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27 February 2025

REF: SHA/ 26391

APPEAL AGAINST NHS ENGLAND DECISION TO RECOVER AN OVERPAYMENT FROM DAYA LTD (FKV67) ("THE APPELLANT")

1 Outcome:

1.1 I dismiss the appeal and confirm the decision of NHS England to recover the overpayment of £11,420.84.

1.2 I note that neither party has submitted a claim for interest with regard to this dispute so I determine that no interest is payable on the sums to be paid from one party to another.

A copy of this decision is being sent to:

Daya Ltd (FKV67)
NHS BSA on behalf of NHS England

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10 South Colonnade
Canary Wharf
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APPEAL AGAINST NHS ENGLAND DECISION TO RECOVER AN OVERPAYMENT FROM DAYA LTD (FKV67) ("THE APPELLANT")

1 INTRODUCTION

1.1 The Appellant appealed the decision of NHS England to recover an overpayment relating to Out of Pocket Expenses ("OOPE").

1.2 The Secretary of State for Health and Social Care, pursuant to the National Health Service Litigation Authority (Pharmaceutical Remuneration – Payment Disputes) (England) Directions 2022 (the "Payment Disputes Directions"), has directed that NHS Resolution determines this type of appeal on their behalf. I, as an authorised officer of NHS Resolution, have made this determination.

2 DECISION

The NHS Business Services Authority ("NHS BSA"), acting on behalf of NHS England, sent a decision to the Appellant on 7 November 2024 in respect of Daya Ltd (ODS code FKV67). The decision stated:

2.1 "Out of Pocket Expenses (OOPE) - Post Payment Verification

2.2 The Pharmacy Provider Assurance Team (PAT), part of NHS Business Services Authority

2.3 (NHSBSA), have been requested by NHS England (NHSE) to undertake a Post Payment Verification (PPV) exercise to provide assurance that pharmacy contractors have claimed correctly for Out of Pocket Expenses between February 2019 and January 2021.

2.4 As part of the verification exercise, your pharmacy has been contacted by the Provider Assurance Team to request that you review all of your Out of Pocket Expense claims between February 2019 and January 2021.

2.5 The NHSBSA PAT concluded that there was not sufficient evidence received to support that 320 OOPE claims totaling [sic] £11,420.84 met the three conditions for claiming OOPE, as outlined in the Drug Tariff. It was therefore our recommendation that an overpayment had been received as a result.

2.6 This recommendation, along with the two attached timelines of correspondence with FKV67 were passed to the NHS England local Pharmaceutical Services Regulations Committee

2.7 (PSRC) to consider whether further action was necessary.

2.8 The NHS England Pharmaceutical Services Regulations Committee has now reviewed this information and noted that:

2.8.1 FKV67 – Daya LTD submitted (805) Out of Pocket Expense claims, totalling (£28,928.49) between February 2019 and January 2021.

2.8.2 FKV67 – Daya LTD was contacted on multiple occasions by the NHSBSA Provider Assurance Team to request evidence to substantiate the claims or agree to the recovery but did not receive sufficient evidence.

2.9 Having reviewed the information provided by the NHSBSA Provider Assurance Team, the NHS England Pharmaceutical Services Regulations Committee has decided that an overpayment in relation to your February 2019 to January 2021 Out of Pocket Expense claims has occurred and has instructed recovery of this overpayment to be progressed in accordance with Regulation 94 (1) of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.

2.10 The below table outlines the total number of claims and the associated recovery value:

Number of Claims	**Total Recovery Value**
320	£11,420.84 deduction

2.11 Action Required

2.12 Please respond to this correspondence at pharmacysupport@nhsbsa.nhs.uk to confirm your agreement for the overpayment to be recovered pursuant to Regulation 94(1) (a) of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013. Please send this confirmation by 7th of December 2024.

2.13 Where you agree an overpayment has been made the amount over paid will be recovered by deduction from a future NHSBSA payment to you.

2.14 If you have any concerns regarding the deduction or would like to discuss an alternative approach to recovering the overpayment, please contact us by 7th of December 2024.

2.15 Once the NHSBSA has received confirmation to recover the overpayment you will be notified of when this will take place. A record of this process will be kept on your NHS England contractor file.

2.16 Please be aware that failing to contact us by 7th of December 2024 to agree that there has been an overpayment DOES NOT mean that the overpayment cannot be recovered. Instead, where you do not agree that an overpayment has been made you have a right of appeal to the Secretary of State against NHS England's decision. Should you choose to appeal then send a concise and reasoned statement of the grounds for your appeal within 30 days of the date of this letter to nhsr.appeals@nhs.net or: NHS Resolution Primary Care Appeals 10 South Colonnade Canary Wharf London E14 4PU.

2.17 If there is no appeal within 30 days from the date of this letter, NHS England has requested that the NHSBSA Provider Assurance Team commence overpayment recoveries under Regulation 94(1) (b) of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, on the basis that the final outcome of our investigation is that there has been an overpayment.

2.18 The NHSBSA will notify you of when the overpayment recovery will take place.

2.19 A record of this process will be kept on your NHS England contractor file.

2.20 For more information or for clarification of any of the details in the letter, please contact by email at pharmacysupport@nhsbsa.nhs.net.

2.21 If you would prefer to speak to us via telephone/Microsoft Teams, please email pharmacysupport@nhsbsa.nhs.net to provide your contact details and a member of the team will get in touch as soon as possible.

2.22 Your co-operation is very much appreciated."

3 THE DISPUTE

In an email dated 18 November 2024 addressed to NHS Resolution, the Appellant appealed against NHS England's decision. The grounds of appeal are:

3.1 "Thank you for getting back to use.

3.2 320 of our claims, totalling £11,420.84, lacked sufficient evidence to meet the Drug Tariff requirements for OOPE. Consequently, the recommendation was made for recovery of this amount. However, I could not see attachment of those 320 claims that " concluded that there was not sufficient evidence received"

3.3 As mentioned, before we doing our best [sic] to cooperate as much as possible however due to the time lapsed since claims was done and that fact claims done prior us taking over Daya makes this case harder for us.

3.4 We would like to appeal and challenge decision taken for the following reasons:

3.4.1 Interpretation of the Drug Tariff Conditions for OOPE Claims: We seek clarification on the specific criteria that the NHSBSA PAT used to assess whether claims met the Drug Tariff conditions. As the Drug Tariff does not always specify in granular detail what constitutes "reasonable" supporting evidence, there may be room for interpretation. We and previous owner believe claims were made in good faith and in accordance with the guidance provided at the time.

3.4.2 It is noted that NHSBSA PAT stated there was "not sufficient evidence received." However, we have attempted submissions of documentation for claims during the review period. Given the volume of claims, a significant effort was made to provide comprehensive supporting documents.

3.4.3 We request a detailed breakdown of which specific claims lacked evidence and in what respect, so we may better understand the areas identified as insufficient. If further documentation or additional explanation of claims is needed, we would appreciate an opportunity to submit any additional supporting documents that may substantiate these claims. We ask that NHSE and NHSBSA PAT consider any extenuating circumstances or administrative barriers that may have impacted our responses during the review period.

3.4.4 The proposed recovery amount represents a substantial deduction and could have significant financial implications.

3.5 We understand from previous owner and pharmacist at time that there was extreme shortages of a lot of drugs and Nursing home nurses, managers, and relatives of residents in these homes were putting extreme pressures on the pharmacy to get these

medicines to them ASAP. Consequently, when efficient suppliers were found the [sic] were been used on a regular basis. The most Important thing being supplying the medicines effectively and efficiently. Moreover, the doctors have been prescribing the specials and I can only say that it is such a large amount because of the sheer volume of items being prescribed by the doctors.

