelitis, and sepsis, Amicapsil also reduces the burden of wounds on the NHS (10).

4.54 In short, Amicapsil represents a first-in-class and only-in-class, innovative treatment approach to wounds.

4.54.1 It is a medical device with an approved treatment claim, i.e. it is not another aid to be used in the treatment of a condition, as medical devices usually are. (It has been approved in the UK and EU since 2016)

4.54.2 It is able to treat antimicrobial resistant (AMR) wound infections (1,18).

4.54.3 It is effective in immunocompromised individuals (1,2,31).

4.54.4 It can prevent severe, long-term side effects of antibiotic treatment in patients by substituting antibiotics (19–23).

4.54.5 It can avoid life-changing follow-on conditions from wounds, ulcers and injuries (1).

4.54.6 It offers the NHS considerable financial savings and savings in nurse resources (1).

4.54.7 It can help the NHS with antibiotic stewardship (AMS), as it replaces the ample use of antibiotics and antiseptics in wound care (1,16–18).

4.54.8 It can help the NHS considerably reduce the CO2 emissions and move towards net-zero (1,26).

4.54.9 It is proved effective in an area of unmet medical need (8).

3.1.1 It is proved safe (1,2,16–18,32).

3.1.2 It is the first and only treatment option available working via the microbiome-immune axis (9).

4.55 In summary, there is no alternative effective treatment available. Amicapsil, therefore, provides benefits unforeseen in the PNA.

4.56 Patients across England are actively requesting access to this innovative treatment. The fact that patients do not see existing treatments as effective but are seeking access to the benefits of Amicapsil can be exemplified by the following statement by the English Spinal Injuries Association, SIA (https://www.spinal.co.uk/news/amicapsil-sci-petition/):

"Petition to make Amicapsil-SCI available on prescription.

As people with a spinal cord injury know only too well, skin damage and pressure ulcers are a constant risk that we have to remain hyper-vigilant about. Sadly, despite best efforts, sometimes things do go wrong and treatment is then required to help the pressure ulcer heal – which is where the wound treatment product Amicapsil-SCI may come in.

Amicapsil-SCI has a microcapillary action and evaporative properties, and is effective on all types of wounds, ulcers and burns, including antimicrobial resistant infections. It removes moisture, toxins and enzymes from the wound bed, and uses the body's own immune system and healthy bacteria to heal the wound. Trials have proven very effective and greatly reduced the healing time, and many people with a spinal cord injury have successfully used the product. However, at present, it can only be purchased independently or via an Independent Funding Request, and work remains ongoing to get it available on NHS prescription."

4.57 Furthermore, access to Amicapsil has been brought to the attention of the All-Party Parliamentary Group for Spinal Cord Injury. Therefore, in relation to choice, a patient group with protected characteristics clearly does not find the current access to pharmaceutical services sufficient.

4.58 In consequence,

4.58.1 the adoption of Amicapsil in community care is important to the NHS, and it falls within the realm of innovation that the NHS has a duty to promote.

4.58.2 Amicapsil is first and only in class and therefore there is no other effective treatment option available, and the patients need, and actively appeal for, access to these unforeseen benefits without delay.

4.59 Provision of advice to patients – Regulation Schedules 4 (10,1) and 5 (9,1)

4.60 According to the 2013-regulation, both pharmacies (Schedule 4) and appliance contractors (Schedule 5) are required to be able to provide advice regarding the specific item provided to patients:

4.61 Schedule 4 - NHS England's Terms of service of NHS pharmacists:

> *10.— (1) In connection with the services provided under paragraph 4, an NHS pharmacist (P) must (a) ensure that appropriate advice is given to patients about any drugs or appliances provided to them*
>
> > *(i) to enable them to utilise the drugs or appliances appropriately, and*
> >
> > *(ii) to meet the patient's reasonable needs for general information about the drugs or appliances;*

4.62 Schedule 5 – NHS England's Terms of service of NHS appliance contractors:

> *9.—(1) In connection with the services provided under paragraph 3, an NHS appliance contractor (C) must ensure that appropriate advice is given to patients about any appliances provided to them*
>
> > *(i) to enable them to utilise the appliances appropriately, and*
> >
> > *(ii) to meet the patient's reasonable needs for general information about the appliances*

4.63 The application submitted by Willingsford specifically stated that "*a requirement under Schedule 5, clause 9 of the Pharmaceutical and Local Pharmaceutical Services Regulations is that the DAC must be able to advise the patient on the general use of the product*". Despite this, the Committee did not address this issue in their response. The issue was omitted in the Letter.

4.64 In relation to wounds, pharmacists are only expected to provide guidance to patients concerning the treatment of minor scratches. Wounds are neither among the 7 conditions for which pharmacists can prescribe, among the conditions pharmacies can support via Pharmacy First, nor among the conditions pharmacies can support via Advanced Services. This shows that pharmacists do not have background knowledge, experience, or training in wound care. Pharmacists are expected to be able to look for signs in a wound that indicate that the patient should seek medical advice. When dispensing based on a prescription, the patient has already sought medical advice as the wound will be more complicated than a simple scratch. Pharmacists' competence and training do not extend to these more complicated wounds, and they do therefore not have the background to offer advice in relation to advanced wound treatments.

4.65 Furthermore, since Amicapsil is novel and first-in-class, with a need to be used fundamentally differently from all current wound appliances, pharmacists will not have any experience with this approach, and they will therefore not have the competency to advice patients as legally required.

