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27 February 2025

REF: SHA/26358

APPEAL AGAINST NHS ENGLAND DECISION TO RECOVER AN OVERPAYMENT FROM FAKENHAM PHARMACY (FQT84) ("THE APPELLANT")

1 Outcome:

1.1 I dismiss the appeal and confirm the decision of NHS England to recover the overpayment of £3,910.87.

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:

Fakenham Pharmacy
NHS BSA on behalf of NHS England

8th Floor
10 South Colonnade
Canary Wharf
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E14 4PU

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APPEAL AGAINST NHS ENGLAND DECISION TO RECOVER AN OVERPAYMENT FROM FAKENHAM PHARMACY (FQT84) ("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") – Post Payment Verification.

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 23 September 2024 in respect of Fakenham Pharmacy (ODS code FQT84). 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 88 OOPE claim totally £3,910.87 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 timelines of correspondence with FQT84 were passed to the NHS England local Pharmaceutical Services Regulations Committee (PSRC) to consider whether further action was necessary. Please note, due to size limitations, you will receive a private link to access the second timeline via Egress. To access this timeline, which covers the 2024 3 – 2024 period, please follow the link within the email which will originate from workspace@egresscloud.com; however, this may go to your 'Junk' folder. Please use your NHS.net account to log in to Egress, the password will be the same password used to access the NHS.net email address. You will then have the option to download a copy of the timeline for reference.

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

2.6.1 FQT84 – Fakenham Pharmacy submitted 228 Out of Pocket Expense claims, totalling £10,134.65 between February 2019 and January 2020.

2.6.2 FQT84 – Fakenham 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 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
88	£3,910.87 deduction

2.9 **Action Required**

2.10 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 23 October 2024.

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

2.12 If you have any concerns regarding the deduction or would like to discuss an alternative approach to recovering the overpayment, please contact us by 23 October 2024.

2.13 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.

2.14 2. **Please be aware that failing to contact us by 23 October 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 of your appeal within 30 days of the date of this letter to nhsr.appeals@nhs.net or:

2.15 NHS Resolution, Primary Care Appeals, 10 South Colonnade, Canary Wharf, London, E14 4PU

2.16 3. 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 Services (Pharmaceutical

and Local Pharmaceutical Services) Regulations 2013, on the basis that the final outcome of our investigation is that there has been an overpayment.

2.17 The NHSBSA will notify you of when the overpayment recovery will take place. A record of this process will be kept on your NHS England contractor file.

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

2.19 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.

2.20 Your co-operation is very much appreciated."

3 THE DISPUTE

In an email dated 22 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 was 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 There 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 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 some times broken – and this affected most suppliers – including mainline wholesalers during this period. This timeframe was during the peak of the pandemic and for example, Metoject is a solus distribution available from the 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.

3.5 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.

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

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

3.8 https://www.alliance-healthcare.co.uk/alliance-healthcare-news-updates/covid-absense-and-driver-shortages-continues-across-country-and

3.9 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 time, especially during an unprecedented pandemic.

3.10 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:

3.11 Prime Minister, Boris Johnson, in March 2020 regarding the government's commitment to funding the NHS during the COVID-19 Pandemic:

3.11.1 "We will give the NHS whatever it needs and we will do whatever it takes. We must like any wartime government and do whatever it takes to support our economy."

3.12 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". He said "I can say absolutely, categorically, the NHS will get whatever resources it needs to get us through this crisis."

3.13 Coronavirus: NHS will get whatever it needs, say chancellor - BBC News

3.14 £300 million annouced for community pharmacies to support them during coronavirus outbreak - GOV.UK (www.gov.uk)

3.15 I think the suggestion that there has been an overpayment of £3,910.87 is concerning in this context. I respectfully ask you to look at this figure again, I do not believe it is fair.

3.16 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 the 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:

3.17 "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.

3.18 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).

3.19 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.

3.20 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.

3.21 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.

3.22 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.

3.23 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 on the 30th of October 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 VIIIIA (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 changes 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 the cost of the product.

February 2019 to January 2020 OOPE PPV

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

4.1.9 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 [sic] cases, in response, PAT was asked to perform a small-scale pilot engaging with a small number of the highest claimers for OOPE. This pilot

resulted in contractors admitting they had not followed the Drug Tariff requirements in claiming OOPE allowances, and therefore a review of other claims and other contractors ensued.