3.6 Request for Reconsideration: In light of the above, we respectfully request that the NHS England Pharmaceutical Services Regulations Committee re-evaluate the decision and consider the provision of an extended deadline or additional channels to submit any supplementary evidence that may validate our OOPE claims. Additionally, we ask for clarification on the interpretation of the Drug Tariff conditions used to determine eligibility, so that any discrepancies may be rectified in future claims.

3.7 We appreciate your attention to this matter and look forward to a constructive resolution."

4 SUMMARY OF REPRESENTATIONS

This is a summary of representations received on the appeal.

4.1 The NHS BSA on behalf of NHS England stated:

4.1.1 "Thank you for your letter on the 10th of December 2024 and the opportunity to provide representations on the appeal.

4.1.2 **Background**

4.1.3 An Out of Pocket Expenses (OOPE) endorsement enables community pharmacy contractors to claim payment, where in exceptional circumstances, the contractor has incurred expenses in obtaining eligible products and where the product is not required to be frequently supplied by the contractor.

4.1.4 Out of Pocket Expenses should only be claimed in exceptional circumstances where items were not to be frequently supplied, and the pharmacy has taken all reasonable step to avoid claiming. If additional expenses were necessary obtaining necessary eligible drugs, appliances or chemical reagents, as per Part II, clause 12 of the Drug Tariff | NHSBSA.

4.1.5 Part II, Clause 12 of the Drug Tariff sets out the 3 conditions which must be met when submitting a claim for OOPE:

4.1.6 *'Where, in exceptional circumstances, out-of-pocket expenses have been incurred in obtaining a drug, appliance or chemical reagent other than those priced in Part VIIIA Category A and M, Part VIIIB, Part IXA, Part IXR of the Tariff and all other specials and products not listed and not required to be frequently supplied by the contractor, or where out-of-pocket expenses have been incurred in obtaining from a manufacturer, wholesaler or supplier specially for supply against a prescription, where such expenses on any occasion exceed 50p payment of the full amount may be made where the contractor sends a claim giving particulars to the Pricing Authority on the appropriate prescription form. The endorsement shall be 'XP' or 'OOP' to indicate that the contractor has taken all reasonable steps to avoid claiming.'*

4.1.7 Only certain products are eligible for a OOPE claim and are as follows:

4.1.7.1 Part VIIIA Category C

4.1.7.2 Readily available medicinal products outside of Part VIIIA (including ACBS)

4.1.7.3 Part IXB

4.1.7.4 Part IXC

4.1.8 Only actual costs incurred during the process of obtaining specific items to fulfil specific prescriptions can be claimed. These costs can cover things such as:

4.1.8.1 Postage and Packaging

4.1.8.2 Handling

4.1.8.3 Cost of phone calls to manufacturers or suppliers to order products

4.1.9 It is important that any charges incurred can be linked back to an order for a specific product on a specific prescription by the pharmacy claiming OOPE. VAT can be included in an OOPE claim as long as the normal criteria for claiming expenses are met i.e. VAT can be claimed on expenses incurred in obtaining that product and not on the cost of the product.

4.1.10 **February 2019 to January 2021 OOPE PPV**

4.1.11 NHSBSA Pharmaceutical Provider Assurance Team (NHSBSA PAT), on behalf of NHSE, were requested to conduct a Post Payment Verification (PPV) exercise to ensure that pharmacy contractors were claiming correctly for OOPE. The assurance activity was initiated in response to cases raised by various Integrated Care Boards (ICB's) that resulted in contractors having money recovered for over-claiming for OOPE following determinations made by NHS Resolution.

4.1.12 The Counter Fraud Authority (CFA) raised concerns around how the allowance was being claimed by a small number of pharmacy contractors following these high profiles cases, in response, PAT was asked to perform a small-scale pilot engaging with a small number of the highest claimers for OOPE. This pilot resulted in contractors admitting they had not followed the Drug Tariff requirements in claiming OOPE allowances, and therefore a review of other claims and other contractors ensued.

4.1.13 PAT began the assurance activity by reviewing OOPE claims over a two-year period, from February 2019 to January 2021. To define and limit the scope of the engagement, PAT included contractors in the sample that had claimed more than £10,000 for the service over a 12-month period focusing on the largest claimers of the service. The CFA also requested that a number of additional pharmacies be included too, due to concerns around their claims. With this stipulation in place, PAT had three separate samples for the proposed assurance activity:

4.1.13.1 Contractors with claims over £10,000 in both years were reviewed over a 24-month period February 2019 to January 2021 (referenced as Sample One)

4.1.13.2 Contractors with claims over £10,000 over a 12-month period from February 2019 to January 2020 (referenced as Sample Two)

4.1.13.3 Contractors with claims over £10,000 from February 2020 to January 2021 (referenced as Sample Three).

4.1.14 Daya Ltd pharmacy was included in Sample One, which ran from February 2019 to January 2021, since its total OOPE claims for 2019–2020 amounted to £12,207.11, and for 2020–2021, the total was £16,721.38.

4.1.15 The approach taken for this assurance activity was, in the first instance, to request contractors perform a self-review of the relevant OOPE claims and the items they had claimed against and ask for confirmation and evidence that the claims were meeting the conditions outlined in the Drug Tariff focusing on the three cumulative conditions necessary:

4.1.15.11. Claims were made only in 'exceptional circumstances'

4.1.15.22. Claims were made only where the item was not required to be frequently supplied

4.1.15.33. The contractor took all reasonable steps to avoid claiming OOPE

4.1.16 NHSE and PAT understood that these 3 conditions were cumulative conditions and that each needed to be met for an OOPE to be considered valid. However, NHSE and PAT also recognised that the 3 conditions were not quantified and were therefore subject to individual circumstances for each pharmacy. This therefore required contractor engagement in the assurance activity with an opportunity for them to provide information and detail in support of their submitted OOPE claims.

4.1.17 The response to PAT's initial engagement around self-reviews was mixed and it was ignored by some contractors included in the sampling. Therefore, PAT took the findings away and several working groups were convened between the PAT, NHSE and CFA to outline an approach for assurance activity on OOPE that would provide a fair, consistent and national approach. A key part of the revised approach was that PAT would highlight claims of OOPE that, upon review of the data, would suggest were failing to meet the conditions outlined in the Drug Tariff. The expectation was that contractors would then need to share the evidence and individual circumstances that showed these claims were meeting the Drug Tariff conditions and if this wasn't the case, then the recommendation would be to the ICB's that the contractors had claimed incorrectly for OOPE.

4.1.18 As part of the proposed re-engagement, it was decided that the PAT would also show a recommended recovery value for any items which fell into the below categories, as the data did not suggest that the items warranted the OOPE claims; these were:

4.1.18.1 **Frequently supplied items** – includes any items which were claimed by the pharmacy on more than 12 occasions in the 12 months reviewed. Any items which fell into this category would be entitled to the first 12 claims, however, it would be recommended that any claims in addition to the initial 12 would be recovered. These items appear to have been supplied frequently throughout the year.

4.1.18.2 **100% of the National claims for an item** – includes any items in which the contractor was the only pharmacy nationally to submit an OOPE claim for an item. It was also considered how many pharmacies

had dispensed the item without an OOPE claim, and the number of occasions it had been dispensed nationally without an OOPE claim. Therefore, a minimum of 500 pharmacies must have dispensed the item on a minimum of 12,000 occasions nationally, before any 100% claims would be considered in a recommendation for recovery.