4.66 In practice, most community pharmacies routinely forward Part IX appliance prescriptions to agency DACs, reflecting their preference not to handle complex appliance dispensing.

4.67 Similarly to pharmacies and as stated in Schedule 5, DACs must equally be able to provide competent advice in relation to products provided to patients, and in the case of Amicapsil, given that it is a new class of wound products with a different mode-of-action, Willingsford is the only entity capable of this.

4.68 Section 2.12 above discussed the consequences for patients of not being treated effectively, leading to life changing, irreversible conditions such as sepsis and osteomyelitis. If Amicapsil is used incorrectly, it will not provide the expected benefits. Therefore, failure to provide correct advice will mean placing the patients at significant risk because a non-healing wound can lead to life threatening and irreversible conditions such as osteomyelitis, sepsis, and pain that will not allow the person to remain in own home. Secondly, it is a waste of NHS resources. In addition, the provision of effective treatment is time dependent. For example, in persons with spinal cord injury, osteomyelitis can develop from a wound within 2 weeks from injury, and at 4 months, the presence of osteomyelitis is to be expected. Therefore, not receiving correct advice from the beginning of treatment can lead to the patient unnecessarily being pushed past this time threshold.

4.69 In summary, the importance of proper and knowledgeable advice is emphasised by its very clear, unambiguous mentioning in the regulation. It is highly surprising that the Committee did not place emphasis on the provision of proper advice, given that it is a clear requirement to both pharmacies and DACs. Instead, the Committee omitted this obligation altogether from the assessment process. In the case of Amicapsil, it is a service that only Willingsford can provide.

4.70 If Amicapsil were forced to be dispensed via a different DAC or via one or more DSPs, Willingsford would need to train and certify all staff at these entities across the entire UK, to ensure the correct advice be provided to the end-user. This would take a very long time. As Willingsford is already providing this service to all users across four continents and has experience in doing this for the past 10 years whilst Amicapsil has held regulatory approval, allowing Willingsford's DAC to provide this advice directly to the NHS community end user would considerably decrease the risk of the end user receiving sub-optimal advice. It would also ensure a timely introduction of Amicapsil. It would therefore benefit the NHS to allow the Willingsford DAC to provide this integrated health support.

Reasonable choice within pharmaceutical services - Regulation 18 (2) b, i

4.71 Regulation 18(2)b,i states: NHS England must have regard to … the desirability of "there being a reasonable choice with regard to obtaining pharmaceutical services in the area of the relevant HWB (taking into account also [F2NHS England's] duties under sections 13I and 13P of the 2006 Act M47 (duty as to

patient choice and duty as respects variation in provision of health services)),", where NHS Act (2006) 13I states: "Duty as to patient choice: [F2NHS England] must, in the exercise of its functions, act with a view to enabling patients to make choices with respect to aspects of health services provided to them.]"

4.72 In the Letter 6.25, the Committee writes: "*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."*

4.73 The Committee has analysed the application from the viewpoint of establishing a local, walk-in pharmacy in Totton, Hampshire, whereas the application was for establishing a DAC. The local conditions within the HWB are irrelevant. This issue has been addressed above under paragraph 1.4.1.

4.74 The Commissioning Hub has responded only to the obligation to offer a choice of physical dispensing outlets without any regard to determining whether these available outlet services actually have the capacity to offer access to the prescribed service. The Committee has omitted the obligation to provide the patient access to the actual treatment that was prescribed; including when this treatment choice was made as a shared decision between the healthcare professional and the patient and in an effort to ensure that the person receives appropriate person-centred care and treatment that is based on an assessment of their needs and preferences; as set out in the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulations 9.

4.75 Given that the existing approaches to wound treatment are known to be ineffective with NICE and FDA concluding that wounds constitute an unmet medical need, and given that studies have shown a significantly superior effect of Amicapsil, as also concluded by Yang et al. 2025, and given that Amicapsil is first and only in class, there cannot be ruled to exist a reasonable choice with regard to accessing pharmaceutical services when patients, because of the refusal of the DAC license, are denying the NHSBSA the ability to provide patients access to the only treatment that has been demonstrated effective for their condition.

4.76 In summary, it is not correct that reasonable choice is available. Amicapsil is the only effective treatment available and it is the only one of its kind. If the Committee prevents this treatment access to the Drug Tariff because no existing pharmacies or DACs are able to dispense it whilst fulfilling the legal requirements associated with dispensing, the treatment will not be made available on the Drug Tariff. This clearly prevents the patient from choosing this kind of treatment and forces the patient to choose between only ineffective treatments.

4.77 Under the Equality Act 2010 and the Public Sector Equality Duty to eliminate discrimination and advance equality of opportunity, NHS bodies have the legal obligation to make treatment equally available to everyone in the country. As Amicapsil is effective, and the only effective choice available to choose from, Amicapsil must be made equally available across the country. This obligation rules out the use of only local dispensing agents, as suggested by the

Committee, as this could signify access for some groups and not others. This obligation has been addressed by means of the Willingsford DAC licence application.

Protected characteristics - Regulation 18 (2) b, ii

4.78 Regulation 18 (2) b, ii states: NHS England must have regard to … the desirability of "*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 [F2NHS England's] duties under section 13G of the 2006 Act M48 (duty as to reducing inequalities))*," where NHS Act (2006) (and as amended in 2022) 13G states: "*Duty as to reducing inequalities: [F2NHS England] must, in the exercise of its functions, have regard to the need to*

> *a) reduce inequalities between [F3persons] with respect to their ability to access health services, and*
>
> *(b) reduce inequalities between patients with respect to the outcomes achieved for them by the provision of health services [F4(including the outcomes described in section 13E(3))]." where the "outcomes" described are effectiveness, safety, and quality*.

