

13 February 2025

REF: SHA/26363

**APPEAL AGAINST NHS ENGLAND DECISION TO
RECOVER AN OVERPAYMENT FROM SCHOOL LANE
PHARMACY (FHW56) ("THE APPELLANT")**

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

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

1 Outcome:

- 1.1 I dismiss the appeal and confirm the decision of NHS England to recover the overpayment of £8,162.41.
- 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:

School Lane Pharmacy (FHW56)
NHS BSA on behalf of NHS England

REF: SHA/26363

**APPEAL AGAINST NHS ENGLAND DECISION TO
RECOVER AN OVERPAYMENT FROM SCHOOL LANE
PHARMACY (FHW56) (“THE APPELLANT”)**Tel: 020 3928 2000
Email: nhsr.appeals@nhs.net**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 27 September 2024 in respect of School Lane Pharmacy (ODS code FHW56). 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 (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 2020 and January 2021.
- 2.3 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 2020 and January 2021.
- 2.4 The NHSBSA PAT concluded that there was not sufficient evidence received to support that 189 OOPE claims totalling £8,162.41 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.
- 2.5 This recommendation, along with the two attached timelines of correspondence with FHW56 were passed to the NHS England local Pharmaceutical Services Regulations Committee (PSRC) to consider whether further action was necessary.
- 2.6 The NHS England Pharmaceutical Services Regulations Committee has now reviewed this information and noted that:
 - 2.6.1 FHW56 – School Lane Pharmacy submitted (266) Out of Pocket Expense claims, totalling (£11,471.65) between February 2020 and January 2021.

2.6.2 FHW56 – School Lane Pharmacy 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.

2.7 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 2020 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.

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

189	£8,162.41 deduction
-----	---------------------

2.9 Action Required

2.9.1 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 27/10/2024.

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

2.9.3 If you have any concerns regarding the deduction or would like to discuss an alternative approach to recovering the overpayment, please contact us by 27/10/2024.

2.9.4 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.

2.9.5 Please be aware that failing to contact us by 27/10/2024 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.

2.9.6 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.

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

2.9.8 A record of this process will be kept on your NHS England contractor file. For more information or for clarification of any of the details in the letter, please contact by email at pharmacysupport@nhsbsa.nhs.net.

2.9.9 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

2.9.10 Your co-operation is very much appreciated.”

3 THE DISPUTE

In an email dated 26 October 2024 addressed to NHS Resolution, the Appellant appealed against NHS England's decision. The grounds of appeal are:

- 3.1 “Thank you for your email, I would like to appeal the decision and set out my points on this below.
- 3.2 Please kindly note that the number of items OOP has been claimed for is about 0.1% of items dispensed in the pharmacy during that period. This is a very busy Pharmacy, operating under extremely challenging conditions during the worst months of the COVID pandemic, when the supply chain was under extreme breaking point, and we are located in a very rural location. Please see attached letter from the Chief Officer of the Norfolk Local Pharmaceutical Committee reflecting the difficulties in obtaining stock. Our priority was getting patients their medication. It should also be noted that it is very hard for us to provide detailed replies as the period in question starts almost five years ago.
- 3.3 These are also costs that have been quite clearly incurred by the pharmacy and this stock has been purchased and OOP claimed in good faith, as we genuinely believed that the conditions for claiming reimbursement had been met, as the primary reason was to provide medication to patients promptly, where we experienced supply issues.
- 3.4 A good proportion of the claims (nearly all) are for Metoject and Methotrexate Injections.
- 3.5 Kindly note, it is commonly known that during this period (the worst months of the pandemic) the supply chain was unreliable and at sometimes broken - and this affected most suppliers - including mainline wholesalers during this period. The timeframe was during the peak of the pandemic and for example, Metoject is a solus distribution available from only one wholesaler. We had a few instances of missed deliveries and patients and surgeries having to reschedule doctor/nurse appointments due to these missed deliveries, creating friction with the doctor's surgeries and increasing risk of infection by forcing people to go back to rescheduled appointments.
- 3.6 I do appreciate the OOP claims for Stexerol were unnecessary. This occurred because it was out of stock at one point and a member of staff ordered it as a OOP claim, she then continued with this despite the product being in stock with mainline wholesalers. I will understand if payment for this product is deducted.
- 3.7 Please see the following links which give an idea of the disruption we faced to the regular supply chain - I hope this provides helpful context to the environment our team was working in.

<https://www.chemistanddruggist.co.uk/CD006402/COVID19-AAH-moves-to-once-a-day-delivery-to-protect-staff>

<https://www.alliance-healthcare.co.uk/alliance-healthcare-news-updates/service-disruption>

<https://www.alliance-healthcare.co.uk/alliance-healthcare-news-updates/covid-absence-and-driver-shortages-continue-across-country-and>

- 3.8 We have a requirement to supply stock in a timely manner. I think solus distribution models (where medicines are only available from a single primary wholesaler) are to blame for these OOP claims - if Metoject was available from more than one mainline wholesaler, there would have likely been no need to purchase this stock as a special obtain. It is a real difficulty to source stock at times, especially during an unprecedented pandemic.
- 3.9 We also genuinely believed Pharmacy was included in the pledge to support the NHS, particularly around the costs in supporting pharmacies to continue providing frontline services, such as the releases below:
- 3.10 Prime Minister, Boris Johnson, in March 2020 regarding the government's commitment to funding the NHS during the COVID-19 pandemic:
- "We will give the NHS whatever it needs and we will do whatever it takes. We must act like any wartime government and do whatever it takes to support our economy."*
- 3.11 Rishi Sunak, pledged to address the outbreak in his first Budget and said the impact of the virus on business "could be significant, but for a temporary period of time".
- 3.12 He said: "I can say absolutely, categorically, the NHS will get whatever resources it needs to get us through this crisis."

