NHS Resolution

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26 March 2025

REF: SHA/26388

APPEAL AGAINST NHS ENGLAND DECISION TO RECOVER AN OVERPAYMENT FROM MANSONS CHEMIST (FL163) ("THE APPELLANT")

1 Outcome:

1.1 I dismiss the appeal and confirm the decision of NHS England to recover the overpayment of £1,107.50.

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:

Mansons Chemist (FL163)
NHS BSA on behalf of NHS England

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APPEAL AGAINST NHS ENGLAND DECISION TO RECOVER AN OVERPAYMENT FROM MANSONS CHEMIST (FL163) ("THE APPELLANT")

1 INTRODUCTION

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

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

2 DECISION

The NHS Business Services Authority ("NHS BSA"), acting on behalf of NHS England, sent a decision to the Appellant on 21 October 2024 in respect of Mansons Chemist (ODS code FL163). 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 15 OOPE claims totalling £1,107.50 met the three conditions for claiming OOPE, as outlined in the Drug Tariff. It was therefore our recommendation that an overpayment had been received as a result.

2.5 This recommendation, along with the two attached timelines of correspondence with FL163 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 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.

2.6 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 FL163 – Mansons Chemist submitted (221) Out of Pocket Expense claims, totalling (£17,059.44) between February 2019 and January 2020.

2.7.2 FL163 – Mansons Chemist was contacted on multiple occasions by the NHSBSA Provider Assurance Team to request evidence to substantiate the claims or agree to the recovery but did not receive sufficient evidence.

2.8 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 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.

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

Number of Claims	Total Recovery Value
15	£1,107.50 deduction

2.10 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 20th of November 2024.

2.10.2 Where you agree an overpayment has been made the amount over paid will be recovered by deduction from a future NHSBSA payment to you. If you have any concerns regarding the deduction or would like to discuss an alternative approach to recovering the overpayment, please contact us by 20th of November 2024.

2.10.3 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.

2.10.4 Please be aware that failing to contact us by 20th of November 2024 to agree that there has been an overpayment DOES NOT mean that the overpayment cannot be recovered. Instead, where you do not agree that an overpayment has been made you have a right of appeal to the Secretary of State against NHS England's decision. Should you choose to appeal then send a concise and reasoned statement of the grounds for your appeal within 30 days of the date of this letter to nhsr.appeals@nhs.net or: NHS Resolution, Primary Care Appeals, 10 South Colonnade, Canary Wharf, London, E14 4PU

2.10.5 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.

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

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

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

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

2.10.10 Your co-operation is very much appreciated."

3 THE DISPUTE

In an email dated 20 November 2024 addressed to NHS Resolution, the Appellant appealed against NHS England's decision. The grounds of appeal are:

3.1 "In response to your email, your reasoning is flawed (your desktop hindsight statistical analysis is not taking account of the circumstances at the time).

3.2 Please also refer to our previous responses dated 26th July 2024, to save us repeating everything again.

3.3 We have already highlighted some of the circumstances below to be contributing factors to the claims which you have noted:

3.3.1 No definitive meaning in the DT for "exceptional circumstances", "not to be frequently supplied" nor "all reasonable steps to avoid claiming"

3.3.2 Urgency of the requirement for an item.

3.3.3 Medicine shortages and supply issues because of Brexit and the Covid-19 pandemic.

3.3.4 Due to risk of catching Covid, patients were reluctant to try obtaining from other pharmacies.

3.3.5 Shortages due to restricted supply of medicines due to wholesaler quotas.

3.3.6 Low spend surcharges, wholesale quotas.

3.3.7 Government guidelines did not allow for bulk ordering of problem lines.

3.3.8 Prescribing patterns changing (e.g. branded generic items changing to generic items and vice versa), Therefore not reasonable to bulk order these items.

3.3.9 Staff resource due to sickness.

3.3.10 Contractual obligation to dispense items reasonably promptly to patients.

3.4 We are surprised that, 5 years on, you are expecting pharmacists working at the time to have made specific notes and circumstances for each item ordered. In a busy

pharmacy where we dispensed approaching 100,000 items a year, this level of recording is neither practical nor in our terms of service in the DT.

3.5 You have undertaken a desktop statistical analysis of data 4 to 5 years on, clearly ignoring our evidence, explanations, and circumstances on the ground at the time.

3.6 To suggest that with products like Fresubin drinks, which come in 6 different flavours, heavy and numerous in quantities prescribed, mainly for elderly, frail and often palliative patients and expensive, that we should keep all of this in stock shows how your comments are not practical and take no consideration of real-life circumstances. They would also occupy considerable space to store (space is at a premium in any pharmacy) and as these are delivered to the patients' home would require us to obtain them as a matter of urgency to coincide with the delivery times which are fixed thus ensuring that the patient does not go without their crucial daily energy and dietary nutrition.

3.7 That we should have predicted and stocked up on items that we have no control over, is not a sensible suggestion. We put to you that your analysis and assumptions (not evidence) is totally flawed in its sampling and being one dimensional and does not prove that the evidence or basis of our claims is wrong.

3.8 With reference to the purchase of Fresubin, it is impossible to predict if a split pack and a specific flavour will be used the following month let alone for the next 12 months (and there are 6 flavours).

3.9 Very often patients are changed to other flavours or brand of drinks because they may not find one suitable and it is often given to end-of-life palliative patients. Also, whilst these Fresubin scripts appear to be frequent, they were not regular. You are also falsely presuming and jumping to the conclusion, that because these scripts were frequent, that there cannot be a reason for an exceptional circumstances supply!

3.10 Bulk ordering and stocking of these lines was not the solution and not a reasonable option, also as the government guidelines were that pharmacies should not hoard stocks of problem lines (although I am sure many did), and secondly, prescribing patterns change without warning.

3.11 It would be very helpful if the NHBSA/NHSE [sic] could suggest how we could have overcome this or is the NHSBSA saying that we should have gone against government guidelines?

3.12 On top of the above numerous explanations, it is obvious from your data that over two thirds of the time we had managed to get the Fresubin from our normal suppliers and it was only under exceptional circumstances ordered from elsewhere. The pharmacists had clearly followed our SOP's.

3.13 One aspect of our ordering system of importance as further proof that we first exhausted checking all our normal 6 wholesalers was (and is existing), is our use of an automatic ordering cascade software which checks stocks from all six main wholesalers one after the other until it finds the supplier that has the medicine and orders.

3.14 Most of the time one of the wholesalers would have the item, however, if all the wholesalers were out of stock, following the SOPs, the pharmacist would assess the urgency of supplying the medicine and take reasonable steps to avoid claiming. If the patient has some in hand and can wait, the pharmacist will continue ordering daily from all the normal wholesalers through the cascade software until the order is accepted by a wholesaler. If the patient has run out and is a medication that requires continuous administration and is still not available from all the normal suppliers, the pharmacist on

duty would decide if the circumstance at the time is considered as “exceptional” and he/she will then try and order from IPS Specials first as the OOP fees are much less, and if out of stock, then from Mymed.

3.15 The pharmacist has also to bear in mind that his contractual duty is to dispense items reasonably promptly if available, to patients. Then there was also the added pressure from patients or their relatives asking why they were not getting their medications or when will get their medication.

