

28 February 2024

REF: SHA/26359

**APPEAL AGAINST NHS ENGLAND DECISION TO
RECOVER AN OVERPAYMENT FROM BECCLES
PHARMACY (ODS CODE FYK08) ("THE APPELLANT")**

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

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

1 Outcome:

- 1.1 I dismiss the appeal and confirm the decision of NHS England to recover the overpayment of £6,945.96.
- 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:

Beccles Pharmacy
NHS BSA on behalf of NHS England

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1 INTRODUCTION

- 1.1 The Appellant appealed the decision of NHS England to recover an overpayment relating to the Medicines Delivery Service.
- 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. The decision stated:

- 2.1 **“Out of Pocket Expenses (OOPE) - Post Payment Verification**
- 2.2 The Pharmacy Provider Assurance Team (PAT), part of NHS Business Services Authority (NHSBSA), have been requested by NHS England (NHSE) to undertake a Post Payment Verification (PPV) exercise to provide assurance that pharmacy contractors have claimed correctly for Out of Pocket Expenses between February 2020 and January 2021.
- 2.3 As part of the verification exercise, your pharmacy has been contacted by the Provider Assurance Team to request that you review all of your Out of Pocket Expense claims between February 2020 and January 2021.
- 2.4 The NHSBSA PAT concluded that there was not sufficient evidence received to support that 163 OOPE claims totaling [sic] £6,945.96 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 two timelines of correspondence with FYK08 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.
- 2.6 To access this timeline, which covers the 2023-2024 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.

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

2.7.1 FYK08 – Beccles HCC Ltd submitted 276 Out of Pocket Expense claims, totalling £11,846.07 between February 2020 and January 2021.

2.7.2 FYK08 – Beccles HCC Ltd was contacted on multiple occasions by the NHSBSA Provider Assurance Team to request evidence to substantiate the claims or agree to the recovery but did not receive sufficient evidence.

2.8 Having reviewed the information provided by the NHSBSA Provider Assurance Team, the NHS England Pharmaceutical Services Regulations Committee has decided that an overpayment in relation to your February 2020 to January 2021 Out of Pocket Expense claims has occurred and has instructed recovery of this overpayment to be progressed in accordance with Regulation 94 (1) of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.

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

Number of Claims	Total Recovery Value
163	£6,945.96 deduction

2.10 **Action Required**

2.11 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 (Insert date 30 days from date of email).**

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

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

2.14 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.

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

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

2.16 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.

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

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

2.19 The NHS BSA provided a copy of the timeline referred to above.

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 is a very busy Pharmacy, operating under extremely challenging conditions during the worst months of the COVID pandemic, when the supply chain was under extreme breaking point, and we are located in a very rural location. Please see attached letter from the Chief Officer of the Norfolk Local Pharmaceutical Committee reflecting the difficulties in obtaining stock. Our priority was getting patients their medication. It should also be noted that it is very hard for us to provide detailed replies as the period in question starts almost five years ago.

3.3 These are also costs that have been quite clearly incurred by the pharmacy and this stock has been purchased and OOP claimed in good faith, as we genuinely believed that the conditions for claiming reimbursement had been met, as the primary reason was to provide medication to patients promptly, where we experienced supply issues.

3.4 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. The timeframe was during the peak of the pandemic and for example, Metoject is a solus distribution available from only one wholesaler. We had a few instances of missed deliveries and patients and surgeries having to reschedule doctor/nurse appointments due to these missed deliveries, creating friction with the doctor's surgeries and increasing risk of infection by forcing people to go back to rescheduled appointments.

3.5 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-absence-and-driver-shortages-continue-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 times, 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:
- 3.12 "We will give the NHS whatever it needs and we will do whatever it takes. We must act like any wartime government and do whatever it takes to support our economy."
- 3.13 Rishi Sunak, pledged to address the outbreak in his first Budget and said the impact of the virus on business "could be significant, but for a temporary period of time".
- 3.14 He said: "I can say absolutely, categorically, the NHS will get whatever resources it needs to get us through this crisis."
- 3.15 Coronavirus: NHS will get whatever it needs, says chancellor - BBC News £300 million announced for community pharmacies to support them during coronavirus outbreak - GOV.UK (www.gov.uk)
- 3.16 I think the suggestion that there has been an overpayment of £6945.96 is concerning in this context. I respectfully ask you to look at this figure again, I do not believe it is fair.
- 3.17 We gave staff the option to order this stock as obtain, due to missing/late deliveries from a specific mainline wholesaler and they were only trying to do what was right by the patient. It is telling that colleagues in the branch chose to use the option of a special obtain rather than the unreliable service of a mainline wholesaler."
- 3.18 The Appellant provided a copy letter from Community Pharmacy Norfolk and Suffolk (Norfolk LPC) as referred to above.