[Coronavirus: NHS will get whatever it needs, says chancellor - BBC News](#)

[£300 million announced for community pharmacies to support them during coronavirus outbreak - GOV.UK](#)

- 3.13 I think the suggestion that there has been an overpayment of £8162.42 is concerning in this context. I respectfully ask you to look at this figure again, I do not believe it is fair.
- 3.14 We gave staff the option to order this stock as obtain, due to missing/late deliveries from a specific mainline wholesaler and they were only trying to do what was right by the patient. It is telling that colleagues in the branch chose to use the option of a special obtain rather than the unreliable service of a mainline wholesaler."

In support of the appeal, the Appellant enclosed a letter from Community Pharmacy Norfolk & Suffolk dated 8 October 2024 which states:

- 3.15 "You have asked for my recollections, as the then Chief Officer of the Norfolk Local Pharmaceutical Committee, of the issues our pharmacies were facing during that first year of the pandemic. Clearly I am unable to comment on very specific circumstances without significant investigations into my emails and records, so the following comments are my general reflections.
- 3.16 This was an immensely challenging time for all healthcare providers. During the early part of that period there was evolving and changing advice on a wide range of matters, from appropriate isolation of patients and staff, to PPE availability and usage etc. Our pharmacies were desperately trying to maintain patient services against the above backdrop, further complicated by distancing guidelines and their own staffing issues due to illness, isolation etc. One must also remember that the community pharmacy workforce in this area had already been disproportionately affected by the already

concerning cuts to funding, but also by the rapid uptake of the Additional Roles Reimbursement Scheme (ARRS).

- 3.17 As such our pharmacies were struggling to cope on a daily basis. This included having to deal with a supply network which naturally faced very similar issues itself. While specifics are hard to evidence, I was aware that wholesaler deliveries could be considerably less reliable than under normal circumstances, and it was not unusual, as far as I was made aware of, for deliveries to be cancelled or delayed. This is no criticism, this was an exceptionally difficult time for everyone.
- 3.18 There is no doubt that, as a large rural area, our pharmacies and medication supply logistical network faced greater challenges than elsewhere. I was frequently on regional and national calls that constantly underlined that.
- 3.19 I also recall that the core message we seemed to be getting from Government and NHSE at that time was basically (and I paraphrase) "Keep things going the best you can, do what's right for patients and we'll support that". At the time I genuinely believed that to be a laudable sentiment that could and should be trusted.
- 3.20 As above, I am clearly unable to provide evidence regarding specific wholesalers on specific dates, nor on the day-to-day availability of specific medication. I am, though, immensely proud of the amazing lengths our pharmacies and pharmacy contractors went through to keep their businesses open and operational, seeing patients face-to-face in a way almost no other healthcare professions did. The challenges, especially in this area, often appeared insurmountable, yet somehow our pharmacies protected patients from all the worst-case scenarios which could so easily have come to pass.
- 3.21 I cannot comment further on the matters you raise, but I would hope and expect that anyone looking at such things accepts that these were exceptional times, that this area was particularly hard hit, and that our pharmacies were often acting on trust that they would be supported."

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 of Monday 4th of November 2024 and the opportunity to provide representations on the appeal.

Background
 - 4.1.2 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.
 - 4.1.3 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 steps 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](#).
 - 4.1.4 Part II, Clause 12 of the Drug Tariff sets out the 3 conditions which must be met when submitting a claim for OOPE:

*'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.**'*

- 4.1.5 Only certain products are eligible for a OOPE claim and are as follows:
 - 4.1.5.1 Part VIIIA Category C
 - 4.1.5.2 Readily available medicinal products outside of Part VIIIA (including ACBS)
 - 4.1.5.3 Part IXB
 - 4.1.5.4 Part IXC
 - 4.1.6 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:
 - 4.1.6.1 Postage and Packaging
 - 4.1.6.2 Handling
 - 4.1.6.3 Cost of phone calls to manufacturers or suppliers to order products
 - 4.1.7 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.
- February 2020 to January 2021 OOPE PPV
- 4.1.8 NHSBSA Pharmaceutical Provider Assurance Team (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 the OOPE service following decisions made by NHS Resolution.
 - 4.1.9 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, and 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.

- 4.1.10 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 OOPE over a 12-month period focusing on the largest claimers of OOPE. 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:
- 4.1.10.1 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)
 - 4.1.10.2 Contractors with claims over £10,000 over a 12-month period from February 2019 to January 2020 (referenced as Sample Two)
 - 4.1.10.3 Contractors with claims over £10,000 from February 2020 to January 2021 (referenced as Sample Three).
- 4.1.11 School Lane Pharmacy was included in Sample Three which covered February 2020 to January 2021 as their total OOPE claims for the period totalled £11,471.65.
- 4.1.12 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:
- 4.1.12.1 Claims were made only in 'exceptional circumstances'
 - 4.1.12.2 Claims were made only where the item was not required to be frequently supplied
 - 4.1.12.3 The contractor took all reasonable steps to avoid claiming OOPE
- 4.1.13 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, the PAT 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 and an opportunity for them to provide information and detail in support of their submitted OOPE claims.
- 4.1.14 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 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 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.
- 4.1.15 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:

4.1.15.1 **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.