4.1.10 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 the service over a 12 month period focusing on the largest claimers of the service. The CFA also requested that a number of additional pharmacies be included too due to concerns around their claims. With this stipulation in place, PAT had three separate samples for the proposed assurance activity:

4.1.10.1 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 Fakenham Pharmacy was included in Sample Two which covered February 2019 to January 2020 as their total OOPE claims for the period was £10,134.65.

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

4.1.14 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 the PAT, NHSE and CFA to outline an approach for assurance activity on OOPE that would provide a fair, consistent and national approach. A key part of the revised approach was that PAT would highlight claims of OOPE that, upon review of the data, would suggest were failing to meet the conditions outlined in the Drug Tariff. The expectation was that contractors would then

need to share the evidence and individual circumstances that showed these claims were meeting the Drug Tariff conditions and if this wasn't the case, then the recommendation would be to the ICB's that the contractors had claimed incorrectly for OOPE.

4.1.15 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 Fakenham Pharmacy with an overview, containing all the pharmacy's claiming data alongside national claiming data for the sample period under review.

4.1.17 Once this was agreed upon, a further phase of engagement with contractors was started, which explains why two separate timelines are provided for these cases, as well as the gap between engagements. The first phase of engagement began in November 2021 and ended in 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 be passed to the NHSE regional team for review by their Pharmacy Services Regulations Committee (PSRC) for a final decision on whether the claims met the Drug Tariff conditions, and if not to recover the overpayments from the contractor.

Fakenham 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.fqt84@nhs.net) as required by NHSE.

4.1.19 The initial deadline for Fakenham Pharmacy to complete the required OOPE self-review was January 31st, 2022. However, Fakenham Pharmacy did not respond despite three follow-up emails from PAT sent between November 26th, 2021, and January 10th, 2022. A final reminder email was sent to give Fakenham Pharmacy the opportunity to respond to PAT granting an extension to the deadline to respond by 7th March 2022.

4.1.20 Fakenham Pharmacy responded on 12th March 2022, after the stated deadline, with their completed OOPE self-review appendix, highlighting that several Colecalciferol products (7 items, 25 claims) were submitted incorrectly, totaling [sic] £1,091.50. Fakenham Pharmacy stated that the remaining claims in the self-review met all three Drug Tariff conditions for claiming OOPE, but provided no explanation or supporting evidence for how the remaining claims met these conditions.

4.1.21 PAT assessed Fakenham Pharmacy's OOPE self-review appendix and in response requested additional information on the following points:

4.1.21.1 Metoject and Methotrexate drugs in their various strengths of pre-filled pens/ disposable devices were the most common items listed that the pharmacy had claimed OOPE on. Metoject Pen 20mg/0.4ml injection pre-filled pens was dispensed and claimed for 66 times, multiple times a month through the sample period. At no point was this dispensed without a claim.

4.1.21.2 Requested information on the circumstances which the pharmacy believed to be exceptional? For example, issues with suppliers or stock shortages.

4.1.21.3 Requested details on the suppliers used by the pharmacy.

4.1.21.4 Requested information for if the pharmacy was contracted by any groups to only be able to use certain suppliers.

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

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

4.1.24 After reviewing the data and limited information provided by the contractor, PAT found that the pharmacy had submitted OOPE claims for three items (Metoject pre-filled pens of varying strengths) on more than 12 occasions within the 12 months reviewed. The PAT therefore 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 an overpayment of £,2,819.37 for these items. In addition to this, the contractor had previously highlighted that 7 items (25 claims) totaling [sic] £1,091.50 had been claimed incorrectly.

4.1.25 PAT therefore concluded that a total recommended recovery figure of £3,910.87 should be reclaimed for OOPE claims not meeting the three conditions of the Drug Tariff.

4.1.26 Regardless of PAT's attempts to communicate with Fakenham 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 £3,910.87. This total was calculated from items claimed above the assurance activity parameters where no further evidence was provided and alongside the items the pharmacy admitted to claiming incorrectly, ultimately covering 10 separate items with OOPE claims. This notification was sent on 1st July 2024 giving the pharmacy 28 days (until 29th July 2024) to respond with any evidence or representations that they wished to provide to PSRC for consideration.