4.79 In the Letter, the Committee writes:

> *"6.29 The Committee noted that whilst these statements had been included by the Applicant there was no evidence provided that identified a group of patients in the Totton area, sharing a protected characteristic who were having difficulty accessing services that meet a specific need.*
>
> *6.30 The representations from Community Pharmacy HIOW LPC did not include comments relating to groups of patients having difficulty accessing pharmaceutical service"*

4.80 The Application stated:

> *"In relation to the Pharmaceutical and Local Pharmaceutical Services Regulations (2013/349), protected characteristics include people with disability such as spinal cord injury, who are particularly prone to developing pressure injuries. They will, due to their condition, have difficulty collecting the treatment from a pharmacy. They would therefore as an unforeseen benefit gain from the implementation of home delivery."*

4.81 The PNA did not state that Protected Characteristics were absent in Totton or that the demographics in this respect were significantly different compared to the rest of the UK. As concluded in paragraph 1.4.2 above, it is acceptable to use disease prevalence data for the UK to describe conditions "in Totton and further afield". Consequently, individuals with disability and wounds affecting mobility will be present and these conditions will necessarily affect their ability to access a local pharmacy.

4.82 As established in paragraph 1.4.1, the Committee was analysing the application from the viewpoint of establishing a local, walk-in pharmacy in Totton, Hampshire, whereas the application was for establishing a DAC. The

local conditions within the area of the HWB are irrelevant, since a DAC will deliver across England.

4.83 HIOW specifically made the representation that the regulations should be followed. They made no comments anywhere regarding Protected Characteristics. The interpretation by the Committee in relation to Protected Characteristics is therefore not supported in the actual statement made by the HIOW.

4.84 Given that mobility issues, whether people with disabilities or who develop wounds affecting their mobility, will result in difficulty physically visiting the local walk-in pharmacy, they will necessarily be at a disadvantage in accessing services. To address such inequality, home delivery is needed. Given that Amicapsil requires cold-chain, home delivery with cold chain must be provided.

Implementation of delivery and financial considerations.

4.85 In paragraph 6.23 of the Letter (regarding cold chain), the Committee states that DACs "*have the choice to use cold chain delivery services."* However, as stated by NHSBSA existing DACs do not have established cold-chain distribution and the provision of such services will require 1) inhouse investment in cold storage equipment, cold chain packaging materials and developing the optimal procedures to keep the product within the correct temperature range for the duration of the transit, 2) comprehensive staff training in cold chain procedures, and 3) regulatory approval of cold chain policies and procedures with initial regulatory inspection and annual regulatory audits as required by MHRA and the ISO13485 Quality Management System. Most DACs will be reluctant to make this investment up front before Amicapsil has been widely adopted in NHS community with their calculations showing profitable return on investment by the DACs. Therefore, the decision whether or not to allow Willingsford to establish a DAC cannot rely on an unfounded assumption that existing DACs will rapidly establish such services. If wrong, the implication will be that patients do not gain access to a new effective treatment and that this will expose them to significant risks of death and irreversible morbidity.

4.86 Furthermore, the timescale for a DAC building up these competences is long and would push the implementation of Amicapsil unpredictably into the future.

4.87 From a cost and time perspective, Willingsford already has established cold-chain distribution and is delivering to NHS Trusts on behalf of NHS Supply Chain, meaning that economy of scale can be gained and used to keep the cost to the NHS contained. It also means that the distribution can be immediately implemented. Furthermore, because Willingsford is the manufacturer, the delivery directly to the patient will only involve a single transit event and this will reduce the risk of damage to the product as well as the time to reach the patient. This faster initiation of treatment is essential because the older the wound, the more complications will have developed.

4.88 Ensuring an unbroken cold chain from manufacturer to end-user is a legal requirement placed with the medical device manufacturer in the legislation around medical devices. This involves MHRA's product approval and the ISO 13485 Quality Management standard to which medical device manufacturers must strictly adhere. The manufacturer cannot transfer this responsibility to a

third party and approval procedures by NHSBSA can therefore not progress until the dispensing method is determined.

Summary and Conclusions

4.89 The analysis, in relation to the fulfilment of the Pharmaceutical Regulations of 2013, the National Health Service Act of 2006, the Equality Act of 2010, and other relevant legislation, of the Letter prepared by the Committee, refusing Willingsford permission to establish a DAC to enable the provision of a new, innovative wound treatment to patients, has found that the Committee failed to take into account and has failed to comply with important parts of the legal framework relevant to the distribution of Amicapsil in NHS community care.

4.90 The alternative solution deductively proposed by the Committee does not meet the legal requirements. As a consequence, the refusal leaves Amicapsil without a legally satisfactory distribution channel in NHS community care. This would prevent or substantially delay the provision of this treatment to patients.

4.91 The current status is:

4.91.1 Wounds not healing spontaneously constitute an unmet medical need due to lack of efficacy of current standard care wound products.

4.91.2 The inability to treat wounds effectively has significant impact on patients, the NHS, and the environment, and this places patients at high risk of death and irreversible morbidity, and it places an ever increasing financial and work burden on the NHS.

4.91.3 Amicapsil is the first wound product clinically effective in treating wound infections and it achieves its effects through the microbiome-immune axis without antimicrobial action.

