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

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

27 March 2025

REF: SHA/26404

APPEAL AGAINST NHS ENGLAND DECISION TO RECOVER AN OVERPAYMENT FROM DUNCANS CHEMIST (FML90) ("THE APPELLANT")

1 Outcome:

1.1 I dismiss the appeal and confirm the decision of NHS England to recover the overpayment of £2,760.97.

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:

Duncans Chemist (FML90)
NHS BSA on behalf of NHS England

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

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

REF: SHA/26404

APPEAL AGAINST NHS ENGLAND DECISION TO RECOVER AN OVERPAYMENT FROM DUNCANS CHEMIST (FML90) ("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 25 October 2024. 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 2019 and January 2020.

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 2019 and January 2020.

2.4 The NHSBSA PAT concluded that there was not sufficient evidence received to support that 53 OOPE claims totalling £2,760.97 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 FML90 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 FML90 – Duncans Chemist submitted (208) Out of Pocket Expense claims, totalling (£10,557.07) between February 2019 and January 2020.

2.6.2 FML90 – Duncans Chemist 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 2019 to January 2020 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:

Number of Claims	Total Recovery Value
53	£2,760.97 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 24th of November 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 24th of November 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 24th of November 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.

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

2.9.10 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.

2.9.11 Your co-operation is very much appreciated."

3 THE DISPUTE

In an email dated 24 November 2024 addressed to NHS Resolution, the Appellant appealed against NHS England's decision. The grounds of appeal are:

3.1 "We have been directed to yourselves by the NHSBSA Provider Assurance team as we would like to appeal on their decision to recover an amount of £2,760.97 for out-of-pocket expenses which were claimed between Feb 2019 and January 2020 in particular for Risperdal Injections.

3.2 We do not agree that an Overpayment has been made as per our previous emails to the pharmacy team explaining why these were ordered at short notice.

3.3 We were charged these amounts by the Supplier of the goods, and we claimed them. Hence, there is no overpayment. What we were charged is what we have claimed.

3.4 I think the Pharmacy support team need to look at the circumstances of each individual pharmacies rather than giving us a generalisation of prescribing. This more so when it comes to expensive fridge line injections and medications.

3.5 Risperdal Injections used to cost us £142.76 Plus Vat which is equivalent to £171.31 per injection.

3.6 If we were to stock 5 of these it would cost us £856.56 a month. I certainly cannot afford to pay that amount.

3.7 We would have to pay the supplier at the end of the following month whilst we get paid by the NHS in approx. 2 months. (We get an initial sum worked out from the previous months claim and the balance in 2 months' time).

3.8 More importantly I would like to stress that the Risperdal injection is on a named patient only. Please note that if the prescriber has prescribed one injection, then ONLY ONE injection will be ordered and delivered to the pharmacy. We had to fax the prescription to the supplier, and they would only send us what is on the prescription. That is the case with any supplier. The nature of this medication was only on named patient basis and the quantity supplied was only what was on the prescription. So can I stress that it would be impossible for us to order more to save the cost of the expense. If the prescriber would have changed the medication and QUANTITY to something else more cost effective then we would oblige. So pls note that MORE cannot be ordered The other very important point here is no other patient requires RISPERDAL medication so I could not have faced [sic] another prescription to procure more medication.

3.9 However, it is impossible to order more than what is on the prescription. The whole ordering process was scrutinised by the supplier.

3.10 The whole process starts from the patient then to the prescriber and as pharmacists we follow what is the best possible care for the patient. In this case we did the best we can to ensure that we delivered the ultimate outcome for the patient. Both prescriber

and Patient have not complained about our service and time of delivery of the medication. Our supply chain has been perfect, and we were chosen as the pharmacy to supply medication to this care home as we have always shown that we care for the patient and their welfare.

3.11 I cannot compromise my service in any way especially time of delivery of important medication to my patients.

3.12 This medication must be given in a very timely manner to this patient and the surgery gave us the responsibility to provide this care.

3.13 Each pharmacy has their own medical care to their patient, and I can only explain what I had to do in these circumstances. By providing us with the information of other pharmacies and the costs associated does not give us the right information of the care and timely manner each pharmacy provided their patient.

3.14 This is why I strongly disagree with their decision and believe that you need to reconsider the decision made."

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:

"Background

4.1.1 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.

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

4.1.3 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.'