4.1.27 Fakenham Pharmacy responded on July 29th, 2024, and detailed that the number of items the pharmacy had claimed OOPE on "is about 0.1% of items dispensed in the pharmacy during that period." They specify that they are in a rural location and their priority is getting patients their medication. They go on to advise that the claims were made in good faith and they "*genuinely believe that the conditions for claiming reimbursement had been met*". They state that the vast majority of claims were for Metoject and Methotrexate injections, and that it is commonly known that during this period the supply chain was unreliable and "*sometimes broken*", during the peak of the pandemic. They go on to specify that Metoject is a "*solus distribution*" available from only one wholesaler, and that this created friction with Doctor's surgeries due to missed deliveries. Therefore, the pharmacy opted to order from other suppliers and incurred the extra charge. The pharmacy also included various links to articles around supply and COVID pandemic issues. They went onto explain they think a "*solus distribution model is anti-competitive and creates so many difficulties for contractors*".

4.1.28 Despite this contact from the contractor, Fakenham Pharmacy still did not provide any specific evidence to demonstrate that the 10 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.

4.1.29 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 Fakenham Pharmacy was limited and did not prove how the claims were meeting the cumulative conditions required before an OOPE claim should be considered.

4.1.30 As a result, PAT were unable to validate the claims for the OOPE claimed by Fakenham Pharmacy during the designated sample period. Therefore, a recommended recovery of £3,910.87 for these 88 claims (10 items) was proposed to the contractor. As Fakenham Pharmacy did not accept the proposed recover, the details of the case were passed to the NHS England regional team for their PSRC to review. A decision was sought as to whether the claims made by the contractor were eligible for a payment under the conditions of the Drug Tariff or whether they felt the 10 identified items did not meet the cumulative conditions and therefore should be recovered under regulation 94-(1)-(a) as an overpayment.

PSRC decision

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

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

4.1.33 Consequently, the PSRC concluded that PAT had been unable to find any evidence to demonstrate that the 10 items (88 claims) claimed by Fakenham Pharmacy between February 2019 and January 2020 met the requirements set out in the drug tariff for claiming OOPE.

4.1.34 Following this conclusion, the PSRC determined that Fakenham Pharmacy was not entitled to the payment which it had received.

4.1.35 Having made this decision, the PSRC then directed that as Fakenham 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.

4.1.36 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 Fakenham Pharmacy for evidence of how the OOPE 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:

4.1.37 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 10 items highlighted in PAT's recommended recovery, Fakenham Pharmacy have not provided any evidence to support that these conditions were met prior to submitting the claims.

4.1.39 In their appeal Fakenham 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, Fakenham 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 Fakenham Pharmacy's OOPE claiming practice rather than comparing it to their overall dispensing activity.

Table 1

4.1.40 (excerpt from PAT Data Overview for FQT84 – Fakenham Pharmacy)

Product (FQT84 – Made at least one OOP claim within the 12-month period)	**FQT84 Claim Occasion Total (19-20)**	**National Claim Occasion Total**	**Percentage of National claims made by FQT84**	**National Dispensed Occasion Total**
Metoject PEN 20mg/0.4ml inj pre-filled pens	66	456	**14.47%**	42441
Metoject PEN 10mg/02.ml inj pre-filled pens	17	104	**16.35%**	13433
Metoject PEN 15mg/0.3ml inj pre-filled pens	16	229	**6.99%**	28595

4.1.41 Above is an excerpt (*Table 1*) from the PAT's data overview that shows the 3 items, (Metoject PEN pre-filled pens of varying strengths) 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 Metoject Pen claims submitted by Fakenham Pharmacy account for a considerable portion of the national Metoject Pen OOPE claims 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. The remaining 7 items, which make up PAT's recovery recommendation, are for varying strengths of Colecalciferol, which Fakenham Pharmacy identified themselves in their self-review as being claimed in error for the OOPE allowance.

4.1.42 In their appeal Fakenham Pharmacy also 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*.' However, the sample period under review concluded just before reports of the first occurrences of COVID and before the Spring 2020 government-imposed limitations on public life in the UK. PAT feel that the difficulties raised in relation to the COVID pandemic are not relevant to this case and do not provide an accurate representation of the situation throughout the sample period in question. NHSE and PAT do not dispute the difficulties of running a busy pharmacy in a rural location, but these comments are of a general nature and do not specifically identify issues which impact the designated prerequisite conditions that must be met before an item can be claimed under OOPE.