4.91.4 Amicapsil is effective against antimicrobial resistant infections and in immunocompromised patients.

4.91.5 Patients and their organisations have indicated a strong desire to gain access to Amicapsil in NHS community care, indicating that they do not see the current access to wound treatments as reasonable.

4.92 The conclusions on which the Committee base their refusal of the Application are:

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

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

4.92.1 The Committee has erroneously limited the interpretation of the legislation to choice between which pharmacy to use and to products with the same mode-of-action. It has not taken into account that choice includes access to new products with different characteristics that are included on the Drug Tariff in order to address an unmet medical need.

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

4.92.2 The PNA did not demonstrate that persons with disabilities and wounds affecting mobility were absent in the HWB region of Totton and Hampshire. It must therefore be assumed that the distribution of such conditions in England also applies to Totton and Hampshire, which will mean that individuals with such characteristics are present and that they necessarily will have difficulty accessing services that require mobility, and that they consequently require home delivery.

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

4.92.3 The required obligation with regard to innovation includes the treatment itself– the Committee has erroneously limited the interpretation of the legislation addressing innovation to the delivery of the device. This is clearly incorrect as stated in the regulation 18,2,b,iii: *"(taking into account also [F2NHS England's] duties under section 13K of the 2006 Act M49 (duty to promote innovation))."*

4.92.4 The present document has 1) explained the limitations of the statements by the Committee listed in paragraph 7.3 above; and 2) highlighted several obligations associated with the dispensing of Amicapsil which have not been addressed and met in the refusal Letter by the Committee.

The duty to promote innovation in the NHS

4.93 Amicapsil is, as demonstrated, innovative, first and only in class. Compared to standard care in NHS community, Amicapsil improves patient safety, is effective, improves patient outcome, improves quality of patient experience, does NOT contribute to AMR (as current standard care does), does NOT contribute to climate change (as current standard care does), and helps the NHS in reaching its net-zero target. Amicapsil is set to provide savings of 50-80% on the NHS community care wound care budget on a per wound basis.

4.94 Apart from the duty to promote innovative products, the NHS, therefore, also has an interest in introducing Amicapsil into community care fast and effectively.

4.95 The table below summarises a few of the most essential requirements associated with the dispensing of Amicapsil. It focuses on the availability of cold-chain, ability to provide advice, and home-delivery. Only Willingsford is able to fulfil them all and only Willingsford would be able to provide this, when Amicapsil becomes available. All other options would need substantial time periods for implementation, which would be to the detriment of patients and would unnecessarily burden the NHS. The points are further touched upon below.

Requirement	Legal requirement	Pharmacy	Distance selling pharmacy (DSP)	Existing Dispensing Appliance	Willingsford DAC

				Contractors (DACs)	
Cold Chain	Product requirement	✓	✓	X	✓
Advice	Yes	X	X	X	✓
Home delivery	Yes	X	✓	✓	✓

4.96 The necessity to provide unbroken cold handling, transport and storage of Amicapsil Cold chain is an indispensable requirement at all times when dispensing Amicapsil. The NHSBSA has informed Willingsford that no currently existing DACs have cold chain procedures in place. DACs can therefore not dispense Amicapsil. Some DSPs offer cold chain but the less handling, i.e. the fewer steps the higher the probability of the patient receiving an effective product (Amicapsil). Willingsford is already sending directly to the patient's home and has 10 years of experience doing so. Allowing Willingsford to send directly to patients would considerably reduce the number of steps and the risk of breaking the cold chain.

4.97 The duty to provide advice to the user – Consideration of this obligation was omitted from the response Letter Amicapsil works in a different manner and requires procedures different from the ones used in standard wound care. The current advice provided by pharmacies and DACs in relation to wounds is directly contrary to the advice needed when using Amicapsil.

4.98 Training and certifying staff in existing dispensing bodies to ensure the correct advice be provided to the end-user, would take considerable time, during which period the introduction of Amicapsil in community care would be blocked. Willingsford has developed the product and all the procedures associated with its use and Willingsford is already providing this advice and has 10 years of experience doing this. The service would therefore be accurate and efficient from the very start.

4.99 The duty to people with disability and protected characteristics – i.e. to deliver to the patient's home Compelling evidence has been provided that people with disability are actively campaigning for Amicapsil to become available in NHS community care.

4.100 The typical users of Amicapsil are people with spinal cord injury or multiple sclerosis, people on prescribed bed rest due to their wound, people with severe ambulatory problems due to pain and weakness from their wounds, and people with long-term illnesses who are bed-bound and develop a pressure ulcer. These are groups with disabilities and protected characteristics and have well documented difficulties getting to the local pharmacy and, consequently, require their Amicapsil delivered to their home. Therefore, offering Amicapsil through local walk-in pharmacy dispensing is not sufficient to meet the regulatory obligations of the NHS. Willingsford has for the past 10 years been delivering directly to these patient groups and has experience with any special requisites.

Overall conclusion

4.101 Amicapsil offers benefits unforeseen in the PNA. The appearance of an effective treatment in an area of unmet medical need could not have been foreseen in the Hampshire Pharmaceutical Needs Assessment (PNA). However, recognising that it is now available and able to make substantial, unexpected improvements to patient outcomes and the NHS service not foreseen in the PNA, warrants approval of the Willingsford DAC, which would be the only entity possessing the required background for dispensing it safely and in agreement with the legal requirements in Hampshire and across the country.