4.1.15.2 **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.

4.1.15.3 **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.

4.1.16 Also included in the PAT's recommended recovery value were any claims the pharmacy had highlighted as having been claimed incorrectly in their initial self-review. The PAT provided School Lane Pharmacy with an overview, containing all the pharmacy's claiming data alongside national claim data.

4.1.17 Once this was agreed upon, it was decided to initiate a further phase of engagement, 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 July 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 then be passed to the NHS England regional team for their Pharmacy Services Regulations Committee (PSRC) to review for a final decision on whether the claims met the Drug Tariff conditions for claiming OOPE, and if not to recover the overpayments from the contractor.

School Lane Pharmacy

4.1.18 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.fhw56@nhs.net) as required by NHSE.

4.1.19 During the first phase of the PAT's PPV engagement, FHW56 - School Lane Pharmacy was contacted on six occasions via emails and telephone calls, between November 10th, 2021, and December 1st, 2022. They were asked to complete a self-review appendix of the items they claimed OOPE on from February 2020 to January 2021, demonstrating how they met the Drug Tariff's requirements. The deadline for School Lane Pharmacy to complete the required OOPE self-review was January 31st, 2022, and after two follow-up

emails from PAT, School Lane Pharmacy responded on 1st February 2022, after the deadline, with their completed self-review appendix.

- 4.1.20 School Lane Pharmacy claimed OOPE on Stexerol D3 1,000-unit tablets on a total of 109 occasions over the 12-month period reviewed. However, in their response, the pharmacy identified that OOPE had been claimed in error on 24 of these occasions, resulting in them receiving an overpayment of £1,047.72 for incorrect claims. They advised that the item could be obtained from a mainline wholesaler that does not require OOPE, therefore, they had implemented changes to avoid claiming on this item in the future. The pharmacy also submitted 41 claims for a different strength of Stexerol D3 (25,000-unit tablets), however, School Lane Pharmacy believed that the remaining claims, submitted by the pharmacy, fulfilled all three Drug Tariff requirements for OOPE. PAT concluded that insufficient explanations or supporting evidence had been provided by the pharmacy to support that the remaining claims met the conditions outlined in the Drug Tariff.
- 4.1.21 During the second phase of engagement, School Lane Pharmacy was contacted on five occasions to request evidence from the contractor 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. However, no response was received.
- 4.1.22 After reviewing the data and limited information provided by the contractor, PAT found that the pharmacy had submitted OOPE claims for three items (Stexerol-D3 1,000unit and 2,000unit tablets, and Metoject PEN 25mg/0.5ml inj pre-filled pens) on more than 12 occasions within the 12 months reviewed. The PAT had no evidence or information provided by the contractor to support that these claims were not required to be frequently supplied. Therefore, after allowing the first 12 occasions of these claims for each item, PAT found that the contractor had received a total overpayment of £8,162.41.
- 4.1.23 The £1,047.72 overpayment School Lane Pharmacy had identified in their self-review for Stexerol-D3 1,000unit tablets is also included within the total figure of £8,162.41.
- 4.1.24 PAT therefore concluded that a total recommended recovery figure of £8,162.41 should be reclaimed for OOPE claims not meeting the three conditions of the Drug Tariff.
- 4.1.25 Regardless of PAT's attempts to communicate with School Lane Pharmacy, the pharmacy did not respond to any of PAT's requests for information until after PAT had sent confirmation of the conclusion of the review with the final recommended recovery figure of £8,162.41. This total was calculated from items claimed above the assurance activity parameters where no further evidence was provided and alongside the claims the pharmacy admitted to claiming incorrectly, ultimately covering 3 separate items with OOPE claims. This notification was sent on 9th July 2024 giving the pharmacy 28 days (until 6th August 2024) to respond with any evidence or representations that they wished to provide to PSRC for consideration.
- 4.1.26 On August 5, 2024, School Lane Pharmacy response and detailed that the number of OOPE claims was approximately "0.1% of the items dispensed in the pharmacy during that period." They state that they are in a rural area and that their priority is to provide patients with their medication. They go on to say that the claims were made in good faith and that they "genuinely believe that the conditions for claiming reimbursement had been met". School Lane Pharmacy go on to specify that the vast majority of claims were for Metoject

and Methotrexate injections, and that it is well known that the supply chain was unreliable and "sometimes broken", during the peak of the COVID pandemic. They go on to explain that Metoject is a "solus distribution" available from only one wholesaler, which caused problems with doctors' surgeries due to missed deliveries. As a result, the pharmacy chose to order from other suppliers, incurring the additional fee. They went on to add that they believe a "solus distribution model is anti-competitive and creates so many difficulties for contractors". The pharmacy also included various links to articles covering supply and COVID pandemic difficulties.

- 4.1.27 Despite this contact from the contractor, School Lane Pharmacy still did not provide any specific evidence to demonstrate that the 3 items highlighted in the data overview provided met the conditions outlined in the Drug Tariff. Therefore, PAT were unable to provide assurance that the claims were made in accordance with the conditions specified in the Drug Tariff.
- 4.1.28 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 School Lane Pharmacy was limited and did not demonstrate how the claims met the cumulative conditions required before an OOPE claim should be considered.
- 4.1.29 As a result, PAT were unable to validate the claims for the OOPE claimed by School Lane Pharmacy during the designated sample period. Therefore, an amount to be recovered was calculated for the 3 items (189 claims) it was considered were not meeting those conditions, rather than every claim submitted by the pharmacy. School Lane Pharmacy did not accept the proposed recovery therefore the details of the case were passed to the NHS regional team for their PSRC review. A decision was sought as whether the claims made by the contractor were eligible for a payment under the conditions of the Drug Tariff or whether they felt the 3 identified items did not meet the cumulative conditions and therefore should be recovered under regulation 94(1)(a) as an overpayment.