4.1.43 Fakenham 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 demonstrate that the first engagement with the pharmacy regarding the disputed OOPE claims began in November 2021. Fakenham 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 Fakenham Pharmacy to validate their OOPE claims in the sample period.

4.1.44 Fakenham Pharmacy base 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 some times 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*.'

4.1.45 As previously mentioned, the sample period for this case was February 2019 to January 2020, in which the COVID pandemic had not yet started in the United Kingdom. Fakenham Pharmacy's depiction of the hardships of the COVID pandemic in relation to this case does not apply to this time period as restrictions around the COVID pandemic only started to come into effect after April 2020.

4.1.46 The other key theme raised by Fakenham 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*."

4.1.47 In responding, PAT appreciates that Alliance Healthcare is the sole wholesaler for Metoject items. However, the situation is the same nationally for pharmacy contractors when sourcing items from a single primary wholesaler. As previously evidenced in Table 1 Metoject was routinely dispensed across the UK by other contractors without the need to use the OOPE endorsement. Table 2 below illustrates Fakenham Pharmacy's claiming behaviour for the Metoject items, for which they claimed OOPE on all occasions and claimed for the item in 11 or more months within the 12-month sample period. PAT concluded that the reasoning provided by Fakenham Pharmacy does not warrant the volume of OOPE claims and in fact demonstrates that the conditions set out in the Drug Tariff have not been met, as also agreed upon in the PSRC decision.

Table 2

4.1.48 (excerpt from PAT Data Overview for FQT84 – Fakenham Pharmacy)

Product (FQT84 – Made at least one OOP	**FQT84 Claim Occasion Total (19-20)**	**National Claim**	**FQT84 Claim Occasion Total (19-20)**	**Months Claimed in by FQT84**

claim within the 12-month period)		**Occasion Total**		
Metoject PEN 20mg/0.4ml inj pre-filled pens	66	66	12	12
Metoject PEN 10mg/02.ml inj pre-filled pens	17	17	11	11
Metoject PEN 15mg/0.3ml inj pre-filled pens	16	16	12	12

4.1.49 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.

4.1.50 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 product 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.

4.1.51 Fakenham Pharmacy provided additional supporting information in their appeal statement, 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 the Joint Chief officer from Community Pharmacy Norfolk and Suffolk. 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 grounds for a contractor to ignore the requirements of Part II, clause 12 of the Drug Tariff when submitting claims for OOPE.

4.1.52 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 Fakenham Pharmacy followed the requirements outlined in the Drug Tariff and that the claims discussed met the cumulative conditions listed in the Drug Tariff.

4.1.53 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 Total**

Metoject PEN 20mg/0.4ml inj pre-filled pens	£2,421.31
Metoject PEN 10mg/0.2ml inj pre-filled pens	£222.20
Colecalciferol 1,000 unit tablets	£703.00
Metoject PEN 15mg/0.3ml inj pre-filled pens	£175.86
Colecalciferol 2,000 unit tablets	£129.50
Colecalciferol 20,000 unit capsules	£86.00
Colecalciferol 20,000 unit tablets	£42.50
Colecalciferol 50,000 unit capsules	£43.50
Colecalciferol 800 unit capsules	£43.50
Colecalciferol 50,000 unit tablets	£43.50
Total of PSRC recovery	**£3,910.87**

4.1.54 NHSE and PAT maintain that Fakenham 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 Metoject Pen items 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 Metoject Pens met the conditions outlined in the Drug Tariff, so the decision to recover £3,910.87 is correct. To reiterate, this amount includes the claims for the seven items (various strengths of Colecalciferol) that Fakenham Pharmacy themselves confirmed as not following the Drug Tariff in their self-review response as this decision was also upheld by PSRC.

Key points for consideration

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

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

4.1.56.1 Claims were made only in ‘exceptional circumstances’.

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

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

4.1.57 The contractor had numerous opportunities to provide assurance that all OOPE claims made during the PPV sample period met the cumulative conditions set out in the Drug Tariff. Only contractors where no or insufficient evidence of meeting the requirements were referred to the PSRC for their ICB. Fakenham 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.

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

4.1.59 The PAT believes that the issues mentioned in respect to the COVID pandemic are irrelevant to this case and do not accurately reflect the circumstances, given the sample period under review occurred before the COVID Pandemic began in the UK.