4.1.4 Only certain products are eligible for an OOPE claim and are as follows:

4.1.4.1 Part VIIIA Category C

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

4.1.4.3 Part IXB

4.1.4.4 Part IXC

4.1.5 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:

4.1.5.1 Postage and Packaging

4.1.5.2 Handling

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

4.1.6 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 2019 – January 2021 OOPE PPV

4.1.7 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 Out-of-Pocket Expenses (OOPE). The assurance activity commenced following a number of cases raised by different Integrated Care Boards (ICB's) which resulted in contractors having money recovered for over-claiming for OOPE following determinations made by NHS Resolution.

4.1.8 The Counter Fraud Authority (CFA) also raised concerns around how the allowance was being claimed by a small number of pharmacy contractors following these high profile cases. In response, PAT was asked to perform a small-scale pilot engaging with a small number of the highest claimers for the service. 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.

4.1.9 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 our engagement, PAT included contractors in the sample that had claimed more than £10,000 in 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:

4.1.9.1 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)

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

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

4.1.10 Duncans Chemist was included in Sample Two which covered February 2019 to January 2020 as their total reimbursement for OOPE claims over the period was £10,557.07.

4.1.11 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:

4.1.11.1 Claims were made only in 'exceptional circumstances'.

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

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

4.1.12 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 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 and an opportunity for them to provide information and detail in support of their submitted OOPE claims.

4.1.13 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 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.

4.1.14 As part of the proposed reengagement, 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:

4.1.14.1 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.

4.1.14.2 100% 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.

4.1.14.3 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.

4.1.15 Also included in the PAT's recommendation were any claims the pharmacy had highlighted as having been claimed incorrectly in their initial self-review. The PAT provided Duncans Chemist with an overview, containing all the pharmacies claiming data, alongside the national data.

4.1.16 Once this was agreed upon, a further phase of engagement with contractors was started – this shows in the 2 different timelines provided for this case – the timelines also demonstrate the gap between the engagement for each. The first phase of engagement began in November 2021 and ended in June 2022 while the following phase lasted 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 DT tests for claiming OOPE, and if not to recover the overpayments from the contractor.

Duncans Chemist

4.1.17 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.fml90@nhs.net) as required by NHSE. PAT also shared correspondence with the following email addresses [xx]@nhs.net and admin@tamrush.co.uk as requested by Duncans Chemist.

4.1.18 During the initial phase of correspondence, Duncans Chemist were contacted on five occasions between 10th November 2021 and 11th August 2022 requesting that they complete a self-review of their OOPE claims. Duncans Chemist responded on 31st January 2022 and enclosed their partially completed appendix following their OOPE self-review. The pharmacy indicated on their appendix, that the 183 claims they had managed to review, were all claimed correctly and met the conditions of the Drug Tariff. The pharmacy requested an extension to complete the review for the remaining 25 items, which the PAT granted. However, during the period of February 2022 to August 2022 no further evidence was provided by the pharmacy, despite numerous engagement requests from PAT trying to obtain this evidence.

4.1.19 During the second phase of engagement, Duncans Chemist were contacted on six occasions via email and telephone between 25th July 2023 and 17th July 2024 to request evidence that the OOPE claims submitted in the period February 2019 - January 2020 met all three cumulative conditions outlined in the Drug Tariff.

4.1.20 The Pharmacy responded on the 7th of August 2023 to confirm that they believe all of the OOPE claims submitted during the period reviewed, met the three

conditions of the Drug Tariff. In their response, FML90 identified that "*Risperdal Consta 50mg Injection (Specials) needed to be ordered on a named patient basis via the surgery and the care provider*" and that the pharmacy "*had a very small window of time to procure and deliver medication*". Alongside this, they advise that the injections "*are very expensive to buy*."

4.1.21 They went on to identify that "*patients only require very specific flavours*" of Fortisip Compact liquid and bottles, which are not available from main line wholesalers and state that it is not reasonable to stock all of the flavours as they are bulky items. The pharmacy claimed that they "*do not have enough resources to look for other suppliers that have no out of pocket charges at short notice*."

4.1.22 The PAT responded to the pharmacy on the 23rd of August 2023 requesting further evidence/information for these claims, as well as detail around the pharmacy's process for obtaining the Risperdal injections and what steps they took to avoid claiming for this item repeatedly.

4.1.23 No further evidence or information was provided by the pharmacy.

4.1.24 On the 13th December 2023, PAT sent an email advising Duncans Chemist that PAT were in the process of collating information to be reviewed by their NHSE local Pharmaceutical Regulations Committee (PSRC), and that the NHSBSA PAT were currently in discussions with their ICB to ask if they would require any further information to review the case in its entirety.