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 29th of October 2024 and the opportunity to provide representations on the appeal.
- 4.1.2 **Background**
- 4.1.3 An Out of Pocket Expenses (OOPE) endorsement enables community pharmacy contractors to claim payment, where in exceptional circumstances, the contractor has incurred expenses in obtaining eligible products and where the product is not required to be frequently supplied by the contractor.

- 4.1.4 Out of Pocket Expenses should only be claimed in exceptional circumstances where items were not 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.
- 4.1.5 Part II, Clause 12 of the Drug Tariff sets out the 3 conditions which must be met when submitting a claim for OOPE:
- 4.1.6 *'Where, **in exceptional circumstances**, out-of-pocket expenses have been incurred in obtaining a drug, appliance or chemical reagent other than those priced in Part VIIIA Category A and M, Part VIIIB, Part IXA, Part IXR of the Tariff and all other specials and products not listed and **not required to be frequently supplied** by the contractor, or where out-of-pocket expenses have been incurred in obtaining from a manufacturer, wholesaler or supplier specially for supply against a prescription, where such expenses on any occasion exceed 50p payment of the full amount may be made where the contractor sends a claim giving particulars to the Pricing Authority on the appropriate prescription form. The endorsement shall be 'XP' or 'OOP' to indicate that **the contractor has taken all reasonable steps to avoid claiming.**'*
- 4.1.7 Only certain products are eligible for a OOPE claim and are as follows:
 - 4.1.7.1 Part VIIIA Category C
 - 4.1.7.2 Readily available medicinal products outside of Part VIIIA (including ACBS)
 - 4.1.7.3 Part IXB
 - 4.1.7.4 Part IXC
- 4.1.8 Only actual costs incurred during the process of obtaining specific items to fulfil specific prescriptions can be claimed. These costs can cover things such as:
 - 4.1.8.1 Postage and Packaging
 - 4.1.8.2 Handling
 - 4.1.8.3 Cost of phone calls to manufacturers or suppliers to order products
- 4.1.9 It is important that any charges incurred can be linked back to an order for a specific product on a specific prescription by the pharmacy claiming OOPE. VAT can be included in an OOPE claim as long as the normal criteria for claiming expenses are met i.e. VAT can be claimed on expenses incurred in obtaining that product and not on the cost of the product.
- 4.1.10 **February 2019 – January 2021 OOPE PPV**
- 4.1.11 NHSBSA Pharmaceutical Provider Assurance Team (NHSBSA PAT), on behalf of NHSE, were requested to conduct a Post Payment Verification (PPV) exercise to ensure that pharmacy contractors were claiming correctly for 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.

- 4.1.12 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 profiles 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.
- 4.1.13 PAT began the assurance activity by reviewing OOPE claims over a two-year period, from February 2019 to January 2021. To define and limit the scope of our engagement, we included contractors in the sample that had claimed more than £10,000 in OOPE over a 12-month period focusing on the largest claimers. The CFA also requested that a number of additional pharmacies be included too due to concerns around their claims. With this stipulation in place, PAT had three separate samples for the proposed assurance activity:
 - 4.1.13.1 Contractors with claims over £10,000 in both years were reviewed over a 24-month period February 2019 to January 2021 (referenced as Sample One)
 - 4.1.13.2 Contractors with claims over £10,000 over a 12-month period from February 2019 to January 2020 (referenced as Sample Two)
 - 4.1.13.3 Contractors with claims over £10,000 from February 2020 to January 2021 (referenced as Sample Three).
- 4.1.14 Beccles Pharmacy was included in Sample Three which covered Feb 2020 to January 2021 as their total OOPE claims for the period totalled £11,846.07
- 4.1.15 The approach taken for this assurance activity was, in the first instance, to request contractors perform a self-review of the relevant OOPE claims and the items they had claimed against and ask for confirmation and evidence that the claims were meeting the conditions outlined in the Drug Tariff focusing on the three cumulative conditions necessary:
 - 4.1.15.1 Claims were made only in 'exceptional circumstances'
 - 4.1.15.2 Claims were made only where the item was not required to be frequently supplied
 - 4.1.15.3 The contractor took all reasonable steps to avoid claiming for the service
- 4.1.16 NHSE and PAT understood that these 3 conditions were cumulative conditions and that each needed to be met for an OOPE to be considered valid. However, 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.
- 4.1.17 The response to PAT's initial engagement around self-reviews was mixed and it was ignored by some contractors included in the sampling. Therefore, PAT

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

- 4.1.18 As part of the proposed 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:
- 4.1.19 **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.
- 4.1.20 **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. - **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.
- 4.1.21 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 Beccles Pharmacy with an overview, containing all the pharmacies claiming data, alongside the national data.
- 4.1.22 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 demonstrates 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.
- 4.1.23 **Beccles Pharmacy**