4.1.18.3 **Commonly dispensed items** – includes any items which NHSE considered to be extremely common items, therefore the pharmacy should not have encountered any additional fees when obtaining the item. As a minimum, these items were required to have been dispensed by 10,000 pharmacies, on a minimum of 2.5 million occasions nationally for the item to have been considered commonly dispensed.

4.1.19 If any pharmacies highlighted any claims that had been incorrectly claimed in their initial self review, then these were also included in PAT's recommended recovery value. The PAT provided Daya Ltd Pharmacy with an overview, containing all the pharmacy's claiming data alongside national claiming data for the sample period under review.

4.1.20 Once this was agreed upon, a further phase of engagement with contractors was started, which explains why two separate timelines are provided for these cases, as well as the gap between engagements. The first phase of engagement began in November 2021 and ended in April 2022, and the second phase lasting from July 2023 to July 2024. The goal of the engagement was for the contractor to show that they had evidence to support their claims or agreed to the proposed recovery; if neither was achieved, the case details would be passed to the NHSE regional team for review by their Pharmacy Services Regulations Committee (PSRC) for a final decision on whether the claims met the Drug Tariff conditions, and if not to recover the overpayments from the contractor.

4.1.21 **Daya Ltd Pharmacy**

4.1.22 All listed pharmacies must have a valid shared NHSmail account that should be regularly monitored by the pharmacy team as part of their terms of service. Therefore, emails were sent to the pharmacy's shared NHS mail address (pharmacy.fkv67@nhs.net) as required by NHSE.

4.1.23 The PAT issued the first correspondence on the 10th of November 2021, requiring Daya Ltd pharmacy to review all the pharmacy's OOPE records from February 2019 to January 2021, with a deadline of the 31st of January 2022, to complete this review. Daya Ltd pharmacy responded on the 31st of January 2022, with a completed review indicating that all their OOPE records for the period in question met all three OOPE obligations outlined in the Drug Tariff, but provided no explanation or supporting evidence for how the claims met these conditions.

4.1.24 PAT assessed Daya Ltd pharmacy's OOPE self-review appendix and in response requested additional information on the following points:

4.1.24.1 The options explored by the pharmacy to source items without additional charges

4.1.24.2 The exceptional circumstances of these items

4.1.24.3 Frequent claims on some of the items, the highest being 164 OOPE claims for one item

4.1.24.4 Nutritional items – could these have been obtained through their mainline wholesaler?

4.1.24.5 The companies used when additional charges were incurred

4.1.25 Daya Ltd pharmacy did not respond in relation to these questions, and PAT contacted the pharmacy to inform them that the findings of PAT's assurance activity will be shared with NHSE before deciding upon next steps.

4.1.26 During the second phase of engagement, Daya Ltd pharmacy was contacted six more times to request evidence and allow them to detail the circumstances that existed within the pharmacy to demonstrate that their OOPE claims met the cumulative conditions outlined in the Drug Tariff.

4.1.27 In a phone conversation to Daya Ltd pharmacy on the 31st July 2023, PAT instructed the pharmacy to respond to the email requesting evidence that the OOPE claims met the three conditions outlined in the Drug Tariff. Daya Ltd pharmacy verified receipt of the email and was in the process of replying; however, due to the passage of time since the initial phase of engagement, the pharmacy's ownership had changed, and some of the claims under review were made by a different owner. PAT advised the deadline to respond was the 8th of August 2023, and to include as much detail as possible in their response.

4.1.28 The deadline passed, and on the 16th of August 2023, PAT sent a follow-up email to Daya Ltd pharmacy requesting a response to the original email and extending the deadline to the 30th of August 2023. Daya Ltd pharmacy responded by email stating that they had purchased the pharmacy in November 2019, and as a result, some of the claims under review were made by the previous owner during the transition period. Due to these circumstances Daya Ltd pharmacy wanted to consult the former proprietor to acquire their input and access any additional information that may be necessary for the review process. Daya Ltd pharmacy requested an extension of an additional 90 days to allow them sufficient time to contact previous owner and gather the required information to provide a comprehensive and accurate response to the OOPE PPV inquiry. PAT accepted the request to extend the deadline and allowed the pharmacy until the 29th of November 2023, to provide any relevant information and evidence. After the requested deadline extension had passed without Daya Ltd pharmacy replying, PAT issued a follow-up email on the 13th of December 2023, requesting that the pharmacy give any information and/or evidence they would like to be assessed as part of the OOPE PPV exercise.

4.1.29 Upon reviewing the limited information provided by Daya Ltd pharmacy alongside their own, and national OOPE claim data, the PAT determined that 6 items (320 claim occasions) were all claimed on more than 24 occasions over the 24 months reviewed. The PAT did not receive any evidence or information that these claims were not required to be frequently supplied, nor that they were claimed under exceptional circumstances. Therefore, after allowing the first 24 occasions of these claims for each item, the PAT concluded that the contractor had received an overpayment of £11,420.84 and that the overpayment for these items should be reclaimed. Regardless of PAT's attempts to communicate with Daya Ltd pharmacy, the pharmacy did not respond to any of PAT's requests for information until after the PAT had

sent confirmation of the conclusion of the review with the final recommended recovery figure of £11,420.84.

4.1.30 This notification was sent on the 26th of June 2024, giving the pharmacy 28 days (24th of July 2024) to respond with any evidence or representations that they wished to provide to PSRC for consideration. This notification also included a Data Overview explaining which claims PAT did not agree met the three conditions for claiming OOPE and showed that all of the items in question fell into the category of 'frequently supplied items'.

4.1.31 On the 15th of July 2024, Daya Ltd pharmacy responded, reiterating the challenges due to time elapsed since the claims under review were submitted, and that the claims were made prior to them taking over ownership of the pharmacy. This is contradicting previous correspondence from Daya Ltd on the 16th August 2023, which stated they took over the pharmacy in November 2019, implying that 8 months of the claims were before their ownership, rather than all the claims under review in the 24-month sample period. Daya Ltd pharmacy went on to advise "We have sent you previously all the data you requested and that we was able to gather" - this is not entirely accurate as in the first phase of engagement, PAT asked specific questions in relation to the case and received no response, and in the second phase of engagement, PAT asked again to review the claims, which Daya Ltd requested an extension to the deadline to complete but didn't respond within that deadline and only replied with this response after the PAT's final recommended recovery figure notification was sent. Daya Ltd originally submitted an appendix indicating that all the claims met the conditions however there was no reasoning or evidence provided to substantiate these claims.

4.1.32 While providing their additional information for PSRC to review, Daya Ltd continued with a quote from the former owner, who handled some of the claims under review at the beginning of the sample period:

4.1.33 "There has been systems in place and SOP's have been followed, where reasonable steps was taken when placing these orders. From what I can recall, there were extreme shortages of a lot of drugs and Nursing home nurses, managers, and relatives of residents in these homes were putting extreme pressures on the pharmacy to get these medicines to them as soon as possible. Consequently when efficient suppliers were found they were been used on a regular basis [sic]. The most Important thing being supplying the medicines effectively and efficiently. Every specials supplied and oops expense claimed have the appropriate paperwork and on no occasion has anything been claimed without the appropriate paperwork. Moreover, the doctors have been prescribing the specials and I can only say that it is such a large amount because of the sheer volume of items being prescribed by the doctors."

4.1.34 The former owner's comment is of a general nature and do not substantiate the claims under consideration with any evidence or specific information. PAT appreciates that time has passed and that recalling details at this point may be difficult, but the OOPE PPV exercise began within the same year of the final claims under review, and there have been multiple opportunities for the pharmacy to respond throughout the PPV process.