4.1.25 After reviewing the data and limited information FML90 initially provided, the PAT found that five items had been claimed on more than 12 occasions over the 12 months reviewed. The PAT had received no evidence or information from the contractor to support that these claims were not required to be frequently supplied, nor that the pharmacy took reasonable steps to avoid claiming OOPE on them. Therefore, after allowing the first 12 occasions of these claims for each item, PAT resolved that the contractor had received an overpayment of £2,670.97 for these items (51 claims).

4.1.26 The data also highlighted that FML90 were the only pharmacy to submit OOPE claims for Fortisip Extra liquid (2 flavours) nationally. Despite this item being dispensed by 1146 other pharmacies on 7995 occasions without the need for an OOPE claim. Without evidence or information to identify what steps the pharmacy took to avoid incurring additional expenses when obtaining this item, it was determined that the two claims for this Fortisip Extra liquid (2 flavours) were also unnecessary, and the pharmacy had received an overpayment of £90.00 for these claims.

4.1.27 The PAT therefore concluded that the pharmacy had received a total overpayment of £2,760.97 for OOPE claims that did not meet the three conditions outlined in the Drug Tariff and recommended that this overpayment be recovered.

4.1.28 These findings were detailed in an email sent to the pharmacy on 24th June 2024 which also advised that a recommendation to recover this overpayment would be referred to PSRC for decision. As outlined, this total was calculated from items claimed above the assurance activity parameters where no further evidence was provided, ultimately covering 6 separate items and 53 OOPE claims. Any further information the pharmacy wished to include in this referral was required to be submitted to PAT by 22nd July 2024.

4.1.29 On the 17th July 2024 Duncans Chemist responded stating "*Risperdal Consta 50Mg Injections – The Surgery initiated the prescriptions. It was done on an Ad Hoc basis, and we could not tell when the prescription would be generated*."

4.1.30 Duncans Chemists specified that two patients were not regular patients of the pharmacy hence why these prescriptions were not on repeat, and the supplier would only send in the necessary number of injections. The pharmacy also goes on to state they sometimes "*exceeded our quota from the main supplier hence, we had no means but to order via another supplier where we had to incur OOPE as the surgery and patient needed this medication*."

4.1.31 Duncans Chemist have not provided PAT with any further information regarding what changes the pharmacy made during this period, on how they sourced items, only that they were required on an ad-hoc basis to provide in a timely manner Risperdal Injections. PAT can see that this medication was dispensed by 285 pharmacies nationally and only 66 pharmacies claimed for the item during our review period, Duncans Chemist made up 10.15% of the national claims. During February 2019- January 2020 Duncans chemist dispensed Risperdal every month, but for the first 3 months a OOPE claim was not made against the item, it was then claimed every month for the following nine months. PAT fail to see how this claiming behaviour demonstrates the pharmacy were following the 3 cumulative conditions set out in the Drug Tariff.

4.1.32 They specify that the patient had mental health problems and needed the medication in a timely manner, or they would have to be admitted to hospital. "*These items are very expensive to keep in stock together with the limited Fridge Space*." Duncans Chemist also state "*Fortisip – We serve approximately Nineteen Care homes together with our community pharmacy patients. Unfortunately, we cannot stock all the flavours especially as they are bulky due to the limited space in the Pharmacy*."

4.1.33 On average, they outlined they dispense 84 bottles per patient and order the flavour that the patient likes. They specify that the pharmacy dispenses 10,000 items monthly with very little storage space. Duncans Chemist also states, "*It is very difficult with the intensity of the dispensary to shop around for the cheapest value and delay the medication to the patient*." PAT appreciate that the pharmacy is busy, but the guidance set out in the Drug Tariff has to be adhered to, and the pharmacy has given no explanations around what the pharmacy did or changed to mitigate the ongoing difficulties the pharmacy was facing regarding staff time constraints.

4.1.34 Despite this contact from the contractor, Duncans Chemist still did not provide any specific evidence to demonstrate that the 6 items 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.

4.1.35 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 Duncans Chemist was limited and did not support that the claims were meeting the cumulative conditions required before an OOPE claim should be considered.

4.1.36 As the PAT was unable to validate that 53 of the OOPE claims submitted by Duncans Chemist during the designated time period met the requirements of the Drug Tariff, a recommended recovery of £2,760.97 for these 53 claims (6 items) was proposed to the contractor. However, Duncans Chemist did not accept the proposed recovery and therefore the details of the case were

passed to the NHS England regional team for their Pharmacy Services Regulations Committee (PSRC) to review. A decision was sought as to whether the claims made by the contractor were eligible for a payment under the strict conditions of the Drug Tariff or whether they felt the 53 identified claims (6 items) did not meet the cumulative conditions and therefore should be recovered under regulation 94(1)(a) as an overpayment.