- 4.1.24 The PAT looked at the 20 items Beccles pharmacy had claimed OOPE on. Following discussions with NHSE, the approach for the PPV was to look at any items that had been claimed consistently, i.e. over 12 occasions in a twelve month period. Any item that the pharmacy had claimed on more than 12 occasions, the PAT made allowances of the first 12 claims but thereafter any claims for an item over that amount were considered to be incorrect and not following the three cumulative conditions for claiming unless further evidence or explanation was provided by the pharmacy contractors.
- 4.1.25 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.fyk08@nhs.net) as required by NHSE.
- 4.1.26 During the initial phase of correspondence, Beccles Pharmacy was contacted on 8 occasions between 10th November 2021 and 22nd June 2022 requesting that they complete a self-review of their OOPE claims. In a telephone call to Beccles Pharmacy on 18th February 2022 the PAT were advised this would be actioned if the information was shared via a separate email address pharmacy@beccleshcc.co.uk.
- 4.1.27 Beccles Pharmacy responded on 3rd March 2022 via the pharmacy manager Mitul and enclosed their completed OOPE self-review appendix. In this response it was indicated by the pharmacy that Colecalciferol 2,000 unit orodispersible tablets sugar free with an OOPE claim of £41.99 was an incorrect claim. Beccles Pharmacy stated that the remaining claims in the self-review met all three conditions for claiming OOPE although no further explanations or supporting evidence was provided.
- 4.1.28 The NHSBSA PAT assessed Beccles Pharmacy's OOPE self-review appendix and on the 25th April 2022, an email was sent to mitul@pharmacoltd.co.uk requesting additional information on how the remaining items met the three cumulative conditions for claiming OOPE. Beccles Pharmacy failed to respond to this request.
- 4.1.29 Following the intermission while NHSE and PAT finalized the assurance activity process previously referenced, the second phase of correspondence commenced and Beccles Pharmacy was contacted on a total of 4 occasions between 25th July 2023 and 29th August 2023 to request evidence that the OOPE claims made in the period February 2020 – January 2021 met the three conditions outlined in the Drug Tariff. This communication was made via telephone calls and emails to pharmacy.fyk08@nhs.net.
- 4.1.30 PAT were unable to speak to the owner on any of the occasions that a telephone call was made, but a message was left regarding the PPV exercise. Staff stated that the owner does not come into the shop but that he does have access to the pharmacy NHS email and that the PAT emails have also been forwarded to the owner's personal email. On 5th October 2023 a follow up email was sent to pharmacy.fyk08@nhs.net and to mitul@pharmacoltd.co.uk that included emails from 25th July and 17th August as attachments, requesting the pharmacy respond by 20th October 2023. This email also explained that where sufficient evidence is not provided to substantiate the OOPE claims, the details of the case will be referred to the PSRC to consider whether further action is necessary.

- 4.1.31 Despite the PAT's attempts to communicate with the pharmacy, they 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 proposed recovery figure of £6,945.96 from the total of £11,846.07 claimed by Beccles Pharmacy for OOPE during the time period reviewed. This total was calculated from items claimed above the assurance activity parameters where no further evidence was provided alongside the item they admitted to claiming incorrectly, ultimately covering 5 separate items with OOPE claims. This notification was sent on 2nd July 2024 giving the pharmacy 28 days (until 30th July 2024) to respond with any evidence or representations that they wished to provide to PSRC for consideration.
- 4.1.32 On the 29th July 2024, Beccles Pharmacy responded via email, stating that the number of items OOPE had been claimed for was about 0.1% of items dispensed in the pharmacy during that period. *"We are in a rural location and our priority is getting patients their medication. The claims were made in good faith, and we genuinely believe all the conditions were met for claiming OOPE".* The pharmacy state that *"the vast majority of claims are for Metoject and Methotrexate injections, and that it is commonly known during this period the supply chain was unreliable and sometimes broken, during the peak of the pandemic".* They went on to state *"Metoject is a solus distribution available from only one wholesaler, we had a few instances of missed deliveries and surgeries having to reschedule appointments creating friction with Doctor's surgeries, so opted to order from other suppliers and incurred the extra charge."* The pharmacy also included various links to articles around supply and covid issues. They explain they think a *"solus distribution model is anti-competitive and creates difficulties for contractors"*.
- 4.1.33 Despite this contact from the contractor, Beccles Pharmacy still did not provide any specific evidence to demonstrate that the 5 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.
- 4.1.34 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 Beccles Pharmacy was limited and did not support that the claims were meeting the cumulative conditions required before an OOPE claim should be considered.
- 4.1.35 As the PAT was unable to validate that 163 of the OOPE claims submitted by Beccles Pharmacy during the designated time period met the requirements of the Drug Tariff, a recommended recovery of £6,945.96 for these 163 claims (5 items) was proposed to the contractor. However, Beccles Pharmacy 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 163 identified claims (5 items) did not meet the cumulative conditions and therefore should be recovered under regulation 94(1)(a) as an overpayment.
- 4.1.36 **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 Beccles Pharmacy. 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, Beccles Pharmacy 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 PAT had been unable to find any evidence to demonstrate that the 5 items (163 claims) claimed by Beccles Pharmacy between February 2020 and January 2021 met the requirements set out in the Drug Tariff for claiming OOPE.
- 4.1.40 Following this conclusion, the PSRC determined that Beccles Pharmacy was not entitled to the payment for which it had received. Having made this decision, the PSRC then directed that as Beccles 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.
- 4.1.41 In making this decision the PSRC relied on the information that it had before it, following the extensive investigation undertaken by the NHSBSA PAT and the repeated requests to Beccles Pharmacy for evidence of how the Out of Pocket Expense claims made between February 2020 and January 2021 met the requirements set out in the Drug Tariff.
- 4.1.42 **Response to the points made in the contractor's appeal**
- 4.1.43 For OOPE claiming the Drug Tariff states:
- 4.1.44 *'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.***
- 4.1.45 Each of the points highlighted are conditions that need to be met before an OOPE claim should be submitted. For the 5 items (163 claims) highlighted, Beccles Pharmacy have not provided any evidence to support that these conditions were met prior to submitting the claims.
- 4.1.46 In their appeal, Beccles 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 Beccles Pharmacy is viewing the wording of 'exceptional circumstances' in overall items dispensed rather than at the individual item level which PAT believe to be incorrect.

