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

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

5 June 2025

REF: SHA/26531

APPEAL AGAINST NHS ENGLAND DECISION TO RECOVER AN OVERPAYMENT FROM SIMMONS PHARMACY (FLH33) ("THE APPELLANT")

1 **Outcome**:

1.1 I dismiss the appeal and confirm the decision of NHS England to recover the overpayment of £11,613.00.

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:

Simmons Pharmacy (FLH33)
NHS BSA on behalf of NHS England

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

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

SHA/26531

APPEAL AGAINST NHS ENGLAND DECISION TO RECOVER AN OVERPAYMENT FROM SIMMONS PHARMACY (FLH33) ("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 24 January 2025 in respect of Simmons Pharmacy (ODS code FLH33). 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 147 OOPE claims totalling £11,613.00 met the three conditions for claiming OOPE, as outlined in the Drug Tariff. It was therefore our recommendation that an overpayment had been received as a result.

2.5 This recommendation, along with the two timelines of correspondence with FLH33 were passed to the NHS England local Pharmaceutical Services Regulations Committee (PSRC) to consider whether further action was necessary. Due to size limitations, you will also receive a link to access the second timeline via Egress.

2.6 To access the second timeline, which covers the 2023-2024 period, please follow the link within the email which will originate from workspace@egresscloud.com. Please use your pharmacy.flh33@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 your reference.

2.7 Please also check any 'Junk' folders. If you have any issues accessing the timeline, please contact us at pharmacysupport@nhsbsa.nhs.uk.

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

2.8.1 FLH33 – Simmons Chemist submitted (335) Out of Pocket Expense claims, totalling (£25,790.29) between February 2019 and January 2020.

2.8.2 FLH33 – Simmons 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.

2.9 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.

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

Number of Claims	Total Recovery Value
147	£11,613.00 deduction

2.11 **Action Required**

2.12 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 23rd February 2025.

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

2.14 If you have any concerns regarding the deduction or would like to discuss an alternative approach to recovering the overpayment, please contact us by 23rd February 2025.

2.15 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.

2.16 Please be aware that failing to contact us by 23rd February 2025 to agree that there has been an overpayment DOES NOT mean that the overpayment cannot be recovered. Instead, where you do not agree that an overpayment has been made you have a right of appeal to the Secretary of State against NHS England's decision. Should you choose to appeal then send a concise and reasoned statement of the grounds for your appeal within 30 days of the date of this letter to nhsr.appeals@nhs.net or:

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

2.18 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.

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

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

3 THE DISPUTE

In an email dated 23 February 2025 addressed to NHS Resolution, the Appellant appealed against NHS England's decision. The grounds of appeal are:

3.1 "NHSBSA PAT's reasoning is flawed (their desktop hindsight statistical analysis is not taking account of circumstances at the time).

3.2 Please also refer to our previous responses dated 16th August 2023 and 23rd September 2024 (both attached), to save us repeating everything again.

3.3 We have highlighted some of the circumstances below to be contributing factors to the claims which PAT have noted and Accepted:

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 Supply of 'branded generics' can be very unreliable and even availability can be inconsistent from one region of the country to another even if same wholesaler.

3.3.3 Urgency of the requirement for an item.

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

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

3.3.6 Shortages due to restricted supply of medicines due to wholesale quotas.

3.3.7 Low spend surcharges and wholesale quotas on medicines.

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

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

3.3.10 Staff resource due to sickness.

3.3.11 Contractual obligation to dispense items reasonably promptly to patients.

3.4 We are surprised that, 5 years on, the NHSBSA 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 They have undertaken a desktop National statistical analysis of data 4 to 5 years on, clearly ignoring our evidence, explanations and circumstances on the ground at the time.

3.6 Furthermore, NHSBSA have not engaged with us during this period, nor suggested where we may obtain the relevant medicines from, nor made any suggestions of how our ordering could have been improved!

3.7 There are 7 items that they are looking to recover OOPE claimed. From them, 2 are branded generics (Sukkarto and Monomil) and 1 is EpiPen where there was well-documented evidence of National shortages and the MHRA even authorised extension of expiry dates to try and overcome the supply issue (see attached notice).

3.8 It is also important to bear in mind that these medicines are of vital importance and patients need to take regularly and cannot be without.

3.9 Regarding Sukkarto (for diabetes), over the 12-month period of the 403 occasions we dispensed, we claimed OOPE 144 times (36%). 259 occasions ordered from normal wholesalers.

3.10 Regarding Monomil (for angina and heart), of the 60 occasions, we claimed OOPE 14 times (23%). 46 occasions ordered from normal wholesalers.

3.11 Regarding EpiPen (for emergency anaphylaxis), of the 27 occasions, we claimed OOPE 17 times (63%), 10 occasions ordered from normal wholesalers, and;

3.12 Regarding Dabigatran, of the 51 occasions, we claimed OOPE 17 times (33%), 34 occasions ordered from normal wholesalers.