3.16 In previous years we have lost money on ‘out of date’ products that we purchased in anticipation that the same will be prescribed the following month. Practically and financially, we cannot hold excess stocks of 6 different flavours of a nutrition drink in sufficient quantities to fulfil scripts that we have no way of knowing that we will receive during the same month let alone next few months.

3.17 There is also a situation of “prescription direction” from the then CCG to inform hospitals and doctors to send all prescriptions with nutritional supplements to Fresinus (Kabi UK), directly. This was another factor where we were not able to predict if we would receive prescription for these items.

3.18 I would say that these met ALL three conditions and would again challenge you to specify how it does not and how we could have overcome that!

3.19 We therefore believe these were obtained in accordance with the DT conditions.

3.20 Of the other 5 lines in question, in orange, over the 12 months in question, all 5 lines have only had OOP claim ONCE.

3.21 This clearly indicates that the pharmacists followed the SOP’s and managed to obtain the items from our main suppliers on all the occasions bar one in the 12-month period. Hardly an excessive amount.

3.22 These 5 lines are only flagged up because statistical analysis is presented which does not look at any other mitigating factors such as the ones already explained like differing quota restrictions, shortages, vertical integration of multiples etc.

3.23 Most of the time one of our normal 6 wholesalers would have the item, however, if all the wholesalers were out of stock, and following the SOPs, the pharmacist would assess the urgency of supplying the medicine and take reasonable steps to avoid claiming. If the patient has some in hand and can wait, the pharmacist will continue ordering daily from all the normal wholesalers through the cascade software until the order is accepted by a wholesaler. If the patient has run out and is a medication that requires continuous administration and is still not available from all the normal suppliers, the pharmacist on duty would decide if the circumstance at the time is considered as “exceptional” and he/she will then try and order from IPS Specials first as the OOP fees are much less, and if out of stock, then from Mymed.

3.24 I am sure you would agree that it is exceptional circumstances if none of the 6 main wholesalers have the medication available.

3.25 The claims between February 2019 and January 2020 were correctly made and according to us have met all 3 conditions. We have submitted all the required evidence (as invoices and explanations) that we were able to gather bearing in mind the time lapsed in you raising this query.

3.26 It is astounding how long it has taken a well-resourced NHSBSA pharmacy support team to review payment verification. These claims relate to February 2019 and January 2020, which go back four and a half years. The very slow pace and the passage of time

at which this has been addressed is prejudicial to any pharmacy, as all the records, information and documents are now not available from the wholesalers. We would not have the resources needed to trace the pharmacists on duty at that given time, to talk to them and see if they remember/recollect the individual circumstances, etc. especially in the middle of the Covid pandemic. Bearing this in mind and with the number of prescriptions dispensed each year (approaching 100,000), is it a surprise that we cannot give you specific individual explanations! It is totally unreasonable to expect us to "confirm specific issues with specific items"

3.27 If we are granted an extension of 90 days (we are now approaching Christmas holidays and the busiest time of the year), we can make further investigations to gather more evidence to support our appeal bearing in mind the circumstances explained in the previous paragraph.

3.28 You have not engaged with us prior during 2019 to 2023 and have provided no evidence or proper basis for asserting that the conditions were not met.

3.29 The DT does not provide either one of us with a definitive meaning nor examples of what is exceptional circumstances, frequently supplied or reasonable steps.

3.30 Therefore, they should be given their everyday meaning, and the DT is expecting the pharmacist to use his/her professional judgement in deciding depending on the specific circumstances at the time.

3.31 The DT does not stipulate that records have to be kept of OOP supply with their "specific issues with specific items" as you are NOW requiring.

3.32 We have provided you with sufficient evidence as is required in the form of invoices and numerous factual explanations of why the pharmacists in question had to resort to obtaining medications which entailed paying OOPE.

3.33 The DT is also expecting that the NHSBSA/NHSE/CCG intervene straight away if it finds unusual occurrences and even perhaps suggest where the item could be sourced from!

3.34 Sending us statistics comparing with National figures and the assertions that have been made without evidence are meaningless and wrong. It is not appropriate to simply say from figures that you think that we have not followed the DT conditions, without setting out plausible reasons why.

3.35 There could be many reasons why other pharmacies do not make or have not made OOPE claims or can obtain the product without incurring OOPE.

3.36 Other pharmacies may have different or no quotas.

3.37 Large multiples are vertically integrated so their own "wholesaler" may have separate reserved allocations for their stores.

3.38 We make every effort to obtain medications for patients which other pharmacies may not do and they ask their patients to try elsewhere some ending up at our doorstep.

3.39 You have therefore made this very general and sweeping statement with assumptions without looking at each pharmacy's individual circumstances.

3.40 We again ask, if there is any aspect of the claims or explanations that you are not sure about, and what evidence you require.

3.41 Please let us know why you think our explanations are not plausible and therefore what additional steps we should have taken within our contractual framework, other than to just keep quoting the 3 DT conditions to us.

3.42 I note that you have not commented on or explained why, with the information and data promptly available to you, the NHSBSA did not approach us at the time to engage with us!"

In an email of 26 July 2024 addressed to NHS BSA the Appellant stated:

3.43 "We are surprised that, 5 years on, you are expecting pharmacists working at the time to have made specific notes and circumstances for each item ordered. In a busy pharmacy where we dispensed approaching 100,000 items a year, this level of recording is neither practical nor in our terms of service in the DT. You have undertaken a desktop analysis of data 4- 5 years on, ignoring our evidence, explanations and circumstances on the ground at the time, and stating, in hindsight, that we should have predicted and stocked up on items that we have no control over, is not a sensible suggestion. We put to you that your analysis is totally flawed in its sampling and being one dimensional and does not prove that the evidence or basis of our claims is wrong.

3.44 With reference to the purchase of Fresubin, it is impossible to predict if a split pack and a specific flavour will be used the following month let alone for the next 12 months (and there are 6 flavours). Very often patients are changed to other flavours or brand of drinks because they may not find one suitable and also it is often given to end-of-life palliative patients. Also, whilst these Fresubin scripts appear to be frequent, they were not regular.

3.45 You are also falsely presuming and jumping to the conclusion, that because these scripts were frequent, that there cannot be a reason for an exceptional circumstances supply!

3.46 It is obvious from your data that over two third's of the time we had managed to get the Fresubin from our normal suppliers and it was only under exceptional circumstances ordered from elsewhere.

3.47 We have clearly outlined our ordering SOP's where the pharmacist would have first tried the 5 or 6 main wholesalers before going to IPS or Mymed. And again, you have not provided us with any evidence that this was not followed. Trying first to obtain a medication from 5 or 6 wholesalers is evidence that we tried all reasonable steps to obtain the drug without claiming OOP. If we have missed your evidence, please let us know!

3.48 In previous years we have lost money on 'out of date' products that we purchased in anticipation that the same will be prescribed the following month. Practically and financially, we cannot hold excess stocks of 6 different flavours of a nutrition drink in sufficient quantities to fulfil scripts that we have no way of knowing that we will receive during the same month let alone next few months.