- 4.1.47 In their appeal, Beccles 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, that does not change the fact that there are certain prerequisite conditions that need to be met before an item can be claimed under OOPE. The overall national data shows that claims for OOPE were actually less for the first 6 months of the Pandemic than the previous year's claims.
- 4.1.48 Beccles 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 dispute this as shown clearly in the timelines. The first engagement with the pharmacy around these disputed OOPE claims actually occurred within the same year the claims were submitted as PAT began its assurance activity in November 2021. Beccles Pharmacy had numerous opportunities to provide detailed responses with the requested evidence at multiple stages as PAT wanted to give contractors additional opportunities to engage with this complex request. Ultimately, the detailed information was not provided by Beccles Pharmacy. PAT would re-iterate that the team appreciate the engagement which did take place but that the detail was not set out, but rather a general statement regarding how the Covid Pandemic affected supplies and therefore their claiming for OOPE.
- 4.1.49 Beccles Pharmacy base the bulk of their OOPE appeal information on two key themes one of which is that: *'The vast majority of the claims (nearly all) are for Metoject and Methotrexate Injections. Kindly note, it is commonly known that during this period (the worst months of the pandemic) the supply chain was unreliable and at sometimes broken - and this affected most suppliers - including mainline wholesalers during this period. We had a few instances of missed deliveries and patients and surgeries having to reschedule doctor/nurse appointments due to these missed deliveries, creating friction with the doctor's surgeries and increasing risk of infection by forcing people to go back to rescheduled appointments.'*
- 4.1.50 PAT's data overview of the case shows that, of the 5 items recommended for recovery, 4 of these items are Metoject Pen pre-filled pens of varying strengths. The additional item is the one item Beccles Pharmacy identified themselves on their self-review that had been claimed in error for OOPE. The argument from Beccles Pharmacy that the claims were mainly in response to the Pandemic is simply not supported by the data. The item with the largest amount of OOPE claims by Beccles Pharmacy is Metoject Pen 20mg/0.4ml pre-filled pen. Overall Beccles pharmacy claimed OOPE on this item over the 12 months reviewed on 127 occasions which was over 97.5% of all times this item was dispensed. This demonstrates that the pharmacy was able to obtain the item without resorting to OOPE on some occasions but also that the pharmacy had a consistent claiming behaviour resorting to claiming OOPE on the item. No information provided by Beccles Pharmacy allowed PAT (and therefore NHSE) to understand the conditions behind these OOPE claims. PAT would also question what the pharmacy is doing to avoid claiming OOPE on the item as outlined in the Drug Tariff if they continue to claim OOPE on it every month? PAT would also ask how those claims meet the other cumulative conditions of not being frequently supplied and being claimed only in exceptional circumstances as, again, nothing in the response from Beccles Pharmacy allows the PAT to understand the reasoning behind those claims and how they were following the Drug Tariff instructions.