4.1.35 Despite this contact from the contractor, Daya Ltd still did not provide any specific evidence to demonstrate that the 320 claims highlighted in the provided data overview met the conditions outlined in the Drug Tariff.

Therefore, the PAT were unable to provide assurance that the claims were made in accordance with the conditions specified in the Drug Tariff.

4.1.36 For the avoidance of doubt, NHSE and the PAT recognises that OOPE claims are difficult to quantify and are open to the individual circumstances of each pharmacy. However, the information provided by Daya Ltd was limited and did not prove how the claims were meeting the cumulative conditions required before an OOPE claim should be considered.

4.1.37 As a result, PAT were unable to validate the claims for the OOPE claimed by Daya Ltd during the designated sample period. Therefore, a recommended recovery of £11,420.84 for these 320 claims (6 items) was proposed to the contractor. As Daya Ltd did not accept the proposed recovery, the details of the case were passed to the NHSE regional team for their PSRC to review. A decision was sought as to whether the claims made by the contractor were eligible for a payment under the conditions of the Drug Tariff or whether they felt the 320 claims did not meet the cumulative conditions and therefore should be recovered under regulation 94-(1)-(a) as an overpayment.

4.1.38 **PSRC decision**

4.1.39 To assist with their review, the PSRC was provided with the dispensing and claim data, along with the timelines of correspondence showing all contact PAT had with Daya Ltd. These documents have been provided to you in addition to this response.

4.1.40 The engagement showed that despite repeated requests by PAT, Daya Ltd was unable to provide assurance and therefore PAT were unable to determine the OOPE claims met all three cumulative conditions required for an OOPE claim as part of the assurance activity.

4.1.41 Consequently, the PSRC concluded that PAT had been unable to find any evidence to demonstrate that the 320 claims claimed by Daya Ltd between February 2019 and January 2021 met the requirements set out in the drug tariff for claiming OOPE.

4.1.42 Following this conclusion, the PSRC determined that Daya Ltd was not entitled to the payment which it had received.

4.1.43 Having made this decision, the PSRC then directed that as Daya Ltd was not entitled to the payment, the overpayment should be reclaimed pursuant to Regulation 94-(1) -(a) of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.

4.1.44 In making this decision the PSRC relied on the information that they had before them, following the extensive investigation undertaken by the PAT and the repeated requests to Daya Ltd for evidence of how the OOPE claims made between February 2019 and January 2021 met the requirements set out in the Drug Tariff.

4.1.45 **Response to the points made in the contractor's appeal**

4.1.46 The Drug Tariff requirements for an eligible claim is detailed in the background section of this representation.

4.1.47 Each of the points in bold are prerequisites that must be met for a claim to be considered before OOPE submission. For the 320 claims highlighted in PAT's recommended recovery, Daya Ltd have not provided any evidence to support that these conditions were met prior to submitting the claims.

4.1.48 In their appeal Daya Ltd stated "I could not see attachment of those 320 claims that 'concluded that there was not sufficient evidence received'." This was highlighted in the data overview document provided by PAT in an email sent to Daya Ltd on the 26th of June 2024 which Daya Ltd responded to with their final representations they'd like to be considered by PSRC.

4.1.49 Daya Ltd go on to state that "due to the time lapsed since claims was done and that fact claims done prior us taking over Daya makes this case harder for us." As already mentioned, this contradicts previous email from Daya Ltd dated the 16th of August 2023, which indicated that they took over the pharmacy in November 2019, meaning that 8 months of claims were prior to their ownership, rather than all claims under review over the 24-month sample period. Also, when changing ownership of the pharmacy and keeping the same ODS code, as new owners, they would still be responsible for all debts and liabilities, and therefore responsible for the OOPE claims made prior to them taking over Daya Ltd.

4.1.50 This information is clearly outlined on the application form that is required to be completed as part of a change of ownership. So, if Daya Ltd completed the change of ownership process, they should have been aware on what basis they were taking over the pharmacy, as they would have to declare that on making the application. Alongside the application form there is further information in the NHS England Pharmacy Manual:

4.1.50.1 *"Allocation of organisation data service codes*

4.1.50.2 *The following information sets out NHS England's policy in relation to the allocation of organisation data service codes (also known as ODS or F codes).*

4.1.50.3 *Buying a retail pharmacy business or DAC business on a debts and liabilities basis means that the electronic prescription nominations do not need to be transferred to a new code. However, it also means that the new owner of the pharmacy or DAC premises will be liable for any monies owed to the commissioner by the previous owner. Applicants should therefore seek their own professional advice before submitting an application that involves a change of ownership."*

4.1.51 In their appeal, Daya Ltd contests the decision taken to recover claims that lacked sufficient evidence to meet the Drug Tariff requirements for OOPE and asked for clarification, *"We seek clarification on the specific criteria that the NHSBSA PAT used to assess whether claims met the Drug Tariff conditions. As the Drug Tariff does not always specify in granular detail what constitutes 'reasonable' supporting evidence, there may be room for interpretation.".* As previously stated in this appeal representation, the proposed re-engagement following various working groups created by the PAT, NHSE, and CFA was to provide a fair, consistent and national approach for the OOPE assurance activity. A crucial component of the approach was that PAT would identify OOPE claims that, based on data analysis, appeared to fail to meet the standards established in the Drug Tariff. The expectation was that contractors would then provide the evidence and specific circumstances that demonstrated

that these claims met the Drug Tariff criteria; if this was not the case, a recommendation would be forwarded to the ICBs PSRC that an overpayment had been received and that the overpayment should be recovered.

4.1.52 For the avoidance of doubt, NHSE and PAT recognises that OOPE claims are difficult to quantify and are subject to the unique circumstances of each pharmacy, but the information provided by Daya Ltd did not demonstrate how the claims met the cumulative conditions required before an OOPE claim should be considered.

4.1.53 As detailed in the background section of this document, The PAT used the following criteria in its data analysis:

4.1.53.1Frequently supplied

4.1.53.2100% of the National claims for an item

4.1.53.3Commonly dispensed items

4.1.54 This criterion was detailed in the data overview and summary documents sent to the contractor on 26th June 2024, along with the recommended recovery value.

4.1.55 **Table 1** (excerpt from PAT Data Overview for FKV67 – Daya Ltd pharmacy)

Product (FKV67 - Made at least one OOPE claim within the 24 month period)	**FKV67 Dispensed occasion Total (19-21)**	**FKV67 Claim Occasion Total (19-21)**	**Months Dispensed in FKV67**	**Months Claimed in by FKV67**
Ensure Compact Liquid (4 flavours)	239	164	24	24
Ensure Plus Milkshake Style Liquid (9 flavours)	157	131	24	24
Aymes Shake powder 57g sachets vanilla	163	86	24	20
Ensure TwoCal liquid (4 flavours)	39	29	24	20
Thick & Easy Original powder	51	27	20	17
Juvela gluten free mix	33	27	21	18

4.1.56 *Table 1* is an excerpt from FKV67's data overview highlighting the 6 items (320 claims) which PAT identified did not appear to meet the conditions for claiming OOPE in the Drug Tariff, along with the data used to reach that decision. All 320 claims fell into the category of *frequently supplied items* (highlighted in yellow) as these items were required routinely over multiple months. For example, Ensure Compact liquid (4 flavours), FKV67 claimed OOPE on this

item on a total of 164 occasions over the 24- month sample period and was dispensed on 239 occasions; the item was claimed by FKV67 in all of the 24 months sampled. This data confirms that the item was required to be frequently supplied.