4.1.60 The NHSBSA data does not corroborate the contractor's statement about supply concerns; there was no notable increase in OOPE claims nationally for the two disputed items, Metoject Pen and Methotrexate, over the sample period.

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

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

4.1.63 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.

4.1.64 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 £3,910.87 overpayment and its subsequent recovery from Fakenham Pharmacy was fair and in accordance with the regulations.

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

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. Further, the period in question pre-dates these statements. I also 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 (February 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 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 £10,134.65.

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, both via email and phone, a total of 17 times, however there was very little, if any, engagement from the Appellant during this time.

6.19 It is noted that the Appellant's pharmacy submitted 228 OOPE claims totalling £10,134.65 between February 2019 to January 2020, however the NHS England Pharmaceutical Services Regulations Committee ("PSRC") determined it that the overpayment to be recovered was for 88 claims totalling £3,910.87. This 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 £3,910.87.

6.20 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 is dated February 2019 as this is the Drug Tariff that was in force at the beginning of the period to which the OOPE claims relate.

6.21 The Drug Tariff at Part II "Requirements enabling payments to be made for the supply of drugs, appliances and chemist 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 Colecalciferol products on 25 occasions. During the first phase and the self-review of these claims, the Appellant identified the 25 occasions as ones claimed in error. This has not been disputed by any party. Therefore, included in the total recovery amount of £3,910.87 is the overpayment of £1,091.50 for the 25 claims which the Appellant identified as being claimed in error.

6.23 I have next moved on to consider the OOPE claims for Metoject pre-filled pens of varying strengths ("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:

6.23.1 That there are exceptional circumstances;

6.23.2 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;

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

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

6.24 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.

6.25 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.

6.26 I first consider exceptional circumstances.

6.27 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 simple 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.

6.28 I note the comments from the Appellant that during this period (February 2019 to January 2020) it was operating under "extremely challenging conditions during the worst months of the COVID pandemic" and the supply chain was unreliable and this had affected suppliers. The Appellant has not provided me with an explanation as to why the COVID pandemic, which officially had its first 'wave' during March 2020, would impact the OOPE claims made during the period of February 2019 to January 2020. Whilst I appreciate the problems that were encountered during the pandemic and 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.

6.29 In response to the criteria of "exceptional circumstances" it is noted that the Appellant makes reference to the COVID-19 pandemic. As noted in the NHS BSA representations, and above, the sample period used was prior to the COVID-19 pandemic starting in the United Kingdom. I am, therefore, of the view that the Appellant's comments regarding the difficulties surrounding pharmacy during the pandemic do not apply to the particular circumstances of the OOPE claims in question. Further, in the appeal there is reference to ongoing supply issues requiring the Pens to be sourced from one wholesaler nationwide. 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 from the NHS BSA's representations that Metoject was, and continues to be, dispensed across the UK by other contractors (sourced from the same wholesaler) without the need to claim OOPE.

6.30 I note the comments from the NHS BSA regarding the analysis of the data, as set out in the table at 4.1.48 above ("Table 2") and note that no response to this has been provided by the Appellant.

6.31 I note the data provided from the NHS BSA shows that the Appellant claimed OOPE expenditure for at least 11 months out of the February 2019 to January 2020 period. I would expect that the repeated conditions that lead the Appellant to claim OOPE for these months would simply become part of the circumstances surrounding the operating of the pharmacy, rather than being exceptional circumstances. 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 spanned more months of the year than not, I consider this suggests continued 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 11 months out of a year would require a level of evidence to support it being *very* unusual.

6.32 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.

6.33 Consequently, I consider that it is reasonable to consider that the Appellant has not met the “exceptional circumstances” condition.

6.34 I have 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 2, the NHS BSA indicate that the Pen was claimed, at least once, every month, for a minimum of 11 months. I consider that 63 claims, across a minimum of 11 months, with at least one being claimed each month, must be considered frequent.

6.35 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 possible 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. 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.

6.36 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 note the Appellant’s statements regarding the remoteness of its location. The NHS BSA indicates that during the period in question, the Appellant’s OOPE claims for the Pens account for a ”considerable portion” of the national claims for the Pen for the same period (as shown in Table 1 at 4.1.40 above). 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.

6.37 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 of ordering. Therefore, taking into account each of these factors, I do not consider that the Appellant took all reasonable steps to avoid claiming OOPE.

6.38 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 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. 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.

6.41 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 £3,910.87.

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