- 4.1.51 The table below refutes the Pandemic reasoning given by Beccles Pharmacy as it shows the pharmacy was claiming OOPE for Metoject Pen 20mg on almost every occasion on a monthly basis in the year previous to the sample (Feb 19 - Jan 20) and also in the year following the sample (Feb 21 - Jan 22). Beccles Pharmacy was not included in the sample for Feb 19 – Jan 20 (Sample 1), as they had claimed less than £10,000 for that year. As these issues have only just come to light, PAT believe it would be unfair to initiate a review of any claims prior to the dates already requested. However, the PAT are yet to initiate PPV for the period after these claims were submitted. Therefore, any claims submitted after January 2021 could still be considered in a future PPV sample.

Metoject PEN 20mg/0.4ml inj pre-filled pen. Data for years Feb 19 - Jan 22 including percentage of OOPE claims in their ICB Area					
Year	Occasions dispensed	Occasions OOPE claimed	Months dispensed	Months OOPE claimed	% of OOPE claims in ICB area
Feb 19-Jan 20	109	103	12	12	27.84%
Feb 20-Jan 21	130	127	12	12	20.82%
Feb 21-Jan 22	89	88	12	12	10.41%

- 4.1.52 PAT looked at three years of data for Beccles Pharmacy in relation to the claims for Metoject Pen and it shows that their claiming behaviour for this item was already evident in the year prior to the Covid-19 pandemic and the year after the height of the pandemic. Therefore, the reasoning Beccles Pharmacy provided regarding deliveries and claiming for the service is not supported by the data. The data actually shows that Beccles Pharmacy's percentage of claims in their ICB area decreased in the year of the Pandemic compared to the previous year.
- 4.1.53 There is a similar pattern for the 3 other strengths of Metoject Pens that the PAT have highlighted that Beccles Pharmacy did not meet the three conditions for claiming OOPE in the sample of Feb 20 – Jan 21. Prior to and post pandemic, all 4 strengths of Metoject pens followed the same claiming behaviour and the data does not support the reasons given by Beccles Pharmacy. It is difficult to understand how Beccles Pharmacy felt that these claims were meeting the three cumulative conditions for claiming OOPE when they were claiming OOPE on these items for a sustained period of time.
- 4.1.54 Within the same explanation Beccles Pharmacy state other potential reasons for claiming for OOPE such as missed deliveries and rescheduled appointments. However, PAT would stress this line of reasoning would not explain the continued pattern of claiming OOPE for the item and how the pharmacy feels the claims were meeting the conditions outlined in the Drug Tariff. The national data shows that the item is being dispensed on a large volume of occasions over the year reviewed (50,000+) but only a small number of pharmacy contractors needed to resort to claiming OOPE on the item and even amongst them Beccles Pharmacy alone has over 15% of the OOPE claims nationally for Metoject Pen 20mg/0.4ml pre-filled pen and PAT feel the explanation above does not show why on 127 occasions Beccles Pharmacy

felt the conditions had been met to support these claims. PAT would argue that the response from Beccles Pharmacy does not provide the level of detail around individual circumstances that would support this volume of claims and outline what conditions existed within their own branch which does not appear to be the case for the majority of pharmacy contractors

- 4.1.55 PAT do not dispute that the Pandemic was stressful for pharmacies and some of the issues raised may have warranted claiming OOPE on an item at a point in time to cover individual circumstances. However, the consistent nature of the claims is where this claiming contradicts the instructions in the Drug Tariff - PAT and NHSE are not recommending the recovery of every claim on these items to make allowance for such circumstances but are instead allowing for occasions up to a point. The recovery figure is based on circumstances where it appears the item is required frequently over multiple months, and the contractor does not appear to be taking all reasonable steps to avoid claiming.
- 4.1.56 Another key theme raised by Beccles 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.'* Beccles Pharmacy also went on to state *"It is telling that colleagues in the branch chose to use the option of a special obtain rather than the unreliable service of a mainline wholesaler."* In the following months after first having difficulties obtaining/delivery of items, Beccles Pharmacy continued to order these items with additional fees when dispensing the item and therefore claiming OOPE on almost every occasion without changing their behaviour as the data clearly shows, Beccles Pharmacy were already claiming OOPE regularly on these items pre-pandemic.
- 4.1.57 PAT would also suggest that the situation is the same for every pharmacy contractor when sourcing items from a single primary wholesaler and we do not see consistent OOPE claims from other pharmacy contractors for this item. PAT do not believe the information provided proves that individual circumstances within the pharmacy warranted the volume of OOPE claims on these items. Instead, PAT would argue the conditions of the Drug Tariff have not been met and that the significant levels of OOPE claims on these items pre-date the Pandemic and exist long after it occurred.
- 4.1.58 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 including requirements on the contractor to take steps to avoid claiming OOPE unless unavoidable
- 4.1.59 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.