The PSRC decision

- 4.1.30 To assist with their review, the PSRC was provided with the dispensing and claim data, along with the timelines of correspondence showing all contact the PAT had with School Lane Pharmacy. These timelines have been provided to you in addition to this response.
- 4.1.31 The engagement showed that despite repeated requests by the PAT, School Lane Pharmacy was still unable to provide evidence to support their claims and the PAT were therefore unable to provide assurance that the OOPE claims met all three cumulative conditions required for an OOPE claim as part of the assurance activity.
- 4.1.32 Consequently, the PSRC concluded that the PAT had been unable to find any evidence to demonstrate that the 3 items (189 claims) claimed by School Lane Pharmacy between February 2020 and January 2021 met the requirements set out in the Drug Tariff for claiming OOPE.
- 4.1.33 Following this conclusion, the PSRC determined that School Lane Pharmacy was not entitled to the payment made for which it had received for these claims.
- 4.1.34 Having made this decision, the PSRC then directed that as School Lane Pharmacy 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.

4.1.35 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 School Lane pharmacy for evidence of how the Out of Pocket Expense claims made between February 2020 and January 2021 met the requirements set out in the Drug Tariff.

4.1.36 In response to the points made in the contractor's appeal:

4.1.37 For OOPE claiming the Drug Tariff 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 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.**'*

4.1.38 Each of the points in bold are prerequisites that must be met for a claim to be considered before OOPE submission. For the 3 items (189 claims) highlighted in PAT's recommended recovery, School Lane Pharmacy have not provided any evidence to support that these conditions were met prior to submitting the claims.

4.1.39 In their appeal School Lane Pharmacy state that "the number of items OOP has been claimed for is about 0.1% of items dispensed in the pharmacy during that period". In this respect School Lane Pharmacy is viewing the wording of 'exceptional circumstances' in overall items dispensed rather than at the individual item level. Comparing the OOPE claims to the national OOPE claims data for that sample provides a far more relevant indication of School Lane Pharmacy's OOPE claiming practice rather than comparing it to their overall dispensing activity.

4.1.40 Table 1
(excerpt from PAT 2020-21 Data Over for School Lane Pharmacy)

Product (FHW56 – Made at least one OOPE claim within the 12-month period)	FHW56 claim occasion total (20-21)	National Claim Occasion Total	Percentage of National Claims made by FHW56	National Dispensed Occasion Total
Stexerol-D3 1,000 unit tablets	109	254	42.91%	242,054
Metoject PEN 25mg/0.5ml inj pre-filled pens	75	593	12.65%	37,886
Stexerol-D3 25,000 unit tablets	41	65	63.08%	37,928

4.1.41 Above is an excerpt (Table 1) from the PAT's Data Overview that shows the 3 items that PAT have recommended for recovery as the items were claimed by the pharmacy on more than 12 occasions in the 12-month sample period. These claims submitted by School Lane Pharmacy account for a considerable portion of the national OOPE claims respectively for each item highlighted for the sample period under review. It also shows that nationally, these items were dispensed regularly by other contractors without the need to submit an OOPE claim.

4.1.42 In their appeal statement, School Lane Pharmacy go on to state: *'This is a very busy Pharmacy, operating under extremely challenging conditions during the worst months of the COVID pandemic, when the supply chain was under extreme breaking point, and we are located in a very rural location.'* Table 2 (below) displays School Lane Pharmacy's OOPE dispensing data for the items recommended for recovery by PAT from February 2019 to January 2022, which includes a year before and after the sample period, as well as the sample period itself. The end column shows a percentage of School Lane Pharmacy's total OOPE claims in relation to their region (QMM) for each of 12-month periods.

4.1.43 Table 2

(School Lane Pharmacy OOPE dispensing data February 2019 to January 2022)

Items Feb 2019 – Jan 2020 period	FHW56 Items Dispensed with OOPE Total	FHW56 - % of total QMM OOPE Claims
Metoject PEN 25mg/0.5ml inj pre-filled pens	27	29.03%
Stexerol-D3 1,000 unit tablets	49	98.00%
Stexerol-D3 25,000unit tablets	39	100.00%
Items Feb 2020 – Jan 2021 period	FHW56 Items Dispensed with OOPE Total	FHW56 - % of total QMM OOPE Claims
Metoject PEN 25mg/0.5ml inj pre-filled pens	75	23.81%
Stexerol-D3 1,000 unit tablets	109	100.00%
Stexerol-D3 25,000unit tablets	41	97.62%
Items Feb 2021 – Jan 2022 period	FHW56 Items Dispensed with OOPE Total	FHW56 - % of total QMM OOPE Claims
Metoject PEN 25mg/0.5ml inj pre-filled pens	98	15.99%
Stexerol-D3 1,000 unit tablets	94	100.00%
Stexerol-D3 25,000unit tablets	46	100.00%

4.1.44 This data demonstrates that School Lane Pharmacy accounts for a significant amount of their region's OOPE claims for each highlighted item throughout the periods, which contradicts the arguments offered for the impact of the COVID pandemic, as they accounted for similar percentages prior to that period and after the height of the COVID pandemic. School Lane Pharmacy confirmed in

their original engagement, which included a self-review appendix, that 24 of the 109 claims for Stexerol-D3, 1,000-unit tables were incorrectly claimed and that they have subsequently implemented changes to avoid incorrectly claiming for this item.