4.1.57 The data also demonstrates that the pharmacy was able to obtain the item without resorting to OOPE on some occasions but also that the pharmacy had a consistent claiming behaviour resorting to claiming OOPE on the item. No information provided by Daya Ltd allowed PAT (and therefore NHSE or the ICB) to understand the conditions behind these OOPE claims. PAT would also question what the pharmacy did to avoid claiming OOPE on the item if they continued to claim OOPE on it in every month. PAT also question how the claims meet the other cumulative conditions of not being frequently supplied and being claimed only in exceptional circumstances as, again, nothing in the response from Daya Ltd allows the PAT to understand the reasoning behind those claims and how they were adhering the Drug Tariff conditions.

4.1.58 It can be seen from the data that the pharmacy required stocks of Ensure Compact Liquid (4 flavours) on a regular basis in each and all the 24 months and could have avoided the extra charges from this supplier by ordering larger amounts, at less frequent intervals.

4.1.59 **Table 2** (excerpt from PAT Data Overview for FKV67 – Daya Ltd pharmacy)

Product (FKV67 - Made at least one OOPE claim within the 24 month period)	**Product (FKV67 - Made at least one OOPE claim within the 24 month period)**	**Product (FKV67 - Made at least one OOPE claim within the 24 month period)**	**Product (FKV67 - Made at least one OOPE claim within the 24 month period)**	**Product (FKV67 - Made at least one OOPE claim within the 24 month period)**	**Product (FKV67 - Made at least one OOPE claim within the 24 month period)**
Ensure Compact liquid (4 flavours)	1019	60	16.09%	455592	15364
Ensure Plus milkshake style liquid (9 flavours)	1439	64	9.10%	628489	15657
Aymes Shake powder 57g sachets vanilla	160	19	53.75%	76935	8993
Ensure TwoCal liquid (4 flavours)	260	30	11.15%	72137	5666
Thick & Easy Original powder	147	24	18.37%	122061	9017
Juvela gluten free mix	366	53	7.38%	78074	Data not available

4.1.60 In their appeal, Daya Ltd state *"We understand from previous owner and pharmacist at the time that there was extreme shortages of a lot drugs"* and the pharmacy was under pressure to get the medicines quickly to patients. As shown in Table 2, Ensure Compact liquid (4 flavours) was routinely dispensed

across the nation by other contractors (National dispensed occasion total = 455,592, National claim occasion total = 1019) without the need for the OOPE endorsement, and that FKV67 accounted for a significant portion, 16.09%, of the national OOPE claims for the item. The other 5 items highlighted follow a similar claiming pattern to the Ensure Compact Liquid data trend, in that they are regularly claimed for over multiple months and the items are widely dispensed nationally without the need for OOPE.

4.1.61 Throughout this PPV exercise, Daya Ltd's correspondence frequently relied upon obtaining the previous owner's recollections and reasonings, which often delayed responses while they sought the information. The current owners took over the pharmacy in November 2019 which shows they were responsible for a larger portion of the OOPE claims submitted in the sample period in question but have provided no reasonings or evidence for the claims themselves.

4.1.62 PAT also contends that Daya Ltd.'s comment "at that time there was extreme shortages of a lot of drugs" is ambiguous and does not refer to a specific period. Nor does the national data support that there were any shortages for these items.

4.1.63 If Daya Ltd are stating that they had extreme shortages for the entire two years of the sample, PAT would argue that this is a very broad statement, and Daya Ltd's assertion that this would be sufficient reasoning for their OOPE claims over a sustained period of time without more specific details is questionable. Daya Ltd has not provided PAT with any evidence to back up their claims.

4.1.64 Daya Ltd go on to request in their appeal "a detailed breakdown of which specific claims lacked evidence and in what respect" and state "It is noted that NHSBSA PAT stated there was 'not sufficient evidence received'. However, we have attempted submissions of documentation for claims during the review period." The expectation was that contractors would share the evidence and individual circumstances that showed these claims were meeting the Drug Tariff conditions. For example, specific evidence that shows there was "extreme shortages" of medicines at the time to illustrate their circumstances. According to PAT's timelines of correspondence with Daya Ltd, they only provided their initial self-review appendix documentation on the 31st of January 2022, stating all claims met the three conditions set out in the Drug Tariff. The only other significant response from Daya Ltd came on 15th of July 2024 where they gave a generic response to why the claims were made without much detail or evidence for PAT to conclude they had followed the Drug Tariff requirements when claiming OOPE.

4.1.65 The PAT have been clear in their requests and detailed all the relevant information in the email sent to the pharmacy on 26th June 2024. Attached to this email was a data overview, a summary of the review and two timelines of all the correspondence with the pharmacy and PAT. All of these documents detailed which of the claims required further explanation, as well as how the PAT had reached their conclusion and recommended recovery figure for items which appeared did not meet the conditions of the Drug Tariff.

4.1.66 Daya Ltd state that "The proposed recovery amount represents a substantial deduction and could have significant financial implications" PAT recognises that this is a challenging time for pharmacies, but this should not be deemed as valid grounds for a contractor to ignore the provisions of Part II, clause 12 of the Drug Tariff when filing claims for OOPE. All conditions must be met to

make a OOPE claim. Daya Ltd appear to have been habitually claiming for items regularly without following the requirements set out in the Drug Tariff.

4.1.67 The eligibility criteria for OOPE claims laid out in the Drug Tariff are there to support contractors who incur costs on an exceptional basis when providing medications to their patients. It also ensures to protect the NHS and ultimately the taxpayer by imposing requirements on the contractor to take steps to avoid claiming OOPE. It is therefore entirely reasonable that the NHS would then expect the contractor to take reasonable steps to limit the costs of obtaining the medications and to limit the costs it passed onto the NHS. Clearly other contractors in similar situations have been able to do this.

4.1.68 PAT concluded that the limited information provided by Daya Ltd does not warrant the volume of OOPE claims and in fact demonstrates that the conditions set out in the Drug Tariff have not been met, as also agreed upon in the PSRC decision.

4.1.69 As a result, without specific evidence explaining individual circumstances for multiple consistent OOPE claims rather than general explanations, PAT have been unable to provide assurance that Daya Ltd followed the requirements outlined in the Drug Tariff and that the claims discussed met the cumulative conditions listed in the Drug Tariff.

4.1.70 The final recovery figure is made up from items which were identified by PAT as failing to meet the conditions within the Drug Tariff.

Product	**Recommended Recovery Total**
Ensure Compact liquid (4 flavours)	£5,018.66
Ensure Plus milkshake style liquid (9 flavours)	£3,844.65
Aymes Shake powder 57g sachets vanilla	£2,152.70
Ensure TwoCal liquid (4 flavours)	£193.45
Thick & Easy Original powder	£103.89
Juvela gluten free mix	£107.50
Total of PSRC Recovery	**£11,420.84**

4.1.71 NHSE and PAT maintain that Daya Ltd did not demonstrate that they had complied with the Drug Tariff conditions, and that the claims made for the OOPE endorsement on the 6 items (320 claims) highlighted did not meet the cumulative conditions indicated as prerequisites for the endorsement. As a result of receiving payment for these excess claims, an overpayment was made. NHSE and PAT believe the contractor has not provided sufficient evidence to support that the claims for the 6 items (320 claims) highlighted met the conditions outlined in the Drug tariff, so the decision to recover £11,420.84 is correct, which was also upheld by PSRC.