- 4.1.60 Alongside those two key themes, Beccles Pharmacy provided other supporting information in their appeal paper, detailing comments made by NHSE, Boris Johnson, Rishi Sunak, and Tony Dean (the Joint Chief officer from Community Pharmacy Norfolk and Suffolk). However, PAT would suggest that these are more general reflections on the response to the Pandemic rather than being focused on how this affected OOPE claiming.
- 4.1.61 PAT would therefore state that without specific evidence explaining individual circumstances for multiple consistent claims for OOPE rather than general explanations the PAT have been unable to provide assurance that Beccles Pharmacy's OOPE claims discussed did not meet the cumulative conditions listed in the Drug Tariff.
- 4.1.62 The final recovery figure is made up of £41.99 for the Colecalciferol 2,000unit orodispersible tablets sugar free that Beccles Pharmacy indicated was an incorrect claim, and the Metoject Pens in their varying strengths as these fell into the category of frequently supplied items. PAT have not included the first 12 claims in this proposed total and instead stated any claims over that amount would be recovered. The recovery for the Metoject pens in their various strengths comes to £6,903.97, thus making the total recovery of £6,945.96.

Drug Name	Recovery Value
Metoject PEN 20mg/0.4ml inj pre-filled pens	£4,894.13
Metoject PEN 15mg/0.3ml inj pre-filled pens	£854.82
Metoject PEN 25mg/0.5ml inj pre-filled pens	£770.24
Metoject PEN 12.5mg/0.25ml inj pre-filled pens	£384.78
Colecalciferol 2,000unit orodispersible tablets sugar free	£41.99
TOTAL	£6,945.96

- 4.1.63 NHS England maintain that Beccles Pharmacy was not compliant with the requirements set out in the Drug Tariff and their claims for the OOPE service on the different strengths of Metoject Pens did not meet the cumulative conditions outlined as pre-requisites for the OOPE service. Therefore, as a consequence of having been paid for these excess claims, NHSE consider that an overpayment had been made. NHSE and PAT consider that the contractor has not provided sufficient evidence to support that the claims for the Metoject Pens were meeting the conditions outlined in the Drug Tariff and therefore the decision to then recover £6,945.96 is the correct one.

4.1.64 **Key points for consideration**

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

- 4.1.66 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:

4.1.66.1 Claims were made only in 'exceptional circumstances'

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

4.1.66.3 The contractor took all reasonable steps to avoid claiming for the service

- 4.1.67 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 Beccles Pharmacy, 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 Beccles Pharmacy, we cannot ascertain that condition 3 (taking all reasonable steps to avoid claiming) was also being met.
- 4.1.68 The initial engagement for the OOPE PPV exercise began in the same year of the sample period under consideration. The contractor's assertion about challenges to respond in detail due to the 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.
- 4.1.69 PAT disputes the contractor's statement that the claims were due to the issues around the Covid-19 pandemic, as the data shows the contractor was claiming OOPE for these items regularly, the year prior to COVID and also post COVID.
- 4.1.70 The PAT data does not corroborate the contractor's statement about supply concerns; there was no notable increase in Out of Pocket claims nationally for the disputed items (different strengths of Metoject Pens) over the sample period.
- 4.1.71 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.
- 4.1.72 The PSRC considered all available information about the case when determining the overpayment under regulation 94.
- 4.1.73 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.
- 4.1.74 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 £6,945.96 is the overpayment and its subsequent recovery from Beccles Pharmacy was fair and in accordance with the regulations."

5 OBSERVATIONS

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

6 CONSIDERATION

- 6.1 Direction 2 of the Payment Disputes Directions directs me to determine a dispute in respect of the recovery of an overpayment from an NHS pharmacist under Regulation 94(1) of the NHS (Pharmaceutical and Local Pharmaceutical Services Regulations) 2013 (the "Regulations") which is in the nature of an appeal against a decision of NHS England that there has been an overpayment.
- 6.2 Direction 4 of the Payment Disputes Directions requires me to determine the appeal by dismissing it if:
- 6.2.1 NHS England has advised that an appeal must be brought within 30 days of the date the Appellant was notified of NHS England's decision and the appeal was not brought within that timescale; or
- 6.2.2 I am of the opinion that notification of the appeal contains no valid grounds of appeal (for example because it amounts to a challenge to the legality or reasonableness of the Payment Disputes Directions, the Regulations or the Drug Tariff).
- 6.3 I consider that I am not required to dismiss the appeal pursuant to Direction 4 as:
- 6.3.1 the NHS BSA advised the Appellant of a 30 days' timescale for appeal and the appeal was received within that timescale; and
- 6.3.2 the grounds of the appeal are valid.
- 6.4 Direction 6 of the Payment Disputes Directions states that I may determine the appeal without hearing any oral representations but if an appellant asks to make oral representations a hearing must be arranged unless I am satisfied that:
- 6.4.1 a hearing is unnecessary; or
- 6.4.2 I must dismiss the appeal by virtue of Direction 4.
- 6.5 The Appellant has not requested a hearing. On the basis of the information before me I have considered that it is unnecessary to hold an oral hearing.
- 6.6 I have before me the papers considered by the NHS BSA. I also have before me the responses to NHS Resolution's own statutory consultations.
- 6.7 Before considering the substantive point, I wish to comment on a point made by the Appellant in its appeal that it "*genuinely believed Pharmacy was included in the pledge to support the NHS, particularly around the costs in supporting pharmacies to continue providing frontline services*", as a result of statements from the former Prime Minister, Boris Johnson, in March 2020 that "*We will give the NHS whatever it needs and we will do whatever it takes. We must act like any wartime government and do whatever it takes to support our economy.*" and by the former Chancellor, Rishi Sunak, that "*I can say absolutely, categorically, the NHS will get whatever resources it needs to get us through this crisis.*"
- 6.8 On this point, the Appellant relies on public statements made by senior government officers at the start of the pandemic to support an argument that the Appellant had a legitimate expectation that each and every cost incurred by it during the pandemic would be repaid. In my view, the statements that the Appellant has set out in its appeal documentation are very broad and wide-ranging; they lack specifics about pharmacies and reimbursement of costs incurred by pharmacies. I note the NHS BSA's comments that these statements were general reflections, rather than specifically about OOPe