- 4.1.45 School Lane Pharmacy was not included in the sample for Feb 19 – Jan 20 (Sample 1), as they had claimed less than £10,000 for that year. As these issues have only just come to light, PAT believe it would be unfair to initiate a review of any claims prior to the dates already requested. However, the PAT are yet to initiate PPV for the period after these claims were submitted. Therefore, any claims submitted after January 2021 could still be considered in a future PPV sample.
- 4.1.46 NHSE and the PAT do not dispute that the Pandemic was a difficult time for community pharmacies alongside the other points raised of being busy and located in a rural location, however that does not impact that there are certain prerequisite conditions that need to be met before an item can be claimed as OOPE. The overall national data shows that claims for OOPE were less for the first 6 months of the Pandemic than the previous year.
- 4.1.47 School Lane Pharmacy go on to state: 'It should also be noted that it is very hard for us to provide detailed replies as the period in question starts almost five years ago.' PAT would contest this, as evidenced by the timelines which demonstrates that the first engagement with the pharmacy regarding the disputed OOPE claims began in November 2021. School Lane Pharmacy had numerous opportunities to provide responses with the requested evidence at multiple stages as PAT wanted to give contractors additional opportunities to engage with this request. Ultimately detailed information was not provided by School Lane Pharmacy to validate their OOPE claims in the sample period.
- 4.1.48 School Lane Pharmacy bases the majority of their OOPE appeal information around the impact of the COVID pandemic and go on to state: 'The vast majority of the claims (nearly all) are for Metoject and Methotrexate Injections. Kindly note, it is commonly known that during this period (the worst months of the pandemic) the supply chain was unreliable and at sometimes broken - and this affected most suppliers - including mainline wholesalers during this period. We had a few instances of missed deliveries and patients and surgeries having to reschedule doctor/nurse appointments due to these missed deliveries, creating friction with the doctor's surgeries and increasing risk of infection by forcing people to go back to rescheduled appointments.'
- 4.1.49 The PAT's data overview shows that one of the three items recommended for recovery is Metoject PEN 25mg/0.5ml pre-filled pens, School Lane Pharmacy believe the supply chain for this item was affected by the COVID pandemic. This statement is not supported by the data for the sample period and also the 12-month period prior to the COVID pandemic, for School Lane Pharmacy.
- 4.1.50 Table 3 (*excerpt from PAT 2020-21 Data Overview for School Lane Pharmacy*)

Item/Product	Metoject PEN 25mg/0.5ml inj pre-filled pens
FHW56 Dispensed Occasion Total (20-21)	77
FHW56 OOPE Claim Occasion Total (20-21)	75
Number of pharmacies claims for item Nationally	32
Percentage of National claims made by FHW56	12.65%
National Dispensed Occasion Total	37,886
Months claimed in by FHW56	12

- 4.1.51 Table 3 is an excerpt from PAT's Data Overview for School Pharmacy that highlights the Metoject PEN 25mg/0.5ml inj pre-filled pens item, along with a breakdown of claim information, for the item. Overall, School Lane Pharmacy claimed OOPE for this item 75 times during the 12-month sample period under review, accounting for more than 97.4% of all times it was dispensed. This exhibits several points, including continuous and frequent OOPE claiming activity for the item and claiming for it in each of the 12 months of the sample period. In addition, School Lane Pharmacy accounted for a significant percentage (12.65%) of national claims for the item, along with being 1 of only 32 pharmacies to claim OOPE for the item nationally. It's also worth noting that, on some occasions, the pharmacy was able to purchase this item without needing to submit an OOPE claim. The PAT have not received any evidence from the pharmacy to support that they took all reasonable steps to avoid incurring additional fees when obtaining this frequently required item. The PAT would also argue that an item required so frequently was not exceptional and that any exceptional circumstances that may have existed would not continue for the full 12 months.
- 4.1.52 As already evidenced in Table 2, where PAT has looked at 3 years of data for School Lane Pharmacy in relation to the items under review, the claiming behaviour for Metoject Pen was apparent in the year prior to the COVID pandemic and the year after the height of the pandemic. Therefore, the reasoning School Lane Pharmacy provided regarding unreliable deliveries due to the pandemic and claiming for the service is not supported by the data.
- 4.1.53 PAT do not dispute that the COVID pandemic was stressful for pharmacies and some of the issues raised may have warranted claiming OOPE on an item at a point in time to cover individual circumstances. However, the consistent nature of the claims is where this claiming contradicts the instructions in the Drug Tariff – PAT and NHSE are not recommending the recovery of every claim on these items to make allowances for such circumstances but are instead allowing for occasions up to a point. The recovery figure is based on circumstances where it appears the item is required frequently over multiple months, and the contractor does not appear to be taking all reasonable steps to avoid claiming. The PAT are not disputing the fact that costs were incurred, but what changes were made within the pharmacy to avoid consistently claiming OOPE on these items, continuing to claim OOPE without any change in behaviour to avoid such claims, deters from conditions set out in the Drug Tariff for claiming OOPE.
- 4.1.54 Another key theme raised by School Lane Pharmacy in their appeal response was: "We have a requirement to supply stock in a timely manner. I think solus distribution models (where medicines are only available from a single primary wholesaler) are to blame for these OOP claims - if Metoject was available from more than one mainline wholesaler, there would have likely been no need to purchase this stock as a special obtain. It is a real difficulty to source stock at times, especially during an unprecedented pandemic.' School Lane Pharmacy went on to state "It is telling that colleagues in the branch chose to use the option of a special obtain rather than the unreliable service of a mainline wholesaler". In the following months after first having difficulties obtaining/delivery of items, School Lane Pharmacy continued to order these items with additional fees when dispensing the item and therefore claimed OOPE on almost every occasion without changing their claiming behaviour, rather than staff exploring other options available to them. As the NHSBSA data clearly shows, School Lane Pharmacy were already claiming OOPE regularly on these items' pre-pandemic.