4.102 The Willingsford DAC would not duplicate existing services.

4.103 No representations were made in opposition to the application.

4.104 The NHSBSA is currently waiting for the DAC license to be granted to allow them to proceed with Amicapsil's inclusion on the Drug Tariff. A positive outcome of this DAC application is therefore essential to patient treatment and for the NHS to fulfil its obligations.

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4 Summary of Representations

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

However, the additional information which was circulated to parties with the appeal which formed part of the Commissioner's decision minutes was provided to the Applicant. In the interests of transparency and fairness, NHS Resolution sought to rely on the discretion afforded in paragraph 7 of Schedule 3 of the Regulations to vary the normal procedures and circulate these comments to the Applicant and for them to make observations on them if they so wished.

5 Observations

5.1 THE APPLICANT

5.1.1 "Thank you for the forwarded information. We very much appreciate the opportunity to see it and respond to it.

5.1.2 The DAC for which we are seeking a licence is not public facing. Its purpose is to make an innovative wound treatment that removes antimicrobial resistant infections in wounds available to the public across England. It seeks to deliver the treatment directly to the patient's home. There are two main reasons for this: 1) The treatment must be kept refrigerated to maintain its efficacy. The fewer steps a cold chain is made up of, the greater the likelihood of success; and 2) people with difficult wounds are often home-bound or very restricted in their movements. Therefore, having to pick up the treatment at a pharmacy would put a strain on them, that is completely unnecessary as we can send the treatment directly to them. In addition, this would present a lower risk of harming the product compared to them picking it up on a sunny afternoon and carrying it home, typically without insulating material.

5.1.3 Furthermore, the Commissioner seems to suggest that local pharmacies could easily dispense this treatment. However, pharmacies are not familiar with advanced wound care nor with the processes around the use of this treatment. Each local pharmacy is therefore not prepared and able to provide the guidance on how to use it correctly. Whereas it is easy for the patient to use, the procedures differ fundamentally from the current, general wound care advice. The issue around proper advice cannot be taken lightly as the treatment is not a simple pill but needs to be used correctly on the wound itself. Failure to use it correctly would 1) fail to heal the patient's wound; and 2) place a completely avoidable burden on the NHS finances as they would continue to have a non-improving wound on their hands in need of continued care, and they would have invested in a product that was rendered ineffective due to sub-optimal, but avoidable, procedures. We can, and would very much like to, provide proper advice, as we are the ones with the knowledge and experience around its use. Alter all, we have developed all the user guidelines and we are currently actively providing such direct patient advice worldwide.

Specifically in relation to the materials provided:

Documents establishing location information on Willingsford's site in relation to local pharmacies and public accessibility:

5.1.4 First, in relation to the location of Willingsford relative to existing pharmacies, we would like to reiterate the fact that the Commissioner has approached our application from the perspective that we were seeking to establish a public facing, local DAC similar to a local pharmacy. This, however, is not the case. The aim of our application is to establish a DAC that delivers the wound treatment Amicapsil to patients at their home address across England. The purpose is not, and has not at any point been, for patients to visit the DAC to bring the product home with them. This would be contradictory to the very purpose of the DAC, since Amicapsil is temperature sensitive and needs to be delivered at their home address such that they can unpack the parcel and place the product directly into the refrigerator immediately upon arrival. Highlighting our physical location, in the documents provided, rather substantiates our argument that the Pharmacy Team under the local ICB have sought to analyse Willingsford's application from the perspective of seeking to establish a new, local, public facing DAC functioning like a local pharmacy, but limiting itself to medical devices, a scenario that is in direct contrast to the non-public-facing DAC providing home delivery across England, that we are seeking permission to establish. We therefore fail to see the relevance of this location information provided by the Commissioner.

Documents establishing location information of Willingsford's site in relation to other Hampshire DACs:

5.1.5 Second, with regards to the relations between our DAC and other DACs, we similarly fail to see the relevance as the map includes all existing DACs, irrespectively of their medical area of focus and whether they fulfil the requirements to dispensing Amicapsil. As stated by the NHS Business Services Authority, none of the existing DACs in England have cold-chain distribution in place, which means that they cannot fulfil the requirement for the delivery of Amicapsil to patients. Before considering applying for a DAC ourselves, we had approached the most relevant DACs regarding the dispensing of Amicapsil. There was no real interest in collaborating. On the contrary, the information provided by NHSBSA was confirmed: none of the existing DACs had cold-chain storage, management, and dispatch facilities and procedures in place. Therefore, if an existing DAC were to take on dispensing Amicapsil, it would first have to install facilities, establish procedures, train staff, and pass regulatory audits regularly. This would take a considerable time and investment, and is probably the main reason why all existing DACs found a collaboration unattractive. In addition, it would add several unnecessary steps to the cold chain, which, from a patient and product perspective, is always a risk and to be avoided wherever possible. Furthermore, as the manufacturer, we are responsible for complying with the ISO13485:2016 medical device regulation, which makes us responsible for the product until it reaches the patient. We are very happy to be responsible, as we want to ensure best possible that our product lives up to our claims, and we have no interest whatsoever in not delivering an optimal product. If we were forced to use a suboptimal

dispensing route it would severely challenge our ability to live up to our legal responsibility. In any event, there exists no DAC in England that is willing to establish cold chain delivery of Amicapsil.

5.1.6 Additionally, none of the existing DACs, including the ones mentioned and shown in the maps provided by the Commissioner, would be able to advice [sic] patients on the use of Amicapsil, which is a legal requirement to the dispensing agent. So, given that the existing DACs do not have cold-chain distribution in place and cannot provide suitable advice to patients on the use of Amicapsil, they cannot fulfil the legal requirements to act as a dispensing agent for Amicapsil. We, therefore, again, fail to see the relevance of mentioning these DACs and providing their location information.