claims. I consider that on this point the NHS BSA is correct, these general statements do not provide reasonable grounds for the Appellant to ignore the express requirements of the Drug Tariff.

6.9 I note the NHS BSA reference to the Drug Tariff and that it has provided me with a link to the Drug Tariff webpage where back copies of the Drug Tariff from December 2019 through to the current Drug Tariff in place (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 three *"Contractors with claims over £10,000 from February 2020 to January 2021"* as the total OOPE for the Appellant for this period totalled £11,846.07.

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

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

- 6.15.2 *Claims were made only where the item was not required to be frequently supplied*
- 6.15.3 *The contractor took all reasonable steps to avoid claiming OOPE”*
- 6.16 I note, from the comments from the NHS BSA that not all contractors engaged with the initial process, so, following further meetings it was proposed that there would also be a recommended recovery value for any items which fell into three further categories:
- 6.16.1 ***“Frequently supplied items*** – includes any items which were claimed by the pharmacy on more than 12 occasions in the 12 months reviewed. Any items which fell into this category would be entitled to the first 12 claims, however, it would be recommended that any claims in addition to the initial 12 would be recovered. These items appear to have been supplied frequently throughout the year.
- 6.16.2 ***100% of the National claims for an item*** – includes any items in which the contractor was the only pharmacy nationally to submit an OOPE claim for an item. It was also considered how many pharmacies had dispensed the item without an OOPE claim, and the number of occasions it had been dispensed nationally without an OOPE claim. Therefore, a minimum of 500 pharmacies must have dispensed the item on a minimum of 12,000 occasions nationally, before any 100% claims would be considered in a recommendation for recovery.
- 6.16.3 ***Commonly dispensed items*** – includes any items which NHSE considered to be extremely common items, therefore the pharmacy should not have encountered any additional fees when obtaining the item. As a minimum, these items were required to have been dispensed by 10,000 pharmacies, on a minimum of 2.5 million occasions nationally for the item to have been considered commonly dispensed.”
- 6.17 The NHS BSA states that this is why there were two engagement periods, the first being from November 2021 to July 2022 and the second from July 2023 to July 2024.
- 6.18 It is accepted by both parties that between November 2021 and July 2024 the pharmacy was contacted by the NHS BSA a total of 12 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 163 OOPE claims totalling £6,945.96 between February 2020 and January 2021, and further following a review the NHS England Pharmaceutical Services Regulations Committee (“PSRC”) confirmed the overpayment to be recovered was for 163 claims totalling £6,945.96. It is noted that the NHS BSA did not include the first 12 claims in this proposed total and instead stated any claims over that amount would be recovered.
- 6.20 I note that the period in question is from February 2020 to January 2021, I am therefore of the view that the relevant Drug Tariff is dated February 2020 as this is the Drug Tariff that was in force at the beginning of the period to which the OOPE claims relates.
- 6.21 The Drug Tariff at Part II “Requirements enabling payments to be made for the supply of drugs, appliances and chemical reagents” Clause 12 with regard to “Out of Pocket Expenses” states:
- “Where, in exceptional circumstances, out-of-pocket expenses have been incurred in obtaining a drug, appliance or chemical reagent other than those priced in Part VIIIA*

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

- 6.22 During the first phase and the self review of its claims, the Appellant identified one occasion when they had claimed in error (for Colecalciferol), however the Appellant is of the view that the remaining claims were made correctly. Included within the total recovery amount of £6,945.96 is the overpayment of £41.99 for the one claim 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 (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 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.
- 6.28 I note the comments from the Appellant that during this period (February 2020 to January 2021) it was the worst months of the pandemic and as a result the supply chain was unreliable and this had affected suppliers. Whilst I appreciate the problems that

were encountered during the pandemic and the also appreciate the lengths that pharmacies went to in order to ensure a continuous supply of medication, I am mindful of the need to balance this against any OOPE claims which have been made alongside the application of the Drug Tariff. I further note the comparisons which the NHS BSA have carried out in respect of the Appellant's claiming for the Pens before, during and after the pandemic.