The PSRC decision

4.1.37 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 Duncans Chemist. These timelines have been provided to you in addition to this information.

4.1.38 The engagement showed that despite repeated requests by the NHSBSA PAT, Duncans Chemist was still unable to provide evidence to support their claims and 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.

4.1.39 Consequently, the PSRC concluded that the PAT had been unable to find any evidence to demonstrate that the 6 items (53 claims) claimed by Duncans Chemist between February 2019 and January 2020 met the requirements set out in the Drug Tariff for claiming OOPE.

4.1.40 Following this conclusion, the PSRC determined that Duncans Chemist was not entitled to the payment which it had received. Having made this decision, the PSRC then directed that as Duncans Chemist 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.

4.1.41 In making this decision the PSRC relied on the information that it had before it, following the extensive investigation undertaken by NHSBSA PAT and the repeated requests to Duncans Chemist for evidence of how the Out of Pocket Expense claims made between February 2019 and January 2020 met the requirements set out in the Drug Tariff.

Response to the points made in the contractor's appeal:

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

4.1.43 Each of the points highlighted are conditions that need to be met before an OOPE claim should be submitted. For the 6 items (53 claims) highlighted in PAT's recommended recovery, Duncans Chemist have not provided any evidence to support that these conditions were met prior to submitting the claims.

4.1.44 In their appeal, FML90 state that "*We do not agree that an Overpayment has been made as per our previous emails to the pharmacy team explaining why these were ordered at short notice. We were charged these amounts by the Supplier of the goods, and we claimed them. Hence, there is no overpayment. What we were charged is what we have claimed. I think the Pharmacy support team need to look at the circumstances of each individual pharmacies rather than giving us a generalisation of prescribing. This more so when it comes to expensive fridge line injections and medications*."

4.1.45 The PAT do not dispute that the pharmacy incurred these additional charges, however, the PPV was initiated to ensure that any claims submitted by pharmacy contractors met the three conditions of the Drug Tariff. Part of this includes that the pharmacy took all reasonable steps to avoid claiming. PAT also recognise that the 3 conditions are not quantified and therefore subject to individual circumstances for each pharmacy. The PAT therefore gave the pharmacy multiple opportunities to provide as much information as possible into their individual circumstances. However, PAT concluded that the information provided by the contractor, did not support their high claims.

4.1.46 Duncans Chemist in particular did not agree to the recovery of Risperdal injections, believing each of the claims was acceptable for OOPE "*Risperdal Injections used to cost us £142.76 Plus Vat which is equivalent to £171.31 per injection. If we were to stock 5 of these it would cost us £856.56 a month. I certainly cannot afford to pay that amount. We would have to pay the supplier at the end of the following month whilst we get paid by the NHS in approx. 2 months*."

4.1.47 The PAT acknowledge that this is an expensive item for the pharmacy to stock, and that it requires refrigeration. However, as shown in the provided data overview, Risperdal Consta 50mg inj vials were dispensed by the pharmacy in all 12 of the months sampled; on average, 4 times a month which would highlight a key point in what was the pharmacy doing to avoid claiming OOPE on this item. PAT have also identified that this item has a shelf life of 30 months. Regardless of any additional expenses incurred when obtaining the item, the pharmacy would still be paying the same drug cost each month, therefore, it is realistic to assume that the pharmacy would be reimbursed for any of this stock in a reasonable timeframe if they ordered once a month for the item. The PAT are not suggesting that all OOPE claims are recovered for would be reimbursed for any of this stock in a reasonable timeframe if they ordered once a month for the item. The PAT are not suggesting that all OOPE claims are recovered for Risperdal, instead, the first 12 occasions will be allowed and only the additional claims over the 12 occasions be recovered. It is reasonable that the pharmacy could stock this item each month as a result.

4.1.48 Duncans Chemist goes on to State "*Risperdal injection is on a named patient only. Please note that if the prescriber has prescribed one injection, then ONLY ONE injection will be ordered and delivered to the pharmacy.*" This was supported when they advised "*it is impossible to order more than what is on the prescription*."

4.1.49 If this particular wholesaler's policy is on a named patient basis for supplying Risperdal injections, Duncans Chemist have never provided any evidence that this is the policy of the relevant wholesaler (copies of correspondence or ordering policies from the wholesaler for example), nor have they responded with any information around Risperdal Injections and how the pharmacy process changed during the sample period in relation to obtaining the injections. PAT reached out for clinical advice on this issue, and were advised that, unfortunately, the fact that expenses are incurred because a second wholesaler is used does not mean that the pharmacy can ignore the Drug Tariff rules. In that situation it would be a reasonable step for the pharmacy to contact their main wholesaler and advise they had more than 1 patient on Risperdal Consta so need to increase their quota.