3.49 There is also a situation of prescription direction from the then CCG to inform hospitals and doctors to send all drinks to Fresinus (Kabi UK).

3.50 This undermines the pharmacy network and adversely affects contractors.

3.51 We have no way of knowing when the doctors will direct the scripts away from us and as there is no mechanism for claiming 'Broken Bulk' on this product, we would have to bear the loss.

3.52 This is a one-way street and unfairly impacts on all contractors when there is no consideration given to the circumstance on the day the patient turns up.

3.53 The stocks are very fluid and there may have been occasions that some pharmacies may have bought up all the stock available to wholesale out which would have created a shortfall in supply. We have no way in knowing what happened at the time. As we can see from the stock issues today, there are many items that appear in stock one minute and out of stock the next where someone buys up all the stock for themselves to supply for their patients and deprive others.

3.54 We do not know what evidence would be required to prove that after 4-5 years, which items were in stock from which supplier on which day. If you can provide guidance, it would be appreciated."

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 3rd of December 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 OOPE 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.

4.1.4 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 an OOPE claim and are as follows:

4.1.5.1 Part VIIIA Category C

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

4.1.5.3 Part IXB

4.1.5.4 Part IXC

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

4.1.6.1 Postage and Packaging

4.1.6.2 Handling

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

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

February 2019 – January 2021 OOPE PPV

4.1.8 NHSBSA Pharmaceutical Provider Assurance Team (PAT), on behalf of NHSE, were requested to conduct a Post Payment Verification (PPV) exercise to ensure that pharmacy contractors were claiming correctly for 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.

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

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

4.1.10.1 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 Mansons Chemist was included in Sample Two which covered February 2019 to January 2020 as their total reimbursement for OOPE claims for the period was £17,059.44.

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

4.1.12.1 Claims were made only in 'exceptional circumstances'.

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

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

4.1.13 NHSE and PAT understood that these 3 conditions were cumulative conditions and that each needed to be met for an OOPE to be considered valid. However, the PAT 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.

4.1.14 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 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 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:

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

4.1.17 Once this was agreed upon, a further phase of engagement with contractors was started – this is shown in the 2 different timelines provided for this case – the timelines also demonstrate the gap between the engagement for each. The first phase of engagement began in November 2021 and ended in June 2022 while the following phase lasted from July 2023 to July 2024. The goal of the engagement was for the contractor to show that they had evidence to support their claims or agreed to the proposed recovery. If neither was achieved, the case details would then be passed to the NHS England regional team for their Pharmacy Services Regulations Committee (PSRC) to review for a final decision on whether the claims met the DT tests for claiming OOPE, and if not to recover the overpayments from the contractor.

Mansons Chemist – Individual Contractor Timeline

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.fl163@nhs.net) as required by NHSE. PAT also shared correspondence with the following email addresses [x] and mansons.pharmacy@nhs.net at the request of the contractor.

4.1.19 During the initial phase of correspondence, the intended deadline for Mansons Chemist to complete the required OOPE self-review was January 31st, 2022. Mansons Chemist responded on the 23rd of November 2021 advising they would undertake the review by the requested date of 31st of January 2022. A final email was sent to Mansons Chemist on the 10th of January 2022 reminding them of the deadline. Mansons Chemist [PP] responded on the 20th of January 2022 requesting an extension until the end of March 2022. PAT granted an extension until the 28th of February 2022 for the pharmacy to respond.

4.1.20 Mansons Chemist eventually responded on the 28th of February 2022 deadline with a completed appendix, highlighting that one claim for Ciclosporin 100mg capsules had been duplicated and therefore claimed incorrectly, totalling £79.00. They also highlighted that one OOPE claim for Colecalciferol 1,000unit tablets should have totalled £47.50 and not £49.00, as was reimbursed. The total value FL163 highlighted as receiving an overpayment for was £80.50. Mansons Chemist stated that the remaining claims in the self-review met all three Drug Tariff conditions for OOPE, but provided no explanation or supporting evidence as to how the remaining claims met all three accumulative conditions set out in the Drug Tariff.

4.1.21 After reviewing Mansons Chemist OOPE self-review appendix, PAT emailed the pharmacy to request additional information on the following points:

4.1.21.1 Items being dispensed with an OOPE claim on multiple occasions, including Fresubin 2kcal drink (6 flavours) which had an OOPE claim on 20 occasions within the 12-month period. As this item was required to be dispensed often did the pharmacy investigate sourcing it through a supplier who did not charge additional fees? Could the pharmacy have ordered in bulk to avoid multiple claims?

4.1.21.2 93% of the claims made by the pharmacy are for £79.00; supplied by MyMed. Did MyMed charge a standard fee regardless of the item? If the pharmacy could not find a supplier who did not charge additional costs for these items, did the pharmacy investigate sourcing these items from a supplier who had lower charges to obtain the item? For instance, all claims for items sourced through IPS Specials range from £47.50 to £62.50. If every item obtained through MyMed was sourced through IPS Specials at a rate of £62.50, it would reduce the claim total by £3,399.00 for example.

4.1.21.3 Occasions in which the pharmacy dispensed items on more occasions than OOPE was claimed on the same item. For example, Ciclosporin 100mg capsules were dispensed 52 times, but OOPE was only claimed on 9 of these occasions. What circumstances led to an OOPE claim for only 9 of these occasions?

4.1.21.4 Other pharmacies in the local area dispensed the same items but did not claim OOPE for them. For example, Sukkarto SR 500mg tablets was dispensed by 4 other pharmacies (combined total of 1647 occasions) but there were no OOPE claims made by any of these pharmacies. Therefore, it appears it may have been possible to source these, and many other items, without the need for an OOPE claim. Had the pharmacy exhausted all supplier options before using a company which required additional fees to obtain the items from them?

4.1.22 Mansons Chemist responded on 8th August 2022 to address the above points stating "*Pharmacist/Dispensing staff would have tried other suppliers before ordering. We do not order in bulk as they are expensive or doctors change brands frequently*." They go on to advise "*The pharmacy would try IPS prior to Mymed and use the latter if IPS too cannot obtain during this time*." For any items which were dispensed on more occasions than an OOPE claim was submitted, they advise it was "*because the item would have been out of stock and not available."* Finally, the pharmacy addressed their ordering process and stated, "*The dispensing team would have checked with our regular suppliers before ordering from elsewhere*."

4.1.23 During the second phase of engagement, Mansons Chemist were contacted on the 25th of July 2023 to request evidence from the contractor and give them an opportunity to provide further detail into the circumstances that existed within the pharmacy, to show that their OOPE claims were meeting the three cumulative conditions outlined in the Drug Tariff by the 8th of August 2023. A call to [V], the pharmacy manager, was made on the 31st of July 2023 and he advised that he does not have access to the shared mailbox and requested that we resend the email to mansons.pharmacy@nhs.net. The PAT resent the email to the new address the same day.

4.1.24 On 9th August 2023, a response was received from the [PP] to advise that due to [X] he had not been able to work since March 2023. He therefore requested

that the PAT allow him an extension to address the matter for FL163 and his two other pharmacies: FV542 and FX076.