- 6.29 I note the comments from the NHS BSA regarding the analysis of the data, as set out in the table at 4.1.51 above and note that no response to this has been provided by the Appellant.
- 6.30 In response to the criteria of "exceptional circumstances" it is noted that the Appellant makes reference to the Pandemic and I accept that the relevant period in question could be considered exceptional. Further, in the appeal there is reference to ongoing supply issues requiring medications to be sourced from alternative suppliers. However, I consider that if circumstances continue for a prolonged period of time, then this would cease to be exceptional, as this would become the norm.
- 6.31 I consider that at the start of the Pandemic, the circumstances would likely have been exceptional, however, I would expect that as these conditions persisted they would become simply the circumstances in which the pharmacy was operating. Therefore, the Appellant would need to evidence that there were continued changing exceptional circumstances, which necessitated the OOPE claims, which they have not done. Similarly, I consider that supply chain issues could be exceptional circumstances. However, the fact that the claims both preceded and followed the Pandemic and the alleged supply issue, I consider suggests continuing circumstances, rather than any exceptionality. As I have noted, exceptional circumstances are more than merely unusual, and I consider that any event that continues for three years would require a level of evidence to support it being very unusual.
- 6.32 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 also not been provided with any information from the Appellant to rebut the NHS BSA's assertion that the product in question was "not required to be frequently supplied". The NHS BSA has provided information confirming the frequency of supply and the Appellant has not provided any response to this either on appeal or in subsequent representations. In the table at 4.1.51 above NHS BSA indicate that the Pen was claimed, at least once, every month, for 12 months. I consider that 127 claims, across 12 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 possibly can to avoid claiming OOPE. It does, however, mean that certain steps need to be taken. It will be always be difficult to quantify exactly the extent to which a party must act to evidence

taking reasonable steps. I note that apart from the statement from the Appellant to “solus distribution models” which has not been expanded upon, I have not been provided with any information as to the steps that the Appellant went to in order to avoid claiming.

- 6.36 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 also note the Appellant's statements regarding the remoteness of its location. The NHS BSA indicates that during the period in question the Appellant made up 20.82% of overall OOPE claims in the ICB area. 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 Further to this, I note that the NHS BSA states 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.*” Given the NHS BSA's statements that the Pen has a 30 month shelf life, I consider that it would have been prudent for the Appellant to order as many of these Pens as possible when supply was available. Given that it dispensed 109 the previous year, I can see no reason why a higher number of Pens was not sought. I note that the Appellant has not explained this. I do not consider that either of these actions are suggestive of all reasonable steps being taken to avoid claiming.
- 6.38 Finally, I note the language used by the Appellant in its appeal, notably “*We gave staff the option to order this stock*” and “*colleagues in the branch chose to use the option of a special obtain*”. I do not consider that this is indicative of any steps being taken to prevent claiming, but rather that it was simply offered as an option alongside the ordinary method for ordering. Therefore, taking into account each of these factors, I do not consider that the Appellant took all reasonable steps to avoid claiming OOPE.
- 6.39 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.
- 6.40 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.
- 6.41 I note the comments from the Appellant with regard to the length of time that has passed since the OOPE for the period February 2020 to January 2021, however I am mindful that the NHS BSA initially contacted the Appellant in November 2021. I am of the view that the Appellant should have been able to provide the initial information as requested by the NHS BSA at this time. Further, I am of the view that the Appellant was aware, from November 2021 onwards, that they were subject to a PPV and therefore the Appellant should have retained any further information that it had with regard to the OOPE for those drugs.
- 6.42 I agree with the NHS BSA that the decision to recover the overpayment is appropriate.

7 DECISION

- 7.1 I have had regard to the Payment Disputes Directions which provide me with three options:
 - 7.1.1 dismiss the appeal and confirm the decision of NHS England; or
 - 7.1.2 substitute for the decision any decision that NHS England could have taken when it took the decision; or
 - 7.1.3 quash the decision, with or without remitting the matter to NHS England for it to take the decision again subject to such directions as NHS Resolution considers appropriate.
- 7.2 I dismiss the appeal and confirm the decision of NHS England to recover the overpayment of £6,945.96.
- 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**