4.1.50 PAT appreciate that Duncans Chemist are trying to do their best for patients. However the Drug Tariff is clear, and the three conditions need to be met before claiming OOPE. Duncans Chemist claimed 9 out of the 12 months which suggest their claiming behaviour did not change, but they have not

provided any evidence as to why this was not possible, or what they tried to change but were unsuccessful in achieving. PAT would also suggest that the situation is the same for every pharmacy contractor when sourcing Risperdal Consta Injections (for a named patient only) and the data does not show consistent OOPE claims from other pharmacy contractors for this item. PAT do not believe the information provided supports 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 as the pharmacy has been consistently claiming OOPE on the item. Even if the pharmacy could not order more than stated on the prescription, the majority of pharmacies dispensing the item nationally, were able to do so without then needing to submit an OOPE claim.

4.1.51 Likewise, Duncans Chemist showed that first 3 months of the sample they did not claim for OOPE for the item, despite still dispensing it. In the following months after first having difficulties obtaining/delivery of items, Duncans Chemist 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. 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.

Table 1
(excerpt from PAT Data Overview for FML90 – Duncans Chemist)

Item/Product	Risperdal Consta 50mg inj vials
FML90 OOPE Claim Occasion Total (19-20)	34
Number of claims for item Nationally	335
Number of pharmacies claimed for item Nationally	66
Percentage of National claims made by FML90	10.15%
National Dispensed Occasion Total	2,957
Number of pharmacies dispensed the item Nationally	285
Months claimed in by FML90	9

4.1.52 Table 1 is an excerpt from PAT's Data Overview for Duncans Chemist that highlights the Risperdal Consta 50mg inj vials item, along with a breakdown of claim information, for the item. Overall, Duncans Chemist claimed OOPE for this item 34 times during the 12-month sample period under review, accounting for 69.39% of all times it was dispensed by the pharmacy. This exhibits several points, including continuous and frequent OOPE claiming activity for the item and claiming for it in almost all of the 12 months of the sample period. In addition, Duncans Chemist accounted for a significant percentage (10.15%) of national claims for the item, along with being 1 of only 66 pharmacies to claim OOPE for the item nationally despite 219 pharmacies dispensing the item on a total of 2,622 occasions without claiming OOPE. 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.

4.1.53 Duncans Chemist state "*Each pharmacy has their own medical care to their patient, and I can only explain what I had to do in these circumstances. By providing us with the information of other pharmacies and the costs associated does not give us the right information of the care and timely manner each pharmacy provided their patient*."

4.1.54 Duncans Chemist have stated that they were required to dispense the item promptly and could not order more than stated on any given prescription. Although the PAT have took [sic] these circumstances, provided by the pharmacy, into account, the PAT also needs to consider the national data, and in this instance, the National data does not support that these issues existed. Therefore, it appears the pharmacy could have obtained the item without incurring additional costs. The wholesaler only being able to supply the prescribed amount and not being able to bulk order, is not reflected in the National data. If this was the case, no contractors would be able to supply the item without submitting OOPE claims, and the data shows this is not the case as 76% of pharmacies dispensing the item did so without submitting an OOPE claim.

Table 2
(excerpt from PAT Data Overview for FML90 – Duncans Chemist)

Product (FML90 – made at least one OOPE claim within the 12 month period)	FML90 Claim Occasion total (19-20)	National Claim Occasion Total	Percentage of National claims made by FML90	Number of National pharmacies who dispensed this item	National Dispensed Occasion Total
Risperdal Consta 50mg inj vials	34	335	10.15%	285	2,957
Fortisip Bottle (8 Flavours)	27	394	6.85%	8,810	422,280
Fortisip Compact liquid (8 flavours)	21	206	10.19%	8,841	350,320
Complan Shake oral powder 57g sachets chocolate	15	32	46.88%	3,387	18,587
Paliperidone 150mg/1.5ml inj pre-filled syringe	14	539	2.60%	Data not available	Data not available

4.1.55 Above is an excerpt (Table 2) from the PAT's data overview that shows the 5 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. Most of these claims submitted by Duncans Chemist account for a considerable portion of the national OOPE claims for the sample period under review. For example, Complan Shake oral powder 57g sachets chocolate were dispensed by 3,387 pharmacies on 18,587 occasions nationally and only 32 contractors claimed OOPE for this item. Duncans Chemist contributed to almost half (46.88%) of the national claims for this item. It also shows that nationally, these items were dispensed regularly by other contractors without the need to submit any OOPE claim.