4.1.25 The PAT granted an extension until the 31st of August 2023. Mansons Chemist responded on the 14th of August 2023 to confirm that they believed all of their OOPE claims submitted between February 2019 and January 2020 met the 3 conditions outlined in the Drug Tariff.

4.1.26 In their response on 14th August 2023, Mansons Chemist state "*It is rather concerning that NHSBSA has chosen to disregard our previous submission, without providing any evidence of how the conditions were not met. The very slow pace at which this has been addressed is prejudicial to any pharmacy, given the passage of time, all the records, information and documents may now not be available, we would not have the resources needed to trace the pharmacists on duty at that given time, to talk to them and see if they remember/recollect the circumstances, etc*."

"Pharmacists and staff follow our Standard Operating Procedures. The pharmacist would order ethical items firstly from our normal mainline wholesalers. Most of the time one of the wholesalers would have the item, however, if all the wholesalers are out of stock, the pharmacist would assess the urgency of supplying the medicine. If the patient has some in hand and can wait, the pharmacist would continue ordering daily from all the wholesalers until in. If the patient has run out and is a medication that requires continuous administration, the pharmacist on duty would decide if it is considered as "exceptional circumstances" and he/she will try and order from IPS Specials first as the OOP fees are much less, and if out of stock, then from Mymed, both of these charging out of pocket fees. It would be the pharmacist on duty's professional discretion to decide whether it is an exceptional circumstance and to order from IPS or Mymed (when all other normal suppliers are unable to supply) so that the patient's needs are met".

4.1.27 They go on to advise "*Apart from the already extraordinary circumstances created by Covid-19 and Brexit, pharmacies had to contend with other supply issues created by the normal wholesalers resulting in pharmacies having to find alternative routes of supply, such as;*

Quotas, where wholesalers restrict supply of medicines to a pharmacy, and once their quota was reached they stopped supplying, which meant we had to source from other suppliers.

Low Spend Surcharges, where if a pharmacy does not have sufficient stipulated monthly spend with a wholesaler, the pharmacy is penalised with a surcharge of hundreds of pounds. This results in the pharmacy using that wholesaler for SOLUS lines only thereby reducing the pharmacy's pool of suppliers to order other lines.

I am sure that after the period of shortages eased off and branded lines became more readily available, correspondingly the OOP claims have reduced drastically".

4.1.28 They specifically mention "*For Branch FL163 – Out of 85 lines, only 1 item was purchased over 10 times in the 12-month period. Fresubin is packed in 4's and some patients may have required odd quantity flavours which we could not split as we could not claim 'broken bulk'*."

4.1.29 The PAT responded to FL163 on 29th August 2023 to thank the contractor for their continued support and engagement. The PAT gave further context into

the length of the PPV exercise, including the discussions with working groups involving PAT, NHSE and CFA. The PAT went on to identify that NHSE wanted to give the contractor as many opportunities to provide as much insight into the circumstances surrounding the claims as the pharmacy could provide. PAT also advised that the pharmacy's previous engagement had also been considered within the review.

4.1.30 PAT would also like to highlight, that, although FL163 used supply issues caused by the Covid-19 Pandemic as part of their reasoning, the sample period under review for FL163 (February 2019 to January 2020) concluded before reports of the first occurrences of Covid-19 in the UK 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 therefore not relevant to this case and do not provide an accurate representation of the situation throughout the sample period in question.

4.1.31 Although PAT appreciate the engagement and information provided by Mansons Chemist PAT would also suggest that the circumstances expressed by FL163 would be the same for every pharmacy contractor when sourcing the same items and that therefore, there would be national trends within the data to support these arguments. However, the national data does not reflect this.

4.1.32 For the avoidance of doubt, NHSE and PAT recognise that OOPE claims are difficult to quantify and are subject to the unique circumstances of each pharmacy. However, the information provided by Mansons Chemist did not demonstrate how the claims met the cumulative conditions required before an OOPE claim should be considered.

4.1.33 After reviewing the data and information FL163 had provided alongside the National data, the PAT found that one item had been claimed on more than 12 occasions over the 12 months reviewed. The PAT had received no evidence or information from the contractor to support that these claims were not required to be frequently supplied, nor that these were exceptional circumstances. Therefore, after allowing the first 12 occasions of these claims for each item, PAT concluded that the contractor had received an overpayment of £632.00 for this item (8 claims).

4.1.34 The data also highlighted that FL163 were the only pharmacy nationally to submit OOPE claims for the following items:

4.1.34.1 Hyoscine hydrobromide 300microgram tablets

4.1.34.2 Fluocinolone acetonide 0.025% gel

4.1.34.3 Salofalk 1g/application foam enema

4.1.34.4 Marol 200mg modified-release tablets (Teva)

4.1.34.5 Tamsulosin 400migrogram Dutasteride 500microgram capsules

4.1.35 FL163 claimed OOPE on these items despite them being dispensed by a minimum of 500 other pharmacies on a minimum of 6,000 occasions without the need for an OOPE claim. Without evidence or information to identify what steps the pharmacy took to avoid incurring additional expenses when obtaining these items, it was determined that the five claims for these items were also unnecessary, and that the pharmacy had received an overpayment of £395.00 for these claims.

4.1.36 In addition to this, the contractor had previously highlighted that 1 claim for Ciclosporin 100mg capsules (£79.00) had been claimed in error and that one claim for Colecalciferol 1,000unit tablets had been overclaimed by £1.50. The contractor therefore identified that they had received an overpayment of £80.50 due to incorrect OOPE claims.

4.1.37 PAT therefore concluded that a total recommended recovery figure of £1,107.50 should be reclaimed for OOPE claims not meeting the three conditions of the Drug Tariff.

4.1.38 The PAT sent an email to the pharmacy on 27th June 2024 with these findings and the final NHSBSA recommended recovery figure. PAT provided both timelines of correspondence and the Data Overview (this has been provided to NHSR in addition to the representations). As outlined, this total was calculated from items claimed above the assurance activity parameters where no further evidence was provided, ultimately covering 8 separate items and 15 OOPE claims. Any further information the pharmacy wished to include in this referral was required to be submitted to PAT by 25th July 2024.

4.1.39 Mansons Chemist responded on 26th of July 2024 stating "*We are surprised that, 5 years on, you are expecting pharmacists working at the time to have made specific notes and circumstances for each item ordered. In a busy pharmacy where we dispensed approaching 100,000 items a year, this level of recording is neither practical nor in our terms of service in the DT. You have undertaken a desktop analysis of data 4- 5 years on, ignoring our evidence, explanations and circumstances on the ground at the time, and stating, in hindsight, that we should have predicted and stocked up on items that we have no control over, is not a sensible suggestion. We put to you that your analysis is totally flawed in its sampling and being one dimensional and does not prove that the evidence or basis of our claims is wrong*.

With reference to the purchase of Fresubin, it is impossible to predict if a split pack and a specific flavour will be used the following month let alone for the next 12 months (and there are 6 flavours). Very often patients are changed to other flavours or brand of drinks because they may not find one suitable and also it is often given to end-of-life palliative patients. Also, whilst these Fresubin scripts appear to be frequent, they were not regular. You are also falsely presuming and jumping to the conclusion, that because these scripts were frequent, that there cannot be a reason for an exceptional circumstances supply!"