4.1.72 **Key points for consideration**

4.1.73 NHS England and PAT respectfully asks that NHS Resolution considers the following key points when making its determination on the appeal:

4.1.74 The requirements outlined in Part II; Clause 12 of the Drug Tariff stipulate that the following three cumulative conditions must be completed before claiming for the OOPE service:

4.1.74.1 Claims were made only in 'exceptional circumstances'.

4.1.74.2 Claims were made only where the item is not required to be frequently supplied.

4.1.74.3 The contractor took all reasonable steps to avoid claiming for OOPE.

4.1.75 The contractor had numerous opportunities to provide assurance that all OOPE claims made during the PPV sample period met the cumulative conditions set out in the Drug Tariff. Only contractors where no or insufficient evidence of meeting the requirements were referred to the PSRC for their ICB. Daya Ltd did not provide any evidence to show how the three conditions were met. Consequently, the PAT were unable to assure NHS England that the claims identified as overclaims met the Drug Tariff requirements.

4.1.76 The initial engagement for the OOPE PPV exercise began within the year of the start of the sample period under consideration. The contractors' assertion about challenges to respond in detail due to the vast amount of time that had passed since the sample period are not accurate. They had numerous opportunities to respond, yet engagement from the contractor was infrequent and often delayed.

4.1.77 The NHSBSA data does not corroborate the contractor's statement about supply concerns; there was no notable increase in OOPE claims nationally for the six disputed items over the sample period.

4.1.78 The PSRC was presented with all timelines of correspondence, showing all contact between the NHSBSA PAT and Daya Ltd, and the relevant data that the NHSBSA PAT has on contractors' dispensing and claiming histories nationally in relation to OOPE.

4.1.79 The PSRC considered all of the information provided about the case by the PAT when determining the overpayment under regulation 94.

4.1.80 The contractors' appeal provides no specific details or evidence on what measures they took to ensure that their claiming of OOPE on a regular basis over the sample period was in line with the Drug Tariff. As a result, the OOPE claims are invalid under Part II, Clause 12 of the Drug Tariff, and an overpayment has been made.

4.1.81 Having considered these matters PAT and NHS England respectfully suggests that NHS Resolution conclude that the decision made by the PSRC in respect of the £11,420.84 overpayment and its subsequent recovery from Daya Ltd was fair and in accordance with the regulations.

4.1.82 Please let me know if you require any further information to help with these deliberations."

4.1.83 [Two timelines of correspondence between the NHS BSA and the Appellant and a data overview spreadsheet were enclosed].

5 OBSERVATIONS

The following late observations were received by NHS Resolution in response to the representations received on appeal.

5.1 Daya Ltd (FKV67)

5.1.1 "I am writing to formally challenge the decision regarding the overpayment of out-of-pocket expenses. This claim was made under exceptional circumstances and is not a frequent occurrence. Based on the number of items Daya Pharmacy dispenses the number reflected are over longer period. The Following items highlighted are usually prescribed in larger quantities, in order to ensure medication delivered to nursing homes and care homes for vulnerable patients these where [sic] order to reliable supplies that could ensure medication delivered with promised time frames to avoid delay of medication supply to those vulnerable patients.

5.1.2 I would like to emphasize that reasonable steps were taken in accordance with the SOPs to ensure compliance. The circumstances necessitated immediate action, which aligned with professional judgment to safeguard patient care. While I understand the importance of adhering to financial guidelines, I believe this instance falls within acceptable parameters due to its unique nature.

5.1.3 I kindly request the committee to reconsider this matter and review the documentation provided previously, which outlines the efforts made to adhere to standard protocols. As also explained due to time lapsed for when these claims where [sic] made and the fact there has been change of owner ship during that period make is [sic] very challenging to provide much further concrete evidence if requested."

6 CONSIDERATION

6.1 Direction 2 of the Payment Disputes Directions directs me to determine a dispute in respect of the recovery of an overpayment from an NHS pharmacist under Regulation 94(1) of the NHS (Pharmaceutical and Local Pharmaceutical Services Regulations) 2013 (the "Regulations") which is in the nature of an appeal against a decision of NHS England that there has been an overpayment.

6.2 Direction 4 of the Payment Disputes Directions requires me to determine the appeal by dismissing it if:

6.2.1 NHS England has advised that an appeal must be brought within 30 days of the date the Appellant was notified of NHS England's decision and the appeal was not brought within that timescale; or

6.2.2 I am of the opinion that notification of the appeal contains no valid grounds of appeal (for example because it amounts to a challenge to the legality or reasonableness of the Payment Disputes Directions, the Regulations or the Drug Tariff).

6.3 I consider that I am not required to dismiss the appeal pursuant to Direction 4 as:

6.3.1 the NHS BSA advised the Appellant of a 30 days' timescale for appeal and the appeal was received within that timescale; and

6.3.2 the grounds of the appeal are valid.

6.4 Direction 6 of the Payment Disputes Directions states that I may determine the appeal without hearing any oral representations but if an appellant asks to make oral representations a hearing must be arranged unless I am satisfied that:

6.4.1 a hearing is unnecessary; or

6.4.2 I must dismiss the appeal by virtue of Direction 4.

6.5 The Appellant has not requested a hearing. On the basis of the information before me I have considered that it is unnecessary to hold an oral hearing.

6.6 I have before me the papers considered by the NHS BSA. I also have before me the responses to NHS Resolution's own statutory consultations. I note that the observations received from the Appellant were late and that no explanation for this has been provided, but in the interests of fairness I have considered these albeit they repeat the grounds of appeal and add little of substance.

6.7 I note the NHS BSA reference the Drug Tariff and that it has provided me with a link to the Drug Tariff webpage where back copies of the Drug Tariff through to the current Drug Tariff in place (February 2025) could be found. I further note that the Drug Tariff has not been disputed by the Appellant.

6.8 The appeal relates to payments made to the Appellant in respect of claims for Out of Pocket Expenses ("OOPE"). The NHS BSA states that *"An Out of Pocket Expenses (OOPE) endorsement enables community pharmacy contractors to claim payment, where in exceptional circumstances, the contractor has incurred expenses in obtaining eligible products and where the product is not required to be frequently supplied by the contractor.*

Out of Pocket Expenses should only be claimed in exceptional circumstances where items were not to be frequently supplied, and the pharmacy has taken all reasonable step to avoid claiming. If additional expenses were necessary obtaining necessary eligible drugs, appliances or chemical reagents, as per Part II, clause 12 of the Drug Tariff."

6.9 The NHS BSA was requested to conduct a Post Payment Verification exercise (PPV) for OOPE following a request from various ICBs. In addition, the Counter Fraud Authority ("CFA") had raised concerns and after a small scale pilot where contractors had admitted that they had not followed the Drug Tariff requirements, it was considered that a review of other claims and other contractors should be carried out. I should add that there is no suggestion from the NHS BSA that the claims subject to this dispute were fraudulent.

6.10 The NHS BSA confirms that they commenced the PPV by reviewing claims over a two year period from February 2019 to January 2021. It is noted that the NHS BSA were conscious of the number of claims and therefore concentrated on those that were the largest claimers of OOPE. It is noted that the CFA were also involved with the PPV exercise and had requested *"that a number of additional pharmacies be included too due to concerns around their claims".*

6.11 As set out above, the NHS BSA split the review into three separate samples for the OOPE PPV exercise:

6.11.1 *"Contractors with claims over £10,000 in both years were reviewed over a 24-month period February 2019 to January 2021 (referenced as Sample One)*

6.11.2 *Contractors with claims over £10,000 over a 12-month period from February 2019 to January 2020 (referenced as Sample Two)*

6.11.3 *Contractors with claims over £10,000 from February 2020 to January 2021 (referenced as Sample Three)."*

6.12 The NHSA BSA states that the Appellant falls into sample one *"Contractors with claims over £10,000 in both years were reviewed over a 24-month period February 2019 to January 2021"* as the total OOPE for the Appellant for this period totalled £12,207.11 for the 2019 to 2020 period and £16,721.38 for the 2020 to 2021 period.