4.1.56 As previously mentioned, the data also highlighted that Duncans Chemist were the only pharmacy to submit OOPE claims for Fortisip Extra liquid (2 flavours) nationally. Despite this item being dispensed by 1,146 other pharmacies on 7,995 occasions without the need for an OOPE claim. Without evidence or information to identify what steps the pharmacy took to avoid incurring additional expenses when obtaining this item, it was determined that the two claims for this Fortisip Extra liquid (2 flavours) were also unnecessary, and the pharmacy had received an overpayment of £90.00 for these claims.

4.1.57 In their response Duncans Chemist state "*I think the Pharmacy support team need to look at the circumstances of each individual pharmacies rather than giving us a generalisation of prescribing. This more so when it comes to expensive fridge line injections and medications*." PAT would agree with the point around the circumstances of each pharmacy unfortunately in this case this is the evidence we have requested from Duncans Chemist, and they have not been able to provide more than generalisations themselves in support of their OOPE claims. Without this individual pharmacy evidence, PAT cannot assure NHSE that these claims are following the Drug Tariff. 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 Duncans Chemist followed the requirements outlined in the Drug Tariff and that the claims discussed met the cumulative conditions listed in the Drug Tariff.

4.1.58 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 admitted were not meeting the same conditions.

Product	Recommended Recovery
Risperdal Consta 50mg inj vials	£1,275.58
Fortisip Bottle (8 Flavours)	£684.44
Fortisip Compact liquid (8 flavours)	£404.14
Complan Shake oral powder 57g sachets chocolate	£133.80
Paliperidone 150mg/1.5ml inj pre-filled syringe	£173.00
Fortisip Extra Liquid (2 flavours)	£90.00
Total of PSRC Recovery	**£2,760.97**

4.1.59 NHSE and PAT maintain that Duncans Chemist did not demonstrate that they had complied with the Drug Tariff's conditions, and that the claims made for OOPE on Risperdal Consta 50mg Inj, Fortisip bottle (8 flavours), Fortisip Compact liquid (8 flavours), Complan Shake oral powder 57g sachets chocolate and Paliperidone 150mg/1.5ml inj pre-filled syringes 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 listed items met the conditions outlined in the Drug Tariff, so the decision to recover £2,760.97 is correct. To reiterate, this amount includes the claim for the other item listed Fortisip extra liquid (2 flavours) on the table above.

Key points for consideration

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

4.1.61 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:

4.1.61.1 Claims were made only in 'exceptional circumstances'.

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

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

4.1.62 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. In the case of Duncans Chemist, they did not provide any evidence to show the three conditions were met and PAT have been able to show the items were being ordered relatively frequently showing that condition 2 (not required to be frequently supplied) is not met and that condition 1 (exceptional circumstances) is unlikely to be met. Without any further explanation from Duncans Chemist, we cannot ascertain that condition 3 (taking all reasonable steps to avoid claiming) was also being met.

4.1.63 The PSRC was presented with all timelines of correspondence, showing all contact between the PAT and the pharmacy, and all the data that the PAT has on national contractors' dispensing and claiming histories in relation to OOPE.

4.1.64 The PSRC considered all available information about the case when determining the overpayment under regulation 94.

4.1.65 The contractor's appeal provides no specific details or evidence on what measures they took to reduce the requirement for claiming OOPE on a regular basis over the sample period. As a result, the OOPE claims are invalid under Part II, Clause 12 of the Drug Tariff, and an overpayment has been made.

4.1.66 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 £2,760.97 is the overpayment and its subsequent recovery from Duncans Chemist was fair and in accordance with the regulations.

4.1.67 Please let me know of you need anything further to help in these deliberations."

5 OBSERVATIONS

5.1 The Appellant

5.1.1 "I have now had a chance to go through the representation and have the following comments and observations to make.

5.1.2 Under the Duncans Chemist heading, it has been stated that we were contacted on 5 occasions from 10th Nov 21 to 11 Aug 2022.

5.1.3 It should be noted that we responded back on the 22 Nov 21, 31 Jan 2022, 2 Feb 2022 and 11 Aug 2022.

5.1.4 Please note that during this period of review [XXX]. Hence, I was doing my best to answer the queries considering the circumstances.