4.1.40 Mansons Chemist also went on to state that most of the time they managed to order from normal suppliers, and so it was under exceptional circumstances they ordered elsewhere. In previous communications they outlined a SOP for the pharmacy where they would have tried 5/6 wholesalers before going to IPS or Mymed. Having stated they tried 5/6 wholesalers is, in their opinion, evidence they tried all reasonable steps to obtain drugs without the need to claim OOPE. Mansons also made the point that PAT had not supplied Mansons Chemist with evidence that they did not follow the SOP for ordering stock. They also stated that in previous years they had lost money on 'out of date' stock when anticipating the same items would be presented in following months, practically and financially the pharmacy is unable to hold excess stock of 6 different flavours for the nutritional drinks.

4.1.41 Mansons Chemist further mention scripts being directed away from their pharmacy and that they would bear a loss on this product due to not being able to claim any broken bulk on specific items. They also mentioned that other pharmacies bought up all available stock and created a shortfall in supply, and

that they have no-way of knowing what happened at the time. Mansons Chemist also stated that they do not know what evidence would be required to prove that after 4-5 years which items would be in stock from which supplier on which day. PAT appreciate all the factors mentioned and that at times during the period under review may have been a challenge, but this would be the same for all pharmacies and we do not see any trends in our data that other pharmacies were having such issues.

4.1.42 After reviewing all the details given from Mansons Chemist and reviewing all the NHSBSA data for the period under review, PAT were unable to validate the OOPE claims claimed by Mansons Chemist during the designated sample period, an amount to be recovered was calculated for the 8 items it was felt were not meeting those conditions, rather than every claim submitted by the pharmacy. However, Mansons Chemist did not accept the proposed recovery 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 conditions of the Drug Tariff or whether they felt the 8 identified items did not meet the cumulative conditions and therefore should be recovered under regulation 94 (1) (a) as an overpayment.

The PSRC decision

4.1.43 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 Provider Assurance team had with Mansons Chemist for review. These timelines have been provided to you in addition to this information.

4.1.44 The engagement showed that despite repeated requests by PAT, Mansons Chemist 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.

4.1.45 Consequently, the PSRC concluded that PAT had been unable to find any evidence to demonstrate that the 8 items (15 claims) claimed by Mansons Chemist between February 2019 and January 2020 met the requirements set out in the drug tariff for claiming OOPE. Following this conclusion, the PSRC determined that Mansons Chemist was not entitled to the payment made for which it had received.

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

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

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

4.1.48 Each of the points highlighted are conditions that need to be met before an OOPE claim should be submitted. For the 8 items (15 claims) highlighted in PAT's recommended recovery, Mansons Chemist have not provided any evidence to support that these conditions were met prior to submitting the claims.

4.1.49 FL163 state in their appeal "*your reasoning is flawed (your desktop hindsight statistical analysis is not taking account of the circumstances at the time)".*

They go on to suggest "We are surprised that, 5 years on, you are expecting pharmacists working at the time to have made specific notes and circumstances for each item ordered. In a busy pharmacy where we dispensed approaching 100,000 items a year, this level of recording is neither practical nor in our terms of service in the Drug Tariff." The PAT would contest this, as evidenced in the timelines which demonstrate that the first engagement with the pharmacy regarding the disputed OOPE claims began in November 2021; within a reasonable timeframe of the claims being submitted. Mansons Chemist had numerous opportunities to provide evidence and information surrounding the individual circumstances of the pharmacy at multiple stages as PAT wanted to give contractors additional opportunities to engage with the request.

4.1.50 As specified in the background section of this appeal, the Drug Tariff states that OOPE claims should only be submitted for items which are not required to be frequently supplied, only in exceptional circumstances and where the contractor has taken all reasonable steps to avoid claiming. PAT would suggest that any OOPE claims submitted by the pharmacy were the exception and therefore the definitive circumstances should be possible for the pharmacy to provide. Ultimately, PAT found that the information provided by the contractor did not support that, the claims in question, met the three conditions outlined in the Drug Tariff.

4.1.51 The pharmacy suggests the PAT "*have undertaken a desktop statistical analysis of data 4 to 5 years on, clearly ignoring our evidence, explanations, and circumstances on the ground at the time*." This is not correct. The PAT have engaged with the pharmacy on multiple occasions to gather all the essential information surrounding the circumstances of the claims, to then be reviewed alongside the national data and reach a conclusion. All information provided by the contractor has been considered by both the PAT and the NHSE PSRC. Both parties agreed that the contractor had not evidenced or provided information to support that the 8 items (15 claims) highlighted in the provided data overview, met the three conditions of the Drug Tariff.

4.1.52 In their appeal statement Mansons Chemist also state: "*Medicine shortages and supply issues because of Brexit and the Covid-19 pandemic*." However, as mentioned previously, 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. NHSE and PAT do not dispute the difficulties of running a busy pharmacy, 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.

4.1.53 FL163 state "*To suggest that with products like Fresubin drinks, which come in 6 different flavours, heavy and numerous in quantities prescribed, mainly for elderly, frail and often palliative patients and expensive, that we should keep all of this in stock shows how your comments are not practical and take no consideration of real-life circumstances. They would also occupy considerable space to store (space is at a premium in any pharmacy) and as these are delivered to the patients' home would require us to obtain them as a matter of urgency to coincide with the delivery times which are fixed thus ensuring that the patient does not go without their crucial daily energy and dietary nutrition.*"

4.1.54 Table 1
(excerpt from PAT Data Overview for FL163 – Mansons Chemist)

Item/Product	Fresubin 2kcal drink (6 flavours)
FL163 dispensed Occasion Total (19-20)	66
FL163 OOPE Claim Occasion Total (19-20)	20
National claims for the item	129
Number of pharmacies claimed for item nationally	17
Percentage of National claims made by FL163	15.50%
National Dispensed Occasion Total	84,950
Number of pharmacies who dispensed the item nationally	3,433

4.1.55 Above is an excerpt (Table 1) from the PAT's data overview that shows the 1 item, Fresubin 2kcal drink (6 flavours) that PAT have recommended for recovery as the data suggests the item was required to be frequently supplied. FL163 submitted OOPE claims for Fresubin 2kcal drink (6 flavours) on 20 occasions over the 12 months sampled. The claims submitted by Mansons Chemist account for 15.50% of the national claims for the item. It also shows that nationally, Fresubin 2kcal drinks were dispensed on 84,821 occasions by 3,416 pharmacies without any of these occasions requiring the pharmacies to submit an OOPE claim. Only 17 pharmacies nationally submitted 129 claims for this item; 20 of those were submitted by FL163.

4.1.56 While the pharmacy may not believe it is feasible to order these items in bulk due to their size, it is reasonable to question why only a small number of pharmacies incurred additional expenses when obtaining this item when the vast majority (99.5%) of pharmacies could stock the item without incurring additional expenses. The PAT are not suggesting that all OOPE claims are recovered for Fresubin 2kcal drink, instead, the first 12 occasions will be allowed and only the additional claims over the 12 occasions will be recovered. If the pharmacy encountered issues every month, it is realistic to expect the pharmacy to be able to demonstrate what reasonable steps were taken to avoid making claims repeatedly for this item throughout the year. However, the reasons provided, highlight the same issues which would appear in all pharmacies nationally, yet the data does not support this.