- 4.1.55 PAT would also suggest that the situation is the same for every pharmacy contractor when sourcing items from a single primary wholesaler and that this item was not claimed at the same frequency, if at all, by other pharmacy contractors nationwide. The information provided to PAT does not support those individual circumstances within the pharmacy warranted the volume of OOPE claims on these items. Instead, PAT would argue the conditions of the Drug Tariff have not been met and that the significant levels of OOPE claims on these items pre-date the Pandemic and exist long after it occurred. 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 unless unavoidable.
- 4.1.56 It can be seen from the data provided that the pharmacy required stocks of Metoject on a regular basis and so could have avoided the extra charges from this supplier by ordering larger amounts, at less frequent intervals. The summary of product characteristics for this item show that it has a shelf life of 30 months. 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.
- 4.1.57 School Lane Pharmacy provided other supporting information in their appeal response detailing comments made by NHSE, Boris Johnson, Rishi Sunak regarding the support for NHS service providers to address the extra challenges they faced from the added COVID pressures, reiterated by Tony Dean (Joint Chief officer from Community Pharmacy Norfolk and Suffolk). However, PAT would suggest that these are more general reflections on the response to the COVID pandemic rather than being focused on how this affected OOPE claiming. They should not be considered as reasonable ground for a contractor to ignore the requirements of PART II, clause 12 of the Drug Tariff when submitting claims for OOPE.
- 4.1.58 PAT would therefore state that without specific evidence explaining individual circumstances for multiple consistent claims for OOPE rather than general explanations, the PAT have been unable to provide assurance that the School Lane Pharmacy's OOPE claims discussed did not meet the cumulative conditions listed in the Drug Tariff.
- 4.1.59 The final recovery figure is made up from items which were identified by PAT as failing to meet the conditions within the Drug Tariff alongside items the contractor themselves identified were not meeting the same conditions.

Product	Recommended Recovery Total
Stexerol-D3 1,000unit tablets	£4,193.25
Metoject PEN 25mg/0.5ml inj pre-filled pens	£2,711.82
Stexerol-D3 25,000unit tablets	£1,257.34
Total of PSRC Recovery	£8,162.41

- 4.1.60 NHSE and PAT maintain that School Lane Pharmacy did not demonstrate that they had complied with the Drug Tariff's conditions, and that the claims made for the OOPE endorsement on the various strength Stexerol items and Metoject item 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 Stexerol and

Metobject items met the conditions outlined in the Drug Tariff, so the decision to recover £8,162.41 is correct and was also upheld by PSRC. To reiterate, School Lane Pharmacy themselves confirmed that 24 claims for Stexerol-D3 1,000-unit tablets as not following the Drug Tariff in their self-review response and stated that Stexerol in general should not have been claimed for under OOPE. Nevertheless, the remaining Stexerol claims, School Lane Pharmacy indicated as following the Drug Tariff which contradicts their original comments about Stexerol.

- 4.1.61 Key points for consideration
- 4.1.62 NHS England respectfully asks that NHS Resolution considers the following key points when making its determination on the appeal.
- 4.1.63 The requirements outlined in Part II; Clause 12 of the Drug Tariff stipulate that the following three cumulative conditions must be completed before submitting an OOPE claim:
 - 4.1.63.1 Claims were made only in 'exceptional circumstances
 - 4.1.63.2 Claims were made only where the item is not required to be frequently supplied
 - 4.1.63.3 The contractor took all reasonable steps to avoid claiming OOPE
- 4.1.64 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 regional PSRC for their ICB. School Lane Pharmacy 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.
- 4.1.65 The initial engagement for the OOPE PPV exercise began the same year of the sample period under consideration. The contractors' assertion about challenges to respond in detail 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.
- 4.1.66 The PAT disputes the contractor's statement that the claims were due to the issues around the COVID-19 pandemic, as the data shows the contractor was claiming OOPE for these items regularly, the year prior and post the pandemic.
- 4.1.67 The NHSBSA data does not corroborate the contractor's statement about supply concerns; there was no notable increase in OOPE claims nationally for the disputed items over the sample period.
- 4.1.68 The PSRC was presented with all timelines of correspondence, showing all contact between the PAT and the pharmacy, and all the relevant data that the NHSBSA PAT has on contractors' dispensing and claiming histories nationally in relation to OOPE.
- 4.1.69 The PSRC considered all of the information provided about the case by the PAT when determining the overpayment under regulation 94.

4.1.70 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.

4.1.71 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 £8,162.41 overpayment and its subsequent recovery from School Lane Pharmacy was fair and in accordance with the regulations."

5 **OBSERVATIONS**

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

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.