5.1.5 It has also been mentioned in the representation numerous times that we have not provided evidence regarding the ordering of Risperdal Consta. Please note we are dispensing over 10,000 items in the Pharmacy a month and our ordering was done over the phone at that time. If one supplier does not have the product or is unable to deliver in the time frame when the medication is needed, we call the next one. Hence, I am not sure what evidence we can provide as the ordering was done over the phone. We used the supplier who provided the medication in a timely manner for the patient.

5.1.6 The period of PAT review was from Feb 2019 to January 2020, However, we were first contacted by PAT on the 10 November 2021 for initial information which is over one year and 10 months. Even if we were recording our telephone calls, we would not have recording data that far behind.

5.1.7 I find it difficult to understand how PAT can use statistics as each pharmacy has different suppliers and each patient's requirement is different. PAT needs to look at the overall GP prescribing for this medication as you will find the prescriber in our case, did not have a set frequency of prescribing. These patients were in care homes and their requirements are different to that of patients not in the Care homes. Therefore, the statics will not reflect this.

5.1.8 PAT has indicated that the pharmacy did not change to mitigate the ongoing difficulties the pharmacy was experiencing regarding staff / time constraints.

5.1.9 This is an uncontrollable situation and still staff / time constraints is a major issue facing all pharmacies. Hence, to source items per the drug tariff requirements at all times is very challenging for every pharmacy. We all follow this religiously but at times, it is not possible. Therefore, we now have a software where we order online. If one wholesaler does not have the product it is sent to the second wholesaler depending on cost, availability, and delivery time frame. This now helps us in eliminating OOPE. This is another further cost to the Pharmacy for having this software.

5.1.10 As you know, it is our contractual obligation with the NHS to fulfil every prescription that is presented to us which we did. We always endeavour to ensure that patients get the medication in a timely manner. PAT has not mentioned in their representation that we had agreed with the care home and the prescriber that we will deliver the medication in the agreed time period as they had previous experiences where the patient did not receive their medications on time. Hence, to do so, we had to incur charges to have this medication on time for the patients.

5.1.11 We would also like to point out that, had we been informed by the regulators earlier on (as an enquiry of 2019 is very unacceptable to be initiated in 2021) we could have informed the prescriber and the care home that we cannot supply this medication as per their requirement and in the timeline required because we were being charged OOPE.

5.1.12 We also invited PAT to come and visit us at the Pharmacy to see how intense our work load is together with the various constraints we work to provide the best possible patient care. It is also practically impossible to order medications in advance of prescriptions received.

5.1.13 These drugs are only obtained if and when we have a prescription.

5.1.14 Finally, we would like to stress that we have not overclaimed OOPE. We have only claimed for what we were charged by the supplier and what we paid to the supplier. How is it deemed to be fair to deduct this amount from us now as we have already paid this to the suppliers.

5.1.15 We provided a service to the patients as per our contract and we are now being penalised for fulfilling that contract.

5.1.16 I hope you will base your decision in light of the above information and explanations. Should you require any further information, please do not hesitate to contact us."

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 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 (March 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 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."

6.9 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 two "*Contractors with claims over £10,000 over a 12 month period from February 2019 to January 2020*" as the total OOPE for the Appellant for this period totalled £10,577.07.

6.13 Initially any contractor identified was asked to complete a self-review of the relevant OOPE claims and 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 July 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 11 times by the NHS BSA . The NHS BSA contacted the Appellant reminding them of the deadlines and the Appellant engaged with the NHS BSA and this has not been disputed.

6.17 It is noted that the Appellant's pharmacy submitted 208 OOPE claims totalling £10.577.07 between February 2019 and January 2020, however it was determined by the NHS England Pharmaceutical Services Regulations Committee ("PSRC") that the overpayment to be recovered was for 53 claims totalling £2,760.97. 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 NHSA BSA, after taking the frequently supplied items into account is of the view that the Appellant has received a total overpayment of £2,760.97.

6.18 I note that the period in question is from February 2019 to January 2020, I am therefore of the view that the relevant Drug Tariff would be dated February 2019 as this is the Drug Tariff which would have been in force at the beginning of the period to which the OOPE claims relate. I note however that there is no back copy of the Drug Tariff for this period and therefore I am using the Drug Tariff dated December 2019 as this is the earliest Drug Tariff available which would have been in force during the period to which the OOPE claims relate.

6.19 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, in their representations, the NHS BSA states that there were 2 claims (for Fortisip Extra liquid (2 flavours)) which it had been determined were unnecessary as the Appellant was the only pharmacy to submit OOPE nationally. I note that the Appellant does not specially seek to challenge the recovery for these 2 claims. However, the overpayment of £90.00 had been included in the total recovery value of £2,760.97, and the Appellant is seeking to appeal the whole overpayment and states, in its appeal "*would like to appeal on their decision [NHS BSA] to recover an amount*

of £2,760.97 for out of pocket expenses which were claimed between Feb 2019 and January 2020 in particular for Risperdal Injections."