4.1.57 Mansons Chemist go on to state "*With reference to the purchase of Fresubin, it is impossible to predict if a split pack and a specific flavour will be used the following month let alone for the next 12 months (and there are 6 flavours). Very often patients are changed to other flavours or brand of drinks because they may not find one suitable and it is often given to end-of-life palliative patients. Also, whilst these Fresubin scripts appear to be frequent, they were not regular.*" It can be seen from the data provided that the pharmacy dispensed Fresubin 2kcal drink (6 flavours) on a regular basis; in every one of the 12 months under review, therefore PAT would argue that this item was, indeed, required regularly. FL163 have advised that "*over two thirds of the time we had managed to get the Fresubin from our normal suppliers and it was only under exceptional circumstances ordered from elsewhere*." If there were only specific flavours required at short notice which incurred additional charges, it would be reasonable for the pharmacy to stock some level of these on an ongoing basis especially as the Fresubin website states that the item has a shelf life of 12 months, if unopened. Given that the pharmacy has also stressed the importance of this item for end of life palliative patients, holding stock would therefore be paramount to the pharmacy dispensing the item in a reasonable timeframe to give the patients access to this vital source of nutrition. 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.

4.1.58 Mansons Chemist go on to detail their ordering process:

"as further proof that we first exhausted checking all our normal 6 wholesalers was (and is existing), is our use of an automatic ordering cascade software which checks stocks from all six main wholesalers one after the other until it finds the supplier that has the medicine and orders.

Most of the time one of the wholesalers would have the item, however, if all the wholesalers were out of stock, following the SOPs, the pharmacist would assess the urgency of supplying the medicine and take reasonable steps to avoid claiming. If the patient has some in hand and can wait, the pharmacist will continue ordering daily from all the normal wholesalers through the cascade software until the order is accepted by a wholesaler. If the patient has run out and is a medication that requires continuous administration

and is still not available from all the normal suppliers, the pharmacist on duty would decide if the circumstance at the time is considered as "exceptional" and he/she will then try and order from IPS Specials first as the OOP fees are much less, and if out of stock, then from Mymed."

4.1.59 The PAT appreciates the insight into the procurement of stock within the pharmacy, however, it is expected that only a small number of claims would be submitted not consistent claims for the same items. If patients are allowing medication to run out routinely, did the pharmacy educate the patients and advise that they allow appropriate time to collect medication before it has run out? This would give the pharmacy more time to obtain the item in a reasonable timeframe and reduce the chances of incurring additional charges to obtain items at short notice. If this was consistently happening, then PAT would argue that this reasoning does not meet exceptional circumstances, nor does it support that the pharmacy took reasonable steps to avoid claiming if they could have educated the patients to submit their prescriptions allowing for an appropriate window of time for the pharmacy to order in the stock prior to the patient's supply running out.

4.1.60 The pharmacy advise "*In previous years we have lost money on 'out of date' products that we purchased in anticipation that the same will be prescribed the following month. Practically and financially, we cannot hold excess stocks of 6 different flavours of a nutrition drink in sufficient quantities to fulfil scripts that we have no way of knowing that we will receive during the same month let alone next few months."* PAT would not expect the pharmacy to hold this level of stock, however, if there were specific flavours which were not prescribed as often and these are the items which incur additional charges, it would be reasonable for the pharmacy to hold some stock of those specific flavours. As identified previously, some prescriptions were for split packs and so wouldn't require as much stock and the pharmacy were dispensing this item in each of the 12 months, therefore it is likely that these would go on to be dispensed within the item's shelf life.

4.1.61 FL163 advise that "*There is also a situation of "prescription direction" from the then CCG to inform hospitals and doctors to send all prescriptions with nutritional supplements to Fresinus (Kabi UK), directly. This was another factor where we were no able to predict if we would receive prescription for these items*."

4.1.62 Mansons Chemist confirm their stance that "*these met ALL three conditions and would again challenge you to specify how it does not and how we could have overcome that! We therefore believe these were obtained in accordance with the DT conditions*."

4.1.63 The PAT disagrees with this conclusion. The pharmacy argue that they obtained Fresubin 2kcal drinks (6 flavours) through their mainline wholesaler, and only claimed OOPE in exceptional circumstances. However, as previously stated, PAT do not believe that these occasions were exceptional as the pharmacy claimed OOPE on this item in nine of the 12 months reviewed and dispensed it in all 12 of the months. PAT acknowledge that there may be times when the pharmacy did need to claim for this item. However, due to the frequency of the claims, the pharmacy should have looked for other solutions to obtain the item without incurring additional expenses on an almost monthly basis. This is not unreasonable, as the majority of pharmacies nationally were able to dispense this item without incurring additional costs and therefore claiming OOPE.

4.1.64 In reference to the recommended recovery for the five items highlighted in orange on the data overview, FL163 indicate that "over the 12 months in question, all 5 lines have only had OOP claim ONCE." Although these items only had one OOPE claim occasion, PAT has also taken other factors into consideration. These items have only been included as Mansons Chemist was the only pharmacy nationally out of over 10,000 pharmacies to submit an OOPE claim for these items. The same items were also dispensed by a minimum of 500 pharmacies on a minimum of 6,000 occasions to ensure that these were not unique items. For example, Tamsulosin 400microgram / Dutasteride 500microgram capsules were dispensed by 5,864 pharmacies on 109,413 occasions for the 12 months reviewed, this confirms that this item is readily available. Based on these figures this item was being dispensed, on average, 300 times per day nationally.

4.1.65 FL163 state "*The very slow pace and the passage of time at which this has been addressed is prejudicial to any pharmacy, as all the records, information and documents are now not available from the wholesalers." They then appear to contradict this when requesting "an extension of 90 days (we are now approaching Christmas holidays and the busiest time of the year), we can make further investigations to gather more evidence to support our appeal bearing in mind the circumstances explained in the previous paragraph*." PAT have already addressed the length of the review and the circumstances that contributed, primarily to ensure that the contractors, received a fair and consistent review. All throughout the process, FL163 has been updated with progress and the reasons behind any delays. However, PAT contest that that pharmacy receives an extension to carry out further investigations into their claims. The initial engagement began in November 2021, and the PAT have given the pharmacy extensive opportunities to provide the information. Ultimately, both PAT and NHSE PSRC concluded that the reasons provided by the contractor did not support the claims highlighted in the data overview and recommended for recovery due to the overpayment received.

4.1.66 For the avoidance of doubt, the PAT recognise that "*The DT does not provide either one of us with a definitive meaning nor examples of what is exceptional circumstances, frequently supplied or reasonable steps*", therefore, are open to the individual circumstances of each pharmacy. However, the information provided by Mansons Chemist is likely to be the same for every other pharmacy nationally dispensing the same items. None of the circumstances provided appear to be localised to FL163, and the national data supports that other pharmacies did not encounter these issues.