Letter from Community Pharmacy Hampshire & Isle of Wight regarding the principle of procedural fairness:

5.1.7 Third, we highly appreciate the comments by CPHIOW emphasising the need for procedural consistency, fairness, and transparency. We were not aware of this communication, which was clearly ignored by the Commissioner.

5.1.8 By the Pharmacy Team requesting our application to be analysed once more relative to the new PNA published in August 2025, with our application submitted in May 2025, a considerable delay was introduced into the approval process. This will have had detrimental effects on a large number of patients, including unnecessary deaths, and will have increased the burden on the NHS and social care. This may sound exaggerated, but Amicapsil is the first treatment globally to have demonstrated effects on antimicrobial resistant wound infections and on chronic non-healing wounds. The decision to repeat the process using the new PNA is an approach that also delays the income stream of a British SME with a very high investment ratio in research and innovation and with the potential to contribute positively to the UK's economy. Such a delay increases the risk of losing the innovation altogether. The immediate consequence of maintaining status quo cannot be seen as benefitting NHS England or patients considering that non-healing wounds have been characterised as an unmet medical need, denoting the urgent need for an effective treatment.

5.1.9 In conclusion, there are two sets of regulations that need to be met:

5.1.10 Quality Management System ISO13485:2016 for medical devices: The manufacturer is responsible for 1) delivering the product in suitable condition to the end user; and 2) providing information on correct use to the end user. If the manufacturer is not undertaking all steps that the product passes through on its path to the end user, the manufacturer is responsible for ensuring that the entity/entities performing these tasks fulfil these requirements.

5.1.11 Pharmaceutical Regulation 2013 for Pharmacies and DACs: A dispenser has the obligation to provide correct instructions in how to use the product. The dispenser must ensure that the product arrives in suitable condition at the end user's home. The product must be

obtainable in an equal manner across England, including taking into consideration protected characteristics. The NHS has the obligation to support innovation.

5.1.12 We are the developers and manufacturers of Amicapsil. We manufacture in-house at our facilities in England.

5.1.13 If our application for a DAC license is refused, we do not know of an avenue to make Amicapsil available to community care in England whilst complying with the above regulations. The FP10 process has so far been on hold for over one year exclusively due to this issue.

5.1.14 The Commissioner has, by the decision to refuse our application, prevented the introduction into Community care of an innovative wound treatment, that as the first wound treatment globally has demonstrated clinical effectiveness. These delays are not trivial as wounds and their treatment account for approximately 20% of the NHS budget. A study published January 2026, reported that wound outcomes in the NHS have not improved during the period from 2017 to 2025, that 20% of wounds require hospitalisation, and that 45% of all wounds are more than 3 months old, indicating poor efficacy of existing standard care (https://www.magonlinelibrary.com/doi/full/10.12968/bjhc.2026.0005). This further highlights the importance of NHS' obligation to support innovation with the aim to improve patient outcome.

5.1.15 Please let us know if anything is unclear or you need any additional information."

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").

Regulation 31

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

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

(2) This paragraph applies where -

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

6.6 The Committee noted that the Applicant had stated "*Not applicable – no dispensing appliance contractor within 1.6km".* The Committee further noted the Commissioner had considered both Regulation 31(2)(a)(i) and (ii) and had concluded that "*there is no pharmacy providing pharmaceutical services within the area of the proposed premises. The application did not therefore need to be refused in accordance with Regulation 31*". The Committee noted that this had not been disputed either on appeal or in subsequent representations. The Committee therefore determined, based on the information before it, that it was not required to refuse the application under the provisions of Regulation 31.

Regulation 18

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

"(1) If—

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

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

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

(2) Those matters are—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

6.8 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").

6.9 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.

6.10 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).

6.11 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.

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

6.13 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.

6.14 The Committee noted that, following the publishing of the 2025 PNA the Commissioner had recirculated the application and had sought representations based on the 2025 PNA and the Committee noted the comments from parties.

6.15 The Committee considered the Hampshire PNA prepared by Hampshire County 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). Such a statement then forms part of the PNA. The Committee noted that the PNA was dated 2025 and had been published in August 2025 and that no supplementary statements had been issued.

6.16 The Committee noted the Executive Summary of the 2025 PNA had concluded:

"*The conclusion of this assessment is that the number, distribution, and choice of pharmaceutical services meets the current and future needs of Hampshire's*

population, with no gaps in necessary services within the lifetime of this PNA. There are no identified gaps for additional pharmaceutical services or improvements to current arrangements across the county. This is based on the following:

- *There is a good geographical spread of community pharmacies providing necessary services in each district across the county (section 4.2)*

- *A pharmacy in Hampshire is accessible to the majority of the resident population of the county. Overall, 98% live within a 5-mile drive of a pharmacy located within the county. The more urban population can access a pharmacy within a 2.5-mile drive. Most of the population outside of the 5-mile drive zone are resident in sparsely populated rural areas (section 4.2.2)*

- *Housing development is examined at district level in supplementary document two. Examination of provision for areas of expected growth suggests that the needs of the associated increases in population can be met by existing service provision, assuming that market conditions and health needs remain unchanged.*