6.21 In considering all of the claims and in particular the ones for "Risperdal Consta 50mg inj vials" 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:

6.21.1 That there are exceptional circumstances;

6.21.2 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;

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

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

6.22 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.

6.23 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.

6.24 I first consider exceptional circumstances.

6.25 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.

6.26 I note that, from the undisputed information provided by the NHS BSA and set out in Table 1 above, the Appellant supplied "Risperdal Consta 50mg inj vials" on 34 occasions over the 12 month period and that they claimed for OOPE in 9 of those months. From the information provided by NHS BSA, and again not disputed by the Appellant, there was no OOPE for the first 3 months that "Risperdal Consta 50mg inj vials" were prescribed.

6.27 Whilst I accept that there could have initially been a period when the prescribing of this medication was "exceptional" I would have expected this to have been at the beginning of the prescribing period. As it became apparent that this medication was being prescribed on a regular basis I am not of the view that it became exceptional for the last 9 months of the period in question. If, as the Appellant states, they were aware that this medication was being prescribed and with relative regularity then I am of the view that it is not "exceptional".

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

6.29 I have also not been provided with any information from the Appellant to rebut the NHS BSA's assertion that the product "Risperdal Consta 50mg inj vials" was "not required to be frequently supplied". I note the comments from NHS BSA regarding the regularity of the supply of this medication and that it was dispensed every month for a 12 month period and on average 4 times a month. I note, from the information from the NHS BSA at Table 1 above that the Appellant's pharmacy made up 10% of the national claims for this medication. The NHS BSA also confirm that Risperdal Consta 50mg inj vials, which whilst they need to be kept refrigerated do have a shelf life of 30 months.

6.30 I note, from the information provided by the NHS BSA that over a 12 month period Risperdal Consta 50mg inj vials was claimed as an OOPE in 9 of those months and that this was for the last 9 months. I note that initially, for the first 3 months, the Appellant did not appear to have any issues with regard to obtaining this medication. Whilst the Appellant states that they could only order on a "named prescription basis" I have not been provided with any information in the form of correspondence or SOPs from the wholesaler to demonstrate that this was the case. Based on the information before me, I am of the view that "Risperdal Consta 50mg inj vials" was frequently supplied during the period February 2019 to January 2020.

6.31 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 always be difficult to quantify exactly the extent to which a party must act to evidence taking reasonable steps.

6.32 I note the statement from the Appellant that:

"…*Please note we are dispensing over 10,000 items in the Pharmacy a month and our ordering was done over the phone at that time. If one supplier does not have the product or is unable to deliver in the time frame when the medication is needed, we call the next one. Hence, I am not sure what evidence we can provide as the ordering was done over the phone. We used the supplier who provided the medication in a timely manner for the patient"*

6.33 I am of the view that if the Appellant was having to ring round various suppliers to be able to obtain the medication that there must have been some contemporaneous record kept of this which the Appellant should have been able to provide to the NHS BSA. I note no information has been provided as to which supplier the Appellant contacted in the first instance and no evidence has been provided to demonstrate that other suppliers were also contacted.

6.34 I note that the Appellant further states:

"*Therefore, we now have a software where we order online. If one wholesaler does not have the product it is sent to the second wholesaler depending on cost, availability, and delivery time frame. This now helps us in eliminating OOPE"*

6.35 I am mindful that the Appellant has now taken steps to avoid claiming however I have no further information as to when the software was installed and the process for obtaining medications changed to an online ordering system.

6.36 I note the comments from the Appellant that "*[I] find it difficult to understand how PAT can use statistics as each pharmacy has different suppliers and each patient's requirement is different"*, however I am of the view that the NHS BSA has to have some kind of benchmark with regard to the OOPE.

6.37 Turning to the remaining items listed at 4.1.58 that are part of the OOPE overpayment, the onus is on the Appellant to satisfy the requirements of the Drug Tariff to be entitled to payment. The Appellant has provided no evidence that the claims meet the criteria for payment.

6.38 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.

6.39 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.

6.40 I also 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 2020, 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. Given that the Appellant was first contacted in November 2021, I am of the view that it was aware from this date that they were subject to a PPV and records should therefore have been retained along with any further information that it had with regard to OOPE for those medications.

6.41 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 £2,760.97.

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