4.1.67 FL163 state "*The DT does not stipulate that records have to be kept of OOP supply with their "specific issues with specific items" as you are NOW requiring*." However, this advice was circulated in an education piece sent out via email to all pharmacy contractors in July 2020, shortly after the review

period and before the initial engagement. This is also confirmed on the Community Pharmacy England (CPE) website, in which the wording was in place prior to 2020 (formerly known as Pharmaceutical Services Negotiating Committee – PSNC).

4.1.68 Mansons Chemist explain "*There could be many reasons why other pharmacies do not make or have not made OOPE claims or can obtain the product without incurring OOPE. Other pharmacies may have different or no quotas. Large multiples are vertically integrated so their own "wholesaler" may have separate reserved allocations for their stores*."

4.1.69 Although the above factors could contribute to other pharmacies not needing to claim for OOPE on the same items, it is unlikely that the majority of other pharmacies dispensing the same items did have these systems or allocations in place. If they did, PAT then question how the majority of other pharmacies nationally are able to facilitate these allowances while Mansons Chemist could not.

4.1.70 The 2 claims made for Ciclosporin 100mg capsules and Colecalciferol 1,000-unit tablets were made in error, Mansons Chemist recommended recovery of these claims in their self-review. The further 5 items are where Masons Chemist makes up 100% of the National OOPE claims. 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.

4.1.71 With the information provided by the pharmacy, PAT have been unable to provide assurance that Mansons Chemist followed the requirements outlined in the Drug Tariff and that the claims discussed met the cumulative conditions listed in the Drug Tariff.

4.1.72 It is worth noting that the information provided by Mansons Chemist in their appeal, has already been considered by the PAT and PSRC in previous engagement. Therefore, the information provided in the appeal statement does not bring any new arguments to the case.

4.1.73 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
Fresubin 2kcal drink (6 flavours)	£632.00
Ciclosporin 100mg capsules	£79.00
Hyoscine hydrobromide 300microgram tablets	£79.00
Salffalk 1//application foam enema	£79.00
Marol 200mg modified-release tablets (Teva)	£79.00
Colecalciferol 1,000 unit tablets	£1.50
Tamsulosin 400microgram/Dutasteride 500 microgram capsules	£79.00
Total of PSRC Recovery	£1,107.50

4.1.74 NHSE and PAT maintain that the contractor has not provided sufficient evidence to support that the claims for the 8 items (15 claims) highlighted in the data overview met the conditions outlined in the Drug Tariff, so the decision

to recover £1,107.50 is correct. To reiterate, this amount includes £80.50 in which the contractor informed the PAT was claimed/paid incorrectly.

4.1.75 Key points for consideration

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

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

4.1.76.1.1 Claims were made only in 'exceptional circumstances'

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

4.1.76.1.3 The contractor took all reasonable steps to avoid claiming OOPE

4.1.76.2 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. Mansons Chemist did not provide any evidence to show how the three conditions were met. Consequently, the PAT were unable to assure NHSE that the claims identified as overclaims met the Drug Tariff requirements.

4.1.76.3 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 vast amount of time had passed since the sample period are not entirely accurate, as they had numerous opportunities to respond within a reasonable timeframe.

4.1.76.4 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.

4.1.76.5 The NHSBSA data does not corroborate the contractor's statement about supply concerns; there was no notable increase in OOPE claims nationally for the disputed item, Fresubin 2kcal drink (6 flavours), over the sample period.

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

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

4.1.76.8. The contractors' appeal provides no details specific for Mansons Chemist 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, we still consider that the OOPE claims are invalid under Part II, Clause 12 of the Drug Tariff, and an overpayment has been made.

4.1.77 Having considered these matters PAT and NHS England respectfully asks that NHS Resolution conclude that the decision made by the PSRC in respect of the £1,107.50 overpayment recovery from Mansons Chemist was fair and in accordance with the regulations."

4.2 The Appellant

4.2.1 "Please see attached a document I came across from the RPS which highlights the issues of supply and shortages locally and nationally."

4.2.2 Key Extracts from the Royal Pharmaceutical Society's Medicine Shortage Report [see Appendix A].

5 OBSERVATIONS

5.1 The Appellant

5.1.1 "Further to PAT's representations, I have the following comments for your consideration.

5.1.2 It would appear that PAT does not believe we tried sufficiently enough to obtain the said medicines without incurring OOPE.

5.1.3 I have clearly stated that our ordering cascade system looks at 6 major and local wholesalers and our pharmacy team would have tried numerous times to obtain these medicines using this cascade before the pharmacist on duty deemed it necessary to look to IPS and then Mymed.

5.1.4 Each wholesaler has their monthly minimum purchase targets (without penalties) and it would be impractical to have limitless numbers as PAT appears to think that 6 is not sufficient.

5.1.5 PAT also suggests that these items were possible to be sourced without giving us any evidence nor names of suppliers that we could have tried.

5.1.6 The fact that most of the time, apart from only these few situations, the pharmacy team had managed to obtain medicines from our wholesalers clearly shows that they had made every effort to get the medicines without claiming OOPE and only under exceptional circumstances did they use IPS or Mymed.

5.1.7 The 22 claims that PAT is referring to represents less than 0.025% of the items we would have ordered in that period.

5.1.8 The amount £1,107.50 represents 0.15% of our NHS payment for that period.

5.1.9 We have given PAT numerous reasons and explanations of why the claims were made, which they accept wholly and only contest one, yet they seem to want more without specifying what other assurances they require.

5.1.10 Covid, did impact greatly in that our pharmacy team and I were inundated with work and greatly hindered our investigation and ability to respond in a timely manner, as everyone was aware.

5.1.11 It would appear PAT does not understand or is ignoring the fact that when there are medicine supply issues, this can vary from one locality/region to another due to the various reasons already stated in my previous representations such as quotas and vertical integration (pharmacies owned by wholesalers). Pharmacies not claiming OOPE by simply not bothering to, not knowing how to, or endorsing prescriptions incorrectly could be other reasons why the NHSBSA do not have data on other claims from pharmacies.

5.1.12 This is the evidence and data that the PAT need to provide to substantiate their claim.

5.1.13 Relying only on national data and extrapolating, which is PAT's whole case and argument, can be misleading and inaccurate.

5.1.14 PAT's argument may hold if we were obtaining our medicines from a national pool rather than from local wholesaler depots and suppliers.

5.1.15 I believe we have followed the conditions as set out in the DT and provided the required evidence and explanations under which the supplies occurred."

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 the Appellant's comments regarding the medicine shortages report as provided with its representations. I note that, following the link as provided by the Appellant, it can be seen that the report was commissioned in January 2024, which is several years after the relevant period which these claims relate to. Whilst I do not dispute that there have been reported issues with regard to medicine shortages, I am of the view that the Appellant relying on this report without any further context is not helpful.

6.8 I note the NHS BSA reference to the Drug Tariff and that it has provided me with a link to the Drug Tariff webpage where back copies of the Drug Tariff from December 2019 through to the current Drug Tariff in place (March 2025) could be found. I further note that the Drug Tariff has not been disputed by the Appellant.

6.9 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."

6.10 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.

6.11 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*".

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

6.12.1 *"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)*

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

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

6.13 The NHSA BSA states that the Appellant falls into sample two "*Contractors with claims over £10,000 over a 12 month period from February 2019 to January 2020*" as the total OOPE for the Appellant for this period totalled £17,059.44.