- *Overall, there are 14.7 community pharmacies per 100,000 population in Hampshire, suggesting lower level of service provision than the national average but this needs to be contextualised against Hampshire's extensiveness and rurality, hospital pharmacy provision, dispensing GPs and distance selling, the size or staffing levels of these pharmacies, including variation at a district level. Provision is broadly in line with the average across Hampshire, Portsmouth, Southampton and Isle of Wight as a whole(section 4.5)*

- *There are 23 '100-hour' pharmacies in the county. These pharmacies provide extended opening hours both in the morning and late into the evening and weekends. It is important to contextualise this finding against new regulations that allow pharmacies who opened with a 100-hour contract to make reductions in the number of hours they operate. Ten of Hampshire's eleven districts have at least one 100-hour pharmacy operating within its borders. The only district without provision is Eastleigh but there are four 100-hour pharmacies operating over the Hampshire border in the city of Southampton. (section 4.2)*

- *All 210 community pharmacies provide the full range of face-to-face essential pharmacy services which have been defined as 'necessary services' for the purposes of the PNA (section 5.4)*

- *There is good provision of advanced services across the county, with provision in each of its constituent eleven districts (section 5.5)*

- *There is a variety of locally commissioned and enhanced services delivered across Hampshire (section 5.6 and 5.7)*

- *Of those community pharmacies that responded to the questionnaire (79 out of the 210 pharmacies), the majority provide collection of*

prescriptions from GP practices and a delivery service to patients as well as services in a variety of languages (section 4.2.2)

• There has been an increase in the number of items prescribed dispensed to Hampshire residents by distance selling providers, with 8.3% of prescriptions now being dispensed by distance selling providers compared to 5.1% in 2020 (section 4.3)"

6.17 The Committee noted that Dispensing Appliance Contractors ("DAC") were considered specifically in Section 5 "Current Pharmaceutical Services" which states:

"5.2.8 Dispensing Appliance Contractors

Dispensing appliance contractors (DACs) can only dispense prescriptions for appliances and not for drugs. They are not required to have a pharmacist, and their premises do not have to be registered with the General Pharmaceutical Council. Pharmacies dispensing appliances have a narrower range of services that they must provide. These include dispensing of prescriptions, dispensing of repeat prescriptions, minimising waste, signposting to alternative providers when necessary, home delivery of specified appliances, the provision of supplementary items such as wipes and bags, the provision of clinical advice about appliances and the emergency supply of appliances when requested.

These contractors tend to operate remotely, receiving prescriptions via the electronic prescription service or through the post. There are two dispensing appliance contractors located in Hampshire as at September 2024, one in Basingstoke and Deane, and one in Winchester.

Hampshire residents may choose to have their appliances dispensed from a dispensing appliance contractor anywhere in the country. A large proportion of patients who are regular users of appliances will have them delivered."

6.18 The Committee finally noted the Conclusion of the 2025 PNA at section 8 which states:

"The conclusion of this PNA is that the number, geographical distribution, opening hours and choice of pharmaceutical services currently meet the needs of Hampshire's population and will meet future needs within the lifetime of this document, assuming that market conditions and health needs remain unchanged."

6.19 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 pharmacy either at this site or more generally within the area of the HWB either in the 2022-2025 PNA or the 2025 PNA. The Committee considered that whichever PNA it had regard to it would not materially affect its decision.

6.20 The Committee noted that the Applicant seeks to provide unforeseen benefits to those who require appliances and specifically those patients who require wound dressings. 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.

6.21 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)

6.22 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"*

6.23 The Committee noted that the Commissioner had stated "*…was not aware of any plans that would be affected and concluded that granting the application would not have an adverse effect on any future plans …*" and had concluded that "*granting the application would not cause significant detriment in this regard.*" The Committee noted that this had not been disputed either on appeal or in subsequent representations. On the basis of the information available, the Committee was not satisfied that, if the application were to be granted and the pharmacy to open, the ability of the Commissioner thereafter to plan for the provision of services would be affected in a significant way.

6.24 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)

6.25 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"*

6.26 The Commissioner had concluded "*The Committee did not find any significant detriment to proper planning or to the arrangements in place for the provision of pharmaceutical services and therefore was not obliged to refuse the application under Regulation 18(2)(a)"* which again had not been disputed by any party either on appeal or in subsequent representations. On the basis of the information before it, 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.

6.27 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)

6.28 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)

6.29 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.

6.30 The Committee noted that there were two DACs within the Hampshire HWB and that there was a further DAC located in the Portsmouth HWB. The Committee noted that this had not been disputed by the Applicant but that the Applicant comments that the existing DACs were not offering to provide the specific product (Amicapsil) that it was proposing.

6.31 The Applicant believes that a DAC, which would provide nationwide coverage and not just support patients in the Hampshire HWB area, would enable it to provide advice and care specific to those who require wound dressings and supplies.

6.32 The Committee noted that there was nothing provided to demonstrate that patients were experiencing difficulties in accessing existing wound dressings and supplies in this area either on foot or via public or private transport or why

a DAC would improve access for those patients to existing wound dressings and supplies. The Committee noted that there was nothing provided with regard to physical access in the area of the HWB which demonstrated that those who require wound dressings and supplies were not having their prescriptions fulfilled.

6.33 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.

6.34 Whilst the Committee noted that no information had been provided by the Applicant to show that the existing pharmacies or DACs were not providing wound dressings and supplies or that patients were experiencing difficulties in accessing these from the existing pharmacies in the HWB or from DACs in other HWBs it was mindful that the Applicant was proposing to offer Amicapsil which was not currently being offered by DACs.

6.35 The Committee noted the comments from the Applicant that the specific use of Amicapsil was not currently being offered by any other DACs across the country, as supported by the statements from the NHS BSA.