6.13 Initially any contractor identified was asked to complete a self-review of the relevant OOPE claims and was asked to confirm that they had met three cumulative conditions:

6.13.1 *"Claims were made only in 'exceptional circumstances'*

6.13.2 *Claims were made only where the item was not required to be frequently supplied*

6.13.3 *The contractor took all reasonable steps to avoid claiming OOPE"*

6.14 I note, from the comments from the NHS BSA that not all contractors engaged with the initial process, so, following further meetings it was proposed that there would also be a recommended recovery value for any items which fell into three further categories:

6.14.1 *"**Frequently supplied items** – includes any items which were claimed by the pharmacy on more than 12 occasions in the 12 months reviewed. Any items which fell into this category would be entitled to the first 12 claims, however, it would be recommended that any claims in addition to the initial 12 would be recovered. These items appear to have been supplied frequently throughout the year.*

6.14.2 ***100% of the National claims for an item** – includes any items in which the contractor was the only pharmacy nationally to submit an OOPE claim for an item. It was also considered how many pharmacies had dispensed the item without an OOPE claim, and the number of occasions it had been dispensed nationally without an OOPE claim. Therefore, a minimum of 500 pharmacies must have dispensed the item on a minimum of 12,000 occasions nationally, before any 100% claims would be considered in a recommendation for recovery.*

6.14.3 ***Commonly dispensed items** – includes any items which NHSE considered to be extremely common items, therefore the pharmacy should not have encountered any additional fees when obtaining the item. As a minimum, these items were required to have been dispensed by 10,000 pharmacies, on a minimum of 2.5 million occasions nationally for the item to have been considered commonly dispensed."*

6.15 The NHS BSA states that this is why there were two engagement periods, the first being from November 2021 to April 2022 and the second from July 2023 to July 2024.

6.16 It is accepted by both parties that between November 2021 and July 2024 the pharmacy was contacted by the NHS BSA, a total of 12 times, however there was very little engagement from the Appellant during this time.

6.17 It is noted that the Appellant's pharmacy submitted 805 OOPE claims totalling £28,928.49 between February 2019 and January 2021, however it was determined by the NHS England Pharmaceutical Services Regulations Committee ("PSRC") that the overpayment to be recovered was for 320 claims totalling £11,420.84. This is in line with the NHS BSA's "frequently supplied items" category in that they allowed "the first 24 occasions of these claims for each item". The NHSA BSA, after taking the frequently supplied items into account is of the view that the Appellant has received a total overpayment of £11,420.84.

6.18 I note that the period in question is from February 2019 to January 2021, I am therefore of the view that the relevant Drug Tariff is dated February 2019 as this is the Drug Tariff that was in force at the beginning of the period to which the OOPE claims relates.

6.19 I note the comment from the Appellant that *"We seek clarification on the specific criteria that the NHSBSA PAT used to assess whether claims met the Drug Tariff conditions."* The Drug Tariff at Part II "Requirements enabling payments to be made for the supply of drugs, appliances and chemical reagents" Clause 12 with regard to "Out of Pocket Expenses" states:

"Where, in exceptional circumstances, out-of-pocket expenses have been incurred in obtaining a drug, appliance or chemical reagent other than those priced in Part VIIIA Category A and M, Part VIIIB, Part IXA, Part IXR of the Tariff and all other specials and imported products not listed and not required to be frequently supplied by the contractor, or where out-of-pocket expenses have been incurred in obtaining oxygen from a manufacturer, wholesaler or supplier specially for supply against a prescription, where such expenses on any occasion exceed 50p payment of the full amount may be made where the contractor sends a claim giving particulars to the Pricing Authority on the appropriate prescription form. The endorsement shall be 'XP' or 'OOP' to indicate the contractor has taken all reasonable steps to avoid claiming."

6.20 I note that the Appellant claimed for Ensure Compact Liquid (4 flavours) on 164 occasions, Ensure Plus Milkshake Style Liquid (9 flavours) on 131 occasions, Aymes Shake powder 57g sachets vanilla on 86 occasions, Ensure TwoCal liquid (4 flavours) on 29 occasions, Thick & Easy Original powder on 27 occasions and Juvela gluten free mix on 27 occasions ("item 1", "item 2", "item 3", "item 4", "item 5" and "item 6" respectively). I have considered the wording of Part II Clause 12 of the Drug Tariff and consider that the NHS BSA is correct in that it makes clear that for an OOPE claim to be successfully made, there are certain criteria that need to be met:

6.20.1 That there are exceptional circumstances;

6.20.2 That the product is a type of product for which an OOPE claim can be made, with reference to parts and categories of the Drug Tariff;

6.20.3 That the product is not required to be frequently supplied; and

6.20.4 That the contractor has taken all reasonable steps to avoid claiming OOPE.

6.21 I also concur that Part II Clause 12 makes clear that these are cumulative conditions – all must be met in order for a claim for OOPE to be successfully made.

6.22 I note the Appellant's comment that *"As the Drug Tariff does not always specify in granular detail what constitutes "reasonable" supporting evidence, there may be room for interpretation*". I note that there are no definitions for 'exceptional circumstance', 'frequently supplied' or 'take all reasonable steps to avoid claiming' included in the Drug Tariff. They are therefore to be given their everyday meaning. I consider that the use of these unquantified expressions is deliberate by those drafting the Drug Tariff to enable specific circumstances to be considered. If the intent was to give these expressions a quantifiable meaning, this would have been set out. I note that the question being asked of the Appellant was to review their claims and provide evidence to support the claims made for the relevant period. Whilst it is accepted by the NHS BSA that the OOPE can be difficult to quantify due to the criteria as set out in the Drug Tariff, it is noted that, other than the comment in its observations, the Appellant has provided very little information in response to the three relevant criteria.

6.23 I first consider exceptional circumstances.

6.24 I consider that this condition shares some similarity to the "not required to be frequently supplied" condition in that both can be read as relating to the extent to which it is usual for the drug to be supplied. I do consider, however, that "exceptional circumstances" can be read more widely than simply frequency of supply to encompass other circumstances that may make such ordering very unusual. I would consider "exceptional" to indicate that such circumstances are very unusual rather than simply unusual.

6.25 I note the comment from the Appellant that *"We understand from previous owner and pharmacist at time that there was extreme shortages of a lot of drugs and Nursing home nurses, managers, and relatives of residents in these homes were putting extreme pressures on the pharmacy to get these medicines to them ASAP. Consequently, when efficient suppliers were found the* [sic] *were been used on a regular basis"* and *"the doctors have been prescribing the specials and I can only say that it is such a large amount because of the sheer volume of items being prescribed by the doctors".* Whilst I appreciate that the pharmacy may have been under pressure, I need to balance this against any OOPE claims which have been made alongside the application of the Drug Tariff. I further note the comparisons which the NHS BSA have carried out in respect of the Appellant's claiming, compared to the number of claims made by other pharmacies nationally. I note the comments from the NHS BSA regarding the analysis of the data, as set out in the table at 4.1.59 above "Table 2" and note that the Appellant has not provided a response to this.

6.26 In response to the criteria of "exceptional circumstances" it is noted that the Appellant makes reference to ongoing supply issues requiring medications to be sourced from alternative suppliers. However, I consider that if circumstances continue for a prolonged period of time, then this would cease to be exceptional, as this would become the norm. I consider that any event that continues for three years would require a level of evidence to support it being very unusual.

6.27 Consequently, I consider that it is reasonable to consider that the Appellant has not met the "exceptional circumstances" condition.