- 6.7 Before considering the substantive point, I wish to comment on a point made by the Appellant in its appeal that it *"genuinely believed Pharmacy was included in the pledge to support the NHS, particularly around the costs in supporting pharmacies to continue providing frontline services"*, as a result of statements from the former Prime Minister, Boris Johnson, in March 2020 that *"We will give the NHS whatever it needs and we will do whatever it takes. We must act like any wartime government and do whatever it takes to support our economy."* and by the former Chancellor, Rishi Sunak, that *"I can say absolutely, categorically, the NHS will get whatever resources it needs to get us through this crisis."*
- 6.8 On this point, the Appellant relies on public statements made by senior government officers at the start of the pandemic to support an argument that the Appellant had a legitimate expectation that each and every cost incurred by it during the pandemic would be repaid. In my view, the statements that the Appellant has set out in its appeal documentation are very broad and wide-ranging; they lack specifics about pharmacies and reimbursement of costs incurred by pharmacies. I note the NHS BSA's comments that these statements were general reflections, rather than specifically about OOPE claims. I consider that on this point the NHS BSA is correct, these general statements do not provide reasonable grounds for the Appellant to ignore the express requirements of the Drug Tariff.
- 6.9 I note the NHS BSA reference to the Drug Tariff and that it has provided me with a link to the Drug Tariff webpage where back copies of the Drug Tariff from December 2019 through to the current Drug Tariff in place (January 2025) could be found. I further note that the Drug Tariff has not been disputed by the Appellant.
- 6.10 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 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 steps 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](#)."*
- 6.11 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.
- 6.12 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"*.
- 6.13 As set out above, the NHS BSA split the review into three separate samples for the OOPE PPV exercise:
- 6.13.1 *"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)"*

- 6.13.2 *Contractors with claims over £10,000 over a 12-month period from February 2019 to January 2020 (referenced as Sample Two)*
- 6.13.3 *Contractors with claims over £10,000 from February 2020 to January 2021 (referenced as Sample Three)."*
- 6.14 The NHS BSA states that the Appellant falls into sample three "*Contractors with claims over £10,000 from February 2020 to January 2021*" as the total OOPE for the Appellant for this period totalled £11,471.65.
- 6.15 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:
- 6.15.1 *"Claims were made only in 'exceptional circumstances'*
- 6.15.2 *Claims were made only where the item was not required to be frequently supplied*
- 6.15.3 *The contractor took all reasonable steps to avoid claiming OOPE"*
- 6.16 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:
- 6.16.1 ***"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.
- 6.16.2 ***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.
- 6.16.3 ***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."
- 6.17 The NHS BSA states that this is why there were two engagement periods, the first being from November 2021 to July 2022 and the second from July 2023 to July 2024.
- 6.18 It is accepted by both parties that between November 2021 and July 2024 the pharmacy was contacted by the NHS BSA a total of 11 times, however there was very little, if any, engagement from the Appellant between July 2023 and July 2024.
- 6.19 It is noted that the Appellant's pharmacy submitted 266 OOPE claims totalling £11,471.65 between February 2020 and January 2021, however it was determined by the NHS England Pharmaceutical Services Regulations Committee ("PSRC") that the

overpayment to be recovered was for 189 claims totalling £8,162.41. This is in line with the NHS BSA's "frequently supplied items" category in that they allowed *"the first 12 occasions of these claims for each item"*. The NHS BSA, after taking the frequently supplied items into account is of the view that the Appellant has received a total overpayment of £8,162.41.

6.20 I note that the period in question is from February 2020 to January 2021, I am therefore of the view that the relevant Drug Tariff is dated February 2020 as this is the Drug Tariff that was in force at the beginning of the period to which the OOPE claims relates.

6.21 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."

6.22 I note that the Appellant claimed for Stexerol on 109 occasions. During the first phase and the self review of these 109 claims, the Appellant identified 24 occasions when they had claimed in error, however the Appellant remains of the view that the 41 claims for a different strength of Stexerol were made correctly. Included within the total recovery amount of £8,162.41 is the overpayment of £1,047.72 for the 24 claims which the Appellant identified as being claimed in error.

6.23 I note, in their representations, the NHS BSA states that there were 109 Stexerol claims which had been claimed in error and that the overpayment of £1,047.72 had been included in the total recovery value of £8,162.41. The NHS BSA state that the other 41 Stexerol claims (of different strengths) were still to be considered as part of the OOPE claims recovery.

6.24 The Appellant in their appeal states *"I do appreciate the OOP claims for Stexerol were unnecessary"* and goes on to state *"I will understand if payment for this product is deducted."*

6.25 I note that the OOPE claims were for two types of Stexerol (Stexerol-D3 1,000unit and 2,000unit tablets) however, the Appellant has not distinguished between the two strengths but has confirmed that the claims were unnecessary.

6.26 I further note that the NHS BSA have already confirmed that some of the claims for Stexerol had already been confirmed as being claimed in error. I note that the Appellant has not made any distinction between these 109 claims or the other 41 claims that the NHS BSA is looking to recover payment for and the Appellant just refers to "the OOP claims for Stexerol".

6.27 I am of the view that, given that the Appellant has stated that they understand if this payment is deducted and does not appear to challenge this any further or has provided any information as to whether it is for a portion or all of the Stexerol claims, all of the claims for both strengths of Stexerol can be recovered by the NHS BSA. I consider that the NHS BSA should make the necessary arrangements for recovery of the monies in relation to the OOPE claims for Stexerol.