6.36 The Committee noted the comments from the Applicant that whilst there may be wound dressings and supplies provided by other DACs both within the HWB and further afield, the supply of Amicapsil was to be a new service, as developed by the Applicant. The Committee further noted the statement from the Applicant that "*Amicapsil is an innovative new type of wound treatment that currently is being evaluated by NHSBSA for inclusion on the Drug Tariff Part IX*." The Committee noted therefore that the use of the treatment, as proposed by the Applicant was not currently authorised for use by the NHS BSA under the Drug Tariff,.

6.37 The Committee was however mindful that, once included in the Drug Tariff, there was no indication that the provision of this product would not be able to be offered by other DACs or community pharmacies, provided that they received the appropriate training.

6.38 The Committee was mindful that the provision of services by DACs, by their very nature was national and not restricted geographically.

6.39 The Committee had regard to the quotes provided by the Applicant for those who were already using Amicapsil.

6.40 However, taking all of the above into account, the Committee was not satisfied that, having regard to there being a reasonable choice with regard to obtaining services as well as a choice of services being offered by DACs in accordance with the Terms of Service as set out in paragraphs 3 to 12 of Schedule 5, granting the application would confer significant benefits by way of access on persons.

6.41 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 wound dressings and supporting information might be difficult for people with protected characteristics based on age and disability, particularly due to the nature of the services that DACs offer.

6.42 The Committee noted the comments from the Applicant with regard to those who have protected characteristics and in particular those who suffer from spinal injuries which the Applicant states have a higher incidence of pressure sores which would lead to them benefiting from Amicapsil. The Committee also noted the undisputed comments from the Applicant with regard to the prevalence of wounds that require NHS involvement and the growing numbers of patients who require specialist care. The Committee had regard to the information provided by the Applicant from both research journals as well as from patients who had used Amicapsil. The Committee further noted the information from the Applicant with regard to the disability act and those who would benefit from the use of Amicapsil.

6.43 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. The Committee did note the references and information from the National Spinal Injuries Centre at Stoke Mandeville Hospital as well as The Duke of Cornwall Spinal Treatment Centre at Salisbury District Hospital, however it was mindful that these patients are within a secondary care setting, not a primary care setting, and were already able to access Amicapsil. The Committee was, on balance, 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.

6.44 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.

6.45 The Committee noted the comments from the Applicant that "*Amicapsil is an innovative new type of wound treatment that currently is being evaluated by NHSBSA for inclusion on the Drug Tariff Part IX (appliances)"* and further "*Amicapsil (technical name micropore particle technology or MPPT) is a novel first-in class treatment for wounds…".*

6.46 The Committee noted that whilst it appears that Amicapsil is currently being provided to patients, it is not approved by the NSH BSA and is not included within the Drug Tariff. The Committee was of the view that the inclusion of a drug or appliance within the Drug Tariff was not a relevant consideration for it

under the context of the Regulations and specifically with regard to the criteria as set out in Regulation 18 for an Unforeseen Benefits application.

6.47 The Committee however noted the vast array of information provided by the Applicant in support of the application and in particular with regard to the development, provision of and efficiency of using Amicapsil as an alternative wound dressing.

6.48 The Committee was mindful of the Regulations which states "*innovative approaches to the delivery of pharmaceutical services".* The Committee was of the view that the development of a new product did not necessarily mean that it was axiomatic that an application, whether for a DAC or a Pharmacy contract, should be automatically granted. The Committee, was mindful that the provision of Amicapsil was not of itself innovative as it was already being used, as stated by the Applicant. What the Committee had to consider was the innovative approach to the delivery of that pharmaceutical service. The Committee was of the view that there was nothing provided within the information before it that the provision of an alternative wound dressing would be innovative given the various advances in research and science.

6.49 The Committee noted the comments from the Applicant with regard to the delivery of Amiscapil having to be monitored through "cold chain" and that as "*no applicant on the Drug Tariff requires cold-chain, meaning none of the existing DACs would readily be able to be responsible for delivery to patients."* The Committee was mindful that this was not exceptional and whilst existing DACs may not be used to thermolabile drugs this did not mean that the delivery of Amicapsil was innovative in it needing the cold chain to be maintained. The Committee was of the view that, if this was to be used more widely then it would not be inconceivable for existing pharmacies or DACs to establish a cold chain operating procedure which would be adhered to and meet the relevant criteria for such.

6.50 The Committee further noted the comments from the Applicant that they were in the unique position with regard to being able to offer advice and support for those who were using Amicapsil. The Committee was of the view that the ability to understand a product and then offer advice and support for patients was not innovative and that any pharmacist, working in either a community pharmacy setting or an existing dispensing appliance contractor, should be able to be trained to use new products or those unfamiliar to them. Whilst the Committee accepted that this might require time, the Applicant's extensive knowledge and the lack of knowledge of others was not innovative within the context of the Regulations.

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

Regulation 18(2)(b) generally

6.52 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.

6.53 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

6.54 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).

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

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

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

6.58 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.

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

6.59.1 confirm the Commissioner's decision;

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

6.59.3 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.

6.60 Although the Committee had reached the same conclusion as the Commissioner it had done so for different reasons, therefore the Committee determined that the decision of the Commissioner must be quashed.

6.61 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.

6.62 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.

6.63 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 is not satisfied that granting the application would confer significant benefits as outlined above that would secure improvements or better access to pharmaceutical services.

Case Manager
Primary Care Appeals