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

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

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

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

6.15 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:

6.15.1 ***"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.*

6.15.2 ***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.*

6.15.3 ***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."*

6.16 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.

6.17 It is accepted by both parties that between November 2021 and July 2024 the pharmacy was contacted regularly by the NHS BSA. The NHS BSA contacted the Appellant reminding them of the deadlines and the Appellant engaged with the NHS BSA requesting extensions of time during both periods of engagement for them to provide the relevant information.

6.18 It is noted that the Appellant's pharmacy submitted 221 OOPE claims totalling £17,059.44 between February 2019 and January 2020, however it was determined by the NHS England Pharmaceutical Services Regulations Committee ("PSRC") that the overpayment to be recovered was for 15 claims totalling £1,107.50. This is in line with the NHS BSA's "frequently supplied items" category in that they allowed "*the first 12 occasions of these claims for each item"*. The NHSA BSA, after taking the frequently supplied items into account is of the view that the Appellant has received a total overpayment of £1,107.50.

6.19 I note that the period in question is from February 2019 to January 2020, I am therefore of the view that the relevant Drug Tariff would be dated February 2019 as this is the Drug Tariff which would have been in force at the beginning of the period to which the

OOPE claims relate. I note however that there is no back copy of the Drug Tariff for this period and therefore I am using the Drug Tariff dated December 2019 as this is the earliest Drug Tariff available which would have been in force during the period to which the OOPE claims relate.

6.20 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."

6.21 I note, in their representations, the NHS BSA states that there was 1 claim which had been claimed in error as well as another where the amount claimed was incorrect and that the overpayment of £80.50 had been included in the total recovery value of £1,107.50. The NHS BSA state that the other 15 claims were still to be considered as part of the OOPE claims recovery.

6.22 I note that the Appellant does not dispute the overpayment of £80.50. Therefore I consider that the NHS BSA should make the necessary arrangements for recovery of the monies in relation to this OOPE claim.

6.23 I have next moved on to consider the OOPE claims for "Fresubin 2kcal drink (6 flavours)" totalling £632.00. I note that there are other claims for other medicines, however these all appear to be one off claims and the Appellant has not provided information relating to these but has concentrated on the claims for the Fresubin drinks. I have therefore concentrated on the OOPE claims for "Fresubin 2kcal drink (6 flavours)" as these appear to make up the main part of the claim and it is for these that the Appellant has provided reasons as to why they have claimed OOPE.

6.24 In concentrating on the "Fresubin 2kcal drink (6 flavours)" 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:

6.24.1 That there are exceptional circumstances;

6.24.2 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;

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

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

6.25 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.

6.26 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.

6.27 I first consider exceptional circumstances.

6.28 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.

6.29 I note the comments from the Appellant with regard to the Covid-19 pandemic and the different working arrangements that were in place. Whilst I accept that the circumstances at the start of the pandemic could be considered “exceptional” I would expect that as these conditions persisted they would simply become the circumstances in which the pharmacy was operating.

6.30 I note however the comments from the Commissioner that the relevant period for PPV is February 2019 to January 2020 which was before the pandemic and the alternative working arrangements which were not issued until the Spring of 2020. Whilst the pandemic may have been a factor for some OOPE, the fact that the claims preceded the pandemic and the alleged supply issue, I am of the view that the Appellant is not able to rely on this in respect of its own OOPE claims, especially given that the relevant period (February 2019 to January 2020) was before the announcement of the pandemic in the Spring of 2020. Separately, whilst I appreciate the pandemic may have impacted on the Appellant’s ability to gather evidence to support its OOPE claims and respond to the NHS BSA in a timely manner, the pandemic has since passed and evidence has not been provided.

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

6.32 I have also not been provided with any information from the Appellant to rebut the NHS BSA’s assertion that the product “Fresubin 2kcal drink (6 flavours)” was “not required to be frequently supplied”. The Appellant makes reference to the 22 claims representing less than 0.025% of the total items ordered for this period, however OOPE does not look at the percentage of claims made out of the total items ordered. It is concerned with outliers for a particular item.

6.33 I note, from the information provided by the NHS BSA that over a 12 month period Fresubin was claimed as an OOPE in 9 of those months. I consider that this demonstrates that Fresubin was frequently supplied by the pharmacy during the relevant period. I note that I have not been provided with any information from the Appellant to demonstrate that this is not the case or that this could not be considered to be “frequently supplied”. Based on the information before me, I am of the view that “Fresubin 2kcal drink (6 flavours)” was frequently supplied during the period February 2019 to January 2020.

6.34 Finally, I note the third part of the claim for OOPE states “the contractor has taken all reasonable steps to avoid claiming”. The use of “reasonable” to qualify the steps to be taken means the Appellant is not required to do everything it possibly can to avoid

claiming OOPE. It does, however, mean that certain steps need to be taken. It will always be difficult to quantify exactly the extent to which a party must act to evidence taking reasonable steps. I note the statement from the Appellant that:

"Most of the time one of our normal 6 wholesalers would have the item, however, if all the wholesalers were out of stock, and following the SOPs, the pharmacist would assess the urgency of supplying the medicine and take reasonable steps to avoid claiming. If the patient has some in hand and can wait, the pharmacist will continue ordering daily from all the normal wholesalers through the cascade software until the order is accepted by a wholesaler. If the patient has run out and is a medication that requires continuous administration and is still not available from all the normal suppliers, the pharmacist on duty would decide if the circumstance at the time is considered as "exceptional" and he/she will then try and order from IPS Specials first as the OOP fees are much less, and if out of stock, then from Mymed."

6.35 I note that all of the OOPE claims in question were from MyMed and that no evidence has been provided by the Appellant as to why other suppliers were not available.

6.36 I note the comments from the Appellant with regard to "split packs" and being unable to predict if a specific flavour will be used the following month or within the next 12 months. However, I note the comments from the NHS BSA with regard to the shelf life of Fresubin as well as the comments that it is used for palliative care patients. I consider that it would have been prudent for the Appellant to order additional stock when supply was available. Whilst I note the comments from the Appellant with regard to storage space, I can see no reason why additional packs were not sought as an OOPE claim so as to reduce costs when the Appellant considered there to be a supply issue. Given the frequency of the claims, I consider that this was not done, despite it being reasonable. I do not consider that either of these actions are suggestive of all reasonable steps being taken to avoid claiming.

6.37 I note the comments from the Appellant with regard to comparing its pharmacy to the national figures, however I am of the view that the NHS BSA has to have some kind of benchmark with regard to the OOPE.

6.38 Turning to the remaining items listed at 4.1.34 that are part of the OOPE overpayment, the onus is on the Appellant to satisfy the requirements of the Drug Tariff to be entitled to payment. The Appellant has provided no evidence that the claims meet the criteria for payment.

6.39 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 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. I also note the comments from the Appellant "*The DT does not stipulate that records have to be kept of OOP supply with their "specific issues with specific items" as you are NOW requiring."* However, I am mindful that the Appellant was first contacted in November 2021 and therefore I am of the view

that the Appellant was aware from this date that they were subject to a PPV. The Appellant should therefore 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 £1,107.50.

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