- 6.28 I have next moved on to consider the OOPE claims for Metoject PEN 25mg/0.5ml inj pre-filled pens (the "Pens"). In doing so 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:
- 6.28.1 That there are exceptional circumstances;
 - 6.28.2 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;
 - 6.28.3 That the product is not required to be frequently supplied; and
 - 6.28.4 That the contractor has taken all reasonable steps to avoid claiming OOPE.
- 6.29 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.
- 6.30 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 the Appellant has provided very little information in response to the three relevant criteria.
- 6.31 I first consider exceptional circumstances.
- 6.32 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.
- 6.33 I note the comments from the Appellant that during this period (February 2020 to January 2021) it was the worst months of the pandemic and as a result the supply chain was unreliable and this had affected suppliers. Whilst I appreciate the problems that were encountered during the pandemic and the also appreciate the lengths that pharmacies went to in order to ensure a continuous supply of medication, I am mindful of the 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 for the Pens before, during and after the pandemic.
- 6.34 I note that the Appellant has been a consistently high outlier with regard to claims for the Pens for the period February 2019 to January 2020, February 2021 to January 2022 as well as during the period of the pandemic from February 2020 to January 2021.
- 6.35 I further note that the Appellant, whilst being a consistently high claimer for the Pens, was not included in "Sample 1" for the period February 2019 to January 2020 as they had claimed less than £10,000 for that year and so did not trigger a review.

- 6.36 I note the comments from the NHS BSA regarding the analysis of the data, as set out in the table at 4.1.50 above "Table 3" and note that no response to this has been provided by the Appellant.
- 6.37 In response to the criteria of "exceptional circumstances" it is noted that the Appellant makes reference to the Pandemic and I accept that the relevant period in question could be considered exceptional. Further, in the appeal there is 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 also note that the Appellant made OOPE claims for the Pens, according to the NHS BSA's data, both prior to the Pandemic and that in the year after the Pandemic, these numbers actually increased.
- 6.38 I consider that at the start of the Pandemic, the circumstances would likely have been exceptional, however, I would expect that as these conditions persisted they would become simply the circumstances in which the pharmacy was operating. Therefore, the Appellant would need to evidence that there were continued changing exceptional circumstances, which necessitated the OOPE claims, which they have not done. Similarly, I consider that supply chain issues could be exceptional circumstances. However, the fact that the claims both preceded and followed the Pandemic and the alleged supply issue, I consider suggests continuing circumstances, rather than any exceptionality. As I have noted, exceptional circumstances are more than merely unusual, and I consider that any event that continues for three years would require a level of evidence to support it being very unusual.
- 6.39 I also note that the Appellant states that the OOPE process was utilised rather than *"the unreliable service of a mainline wholesaler"*. This is preceded with the explanation that there were *"missing/late deliveries"*. I consider that if there was a missing or late delivery then this event could constitute exceptional circumstances, due to the delivery not materialising, provided that this was very unusual. However, I do not consider that pre-empting the possibility of a delivery being missed or late could be such, as the circumstances had not actually, and may never, have come to pass. I also consider that if this was a regular occurrence, then it would cease to be unusual.
- 6.40 Consequently, I consider that it is reasonable to consider that the Appellant has not met the "exceptional circumstances" condition.
- 6.41 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 3 the NHS BSA indicate that the Pen was claimed, at least once, every month, for 12 months. I consider that 75 claims, across 12 months, with at least one being claimed each month, must be considered frequent. I also note that these claims start the previous year and increase the year after. This pattern, across three years, I consider must mean that it was being frequently supplied.
- 6.42 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 the statement from the Appellant to "solus distribution models" which has not been expanded upon, I have not been provided with any information as to the steps that the Appellant went to in order to avoid claiming.

- 6.43 Regarding this supply chain issue I also note the NHS BSA's data regarding other pharmacies. I consider that if there were supply chain issues then these should have been felt elsewhere as well. I also note the Appellant's statements regarding the remoteness of its location. The NHS BSA indicates that during the period in question 32 pharmacies nationally claimed for the Pen, however, the Appellant made up 12.65% of these. I also note that regionally it made up 23.81%. Whilst it is possible that the Appellant had a noteworthy number of patients requiring the Pen, these numbers suggest that it was a significant outlier. This would either suggest that the supply chain issues were less impactful than the Appellant suggests, or that, if they were, then other pharmacies found solutions to resolving the issues. 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.
- 6.44 Further to this, I note that the NHS BSA's data indicates that on two occasions the Pen was dispensed without an OOPE claim. I consider that this indicates that there was at least one successful delivery, but that only two Pens were ordered (or there were two but only one was ordered each time). Given the NHS BSA's statements that the Pen has a 30 month shelf life, I consider that it would have been prudent for the Appellant to order as many of these Pens as possible when supply was available. Given that it dispensed at least 25 the previous year, I can see no reason why a higher number of Pens was not sought. I note that the Appellant has not explained this. I also note the NHS BSA's comments that it could have bulk ordered the Pens as an OOPE claim so as to reduce costs. Given that at least one claim was made per month, I consider that this was not done, despite it being reasonable. I do not consider that either of these actions are suggestive of all reasonable steps being taken to avoid claiming.
- 6.45 Finally, I note the language used by the Appellant in its appeal, notably "*We gave staff the option to order this stock*" and "*colleagues in the branch chose to use the option of a special obtain*". I do not consider that this is indicative of any steps being taken to prevent claiming, but rather that it was simply offered as an option alongside the ordinary method for ordering. Therefore, taking into account each of these factors, I do not consider that the Appellant took all reasonable steps to avoid claiming OOPE.
- 6.46 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.
- 6.47 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.
- 6.48 I note the comments from the Appellant with regard to the length of time that has passed since the OOPE for the period February 2020 to January 2021, however I am mindful that the NHS BSA initially contacted the Appellant in November 2021. 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. Further, 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.
- 6.49 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 £8,162.41.
- 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**