6.28 I have also not been provided with any information from the Appellant to rebut the NHS BSA's assertion that the product in question was "not required to be frequently supplied". The NHS BSA has provided information confirming the frequency of supply and the Appellant has not provided any response to this either on appeal or in subsequent representations. In Table 1 the NHS BSA indicate that item 1 and item 2 were claimed, at least once, every month, for 24 months. I consider that 164 and 131 claims respectively, across 24 months, with at least one being claimed each month,

must be considered frequent. For the other items, I also note the high number of months these items were claimed. These patterns, across three years, I consider must mean that it was being frequently supplied.

6.29 Finally, I note the third part of the claim for OOPE states “the contractor has taken all reasonable steps to avoid claiming”. The use of "reasonable" to qualify the steps to be taken means the Appellant is not required to do everything it possibly can to avoid claiming OOPE. It does, however, mean that certain steps need to be taken. It will be always be difficult to quantify exactly the extent to which a party must act to evidence taking reasonable steps. I note that apart from reference to the supply chain issues and the urgency to supply the items, I have not been provided with any information as to the steps that the Appellant went to in order to avoid claiming.

6.30 Regarding this supply chain issue and urgency to supply point, I also note the NHS BSA's data regarding other pharmacies. I consider that if there were supply chain issues or a real urgency to supply these items, then these should have been felt elsewhere as well. Looking at each item in turn, the NHS BSA indicates that during the period in question 60 pharmacies nationally claimed for item 1, 64 for item 2, 19 for item 3, 30 for item 4, 24 for item 5 and 53 for item 6. However, the Appellant made up 16.9%, 9.1%, 53.75%, 11.15%, 18.37% and 7.38% of these claims respectively. Whilst it is possible that the Appellant had a noteworthy number of patients requiring these items, these numbers suggest that it was a significant outlier. This would either suggest that the supply chain/urgency issues were less impactful than the Appellant suggests, or that, if they were, then other pharmacies found solutions. Accepting the Appellant's statements on that matter, that there were significant issues, then I must conclude that not every reasonable step was being taken, as other pharmacies were able to resolve the issues and make less claims.

6.31 Further to this, I note that the NHS BSA's data indicates that on at least ten occasions all items were dispensed without an OOPE claim. In particular, I note that item 1 was dispensed 75 times without an OOPE claim. I note the NHS BSA's comments that it could have bulk ordered the items as an OOPE claim so as to reduce costs and further the unclear reasoning as to why some items were claimed as an OOPE and some were not. I note that the Appellant has not provided an explanation for this. I further note the NHS BSA’s question regarding the nutritional items and whether these could have been obtained through the Appellant’s mainline wholesaler. I note the Appellant has not responded to this. I therefore consider this suggestive that all reasonable steps have not been taken to avoid claiming.

6.32 I consider that the Drug Tariff makes clear that the criteria are cumulative - all of the criteria need to be fulfilled and information relating to all three parts needs to be provided in order for a claim to be successfully made. It is not sufficient to claim exceptional circumstances without also providing information regarding the frequency of the supply and how all reasonable steps have been taken to avoid claiming.

6.33 The Appellant, whilst not disputing the Drug Tariff or the amounts that the NHS BSA has determined was overpaid by it, has repeatedly claimed that there are mitigating circumstances that should be considered. This is due to the fact that they allege a change of ownership has taken place.

6.34 I have had regard to the following comments made by the Appellant regarding ownership:

6.34.1 *“we purchased the pharmacy in November 2019”*

6.34.2 *“We understand from previous owner and pharmacist at time that there was…”*

6.34.3 *"the fact there has been change of owner ship during that period make is very challenging to provide much further concrete evidence if requested".*

6.35 The NHS BSA, in response, made a number of comments [see points 4.1.49 to 4.1.50.3 above] regarding ownership of the pharmacy. From these I have noted:

6.35.1 A link to the Chapter 19, Annex 1, Application form 'Application in respect of a change or ownership', which includes the following questions:

6.35.1.1 Please can you confirm whether you are buying the pharmacy business on a:

6.35.1.2 Non debts and liabilities basis Yes? No?

6.35.1.3 Debts and liabilities basis, with or without access to the existing bank account Yes? No?

6.35.2 A quote from the NHS England Pharmacy Manual:

6.35.2.1 *"Allocation of organisation data service codes*

6.35.2.2 *The following information sets out NHS England's policy in relation to the allocation of organisation data service codes (also known as ODS or F codes).*

6.35.2.3 *Buying a retail pharmacy business or DAC business on a debts and liabilities basis means that the electronic prescription nominations do not need to be transferred to a new code. However, it also means that the new owner of the pharmacy or DAC premises will be liable for any monies owed to the commissioner by the previous owner. Applicants should therefore seek their own professional advice before submitting an application that involves a change of ownership. "*

6.35.3 The following comment:

6.35.3.1 *"Also, when changing ownership of the pharmacy and keeping the same ODS code, as new owners, they would still be responsible for all debts and liabilities, and therefore responsible for the OOPE claims made prior to them taking over Daya Ltd."*

6.36 I note the NHS BSA indicates that the ODS code for Daya Ltd has not changed nor has the name of the pharmacy. I note that the Appellant has not responded to this point nor has it provided any further information in respect of the change of ownership. Without evidence to the contrary, I consider that the ODS code and the Appellant are the same and therefore, the Appellant is required to make any necessary repayments in relation to the OOPE.

6.37 Further, I am mindful that the NHS BSA initially contacted the Appellant in November 2021. I note from the comment by the Appellant at 6.34.1 that at this point, the Appellant would have owned the pharmacy for two years. I note the NHS BSA has made the same comment to which the Appellant has not responded. I am of the view that the Appellant should have been able to provide the initial information as requested by the NHS BSA at this time for the period of December 2019 to January 2021 at least. I also note that the NHS BSA provided a 90 day extension to allow the Appellant to gather the required information from the former owner which resulted in no response being provided.

6.38 I note the comments from the Appellant with regard to the length of time that has passed since the OOPE for the period February 2019 to January 2021. I am of the view that the Appellant was aware, from November 2021 onwards, that they were subject to a PPV and therefore the Appellant should have retained any further information that it had with regard to the OOPE for those drugs.

6.39 I note the comments from the Appellant in its appeal in relation to a request for a detailed breakdown of which claims lacked sufficient evidence. I consider that the NHS BSA has relayed what claims are subject to the post payment verification and that there have been numerous opportunities for the Appellant to provide this information which it has failed to do.

6.40 I note the Appellant's comments relating to the impact of the repayment. I would ask the NHS BSA to liaise with NHS England to put in place a phased recovery over several months so as to mitigate the impact.

6.41 I am of the view, given that the Appellant has not provided any information to substantiate their OOPE claims in line with the information expected as set out in the Drug Tariff, that the Appellant does not qualify for OOPE payment in line with the Drug Tariff.

6.42 I agree with the NHS BSA that the decision to recover the overpayment is appropriate.

7 DECISION

7.1 I have had regard to the Payment Disputes Directions which provide me with three options:

7.1.1 dismiss the appeal and confirm the decision of NHS England; or

7.1.2 substitute for the decision any decision that NHS England could have taken when it took the decision; or

7.1.3 quash the decision, with or without remitting the matter to NHS England for it to take the decision again subject to such directions as NHS Resolution considers appropriate.

7.2 I dismiss the appeal and confirm the decision of NHS England to recover the overpayment of £11,420.84.

7.3 I note that neither party has submitted a claim for interest with regard to this dispute so I determine that no interest is payable on the sums to be paid from one party to another.

Head of Appeals
NHS Resolution