3.13 That we should have predicted and stocked up on items such as Sukkarto and Monomil, that we have no control over, is not a sensible suggestion.

3.14 We put to you that your statistical analysis, methodology and assumptions (not evidence) is totally flawed in its sampling and being one dimensional and does not look at circumstances on the ground and does not prove that the evidence or basis of our claims is wrong.

3.15 Bulk ordering and stocking of these lines was not the solution and not a reasonable option.

3.16 Government guidelines were that pharmacies should not hoard stocks of problem lines (although I am sure many did).

3.17 Also, prescribing patterns change without warning. Prescribing of Sukkarto dropped significantly and subsequently over 97% of the scripts are changed and written generically as Metformin MR 500mg tablets.

3.18 It would be very helpful if the NHBSA/NHSE could have suggested at the time or even now, how we could/can overcome this or is the NHSBSA saying that we should have gone against government guidelines?

3.19 Dabigatran was new and only available as the brand Pradaxa which was stocked by only 1 or 2 wholesalers (due to the restricted distribution agreements that manufacturers have) and they also operated quotas of only supplying 3 a month to us, if they had them in stock.

3.20 Regarding the others 3 lines (in orange) that the NHSBSA want to recover OOPE, we claimed OOPE only once over the 12-month period.

3.21 This clearly indicates that the NHSBSA PAT's approach to this whole verification process is defective as it does not consider the OOPE claim individually and adopts a broad-brush approach which does not consider the various complex circumstances in play. It does not look at any other mitigating factors such as the ones already explained like limited stock in local depots, differing quota restrictions, shortages, vertical integration of multiples etc.

3.22 From the spreadsheet data that the NHSABSA [sic] has provided, of the nearly 60 lines, there is no explanation of methodology or reasoning provided of why these 7 lines are picked to reclaim the OOPE.

3.23 As explained in previous emails, the pharmacists had clearly followed our SOP's which is why most of the time we were able to obtain the stocks from our main suppliers as indicated above from the NHSBSA data.

3.24 Our electronic ordering cascade system (which is operational currently too) which checks live stocks was further proof that we would have first exhausted checking and ordering from all our normal 8 wholesalers, one after the other until it finds the supplier that has the medicine and orders.

3.25 Most of the time, as indicated above, one of the wholesalers would have the item, however, if all 8 of 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 from IPS, then from Mymed.

3.26 I am sure they would agree that it is exceptional circumstances if none of the 8 main wholesalers have the medication available.

3.27 I would also say that having 8 normal wholesalers (which is more than what most pharmacies have) is more than sufficient to indicate that we always take reasonable steps to obtain medicines without claiming OOPE.

3.28 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 are not getting their vital medicine or when will they have their medication as they will be running out, especially due to patients not wanting to venture out or too far even after the Covid pandemic.

3.29 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. Prescribing teams or doctors would without notice, change from prescribing branded generics to just generics and visa [sic] versa. Practically and financially, we cannot hold excess stocks of lines such as Sukkarto as we have no way of knowing what we will receive during the same month let alone next few months.

3.30 I would say that these actions and circumstances met ALL three conditions as laid out in the DT and would again challenge you to specify how it does not and how we could have overcome that!

3.31 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.

3.32 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.

3.33 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".

3.34 NHSBSA 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.

3.35 **DT - CLAUSE 12 OUT OF POCKET EXPENSES**

3.36 *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 VIIID, 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**. An exception to this will be made for Cefuroxime 5% preservative free eye drops, for which there will be an additional fixed out-of-pocket expense payment of £50 automatically applied without the need for any 'XP' or 'OOP' endorsements. This payment will also be retrospectively applied to all prescriptions for this item dispensed between the months of April 2023 to February 2024. Other applicable fees and allowances will continue to be paid as usual.*

3.37 The DT does not intentionally provide us with a definitive meaning nor examples of what is exceptional circumstances, frequently supplied or reasonable steps. One can only conclude that these unquantified expressions are deliberate by those drafting the DT to enable specific circumstances to be considered and implemented according to the pharmacist's professional judgement. I can only presume this is why the NHSBSA PAT are unable to provide specific reasons why they think we have not met the 3 DT conditions.

3.38 Therefore, these conditions should be given their everyday meaning, and the DT is expecting the pharmacist to use his/her professional judgement in line with the DT and SOPs to make decisions based on the specific circumstances at the time.

3.39 We have complied with the DT with what evidence is required. The DT does not stipulate that records (apart from invoices) must be kept of each OOP supply with their "specific circumstances and evidence" as the NHSBSA PAT are requiring.

3.40 We have provided the PAT with sufficient evidence as is required in the form of invoices (which we have paid) and numerous factual plausible explanations of why the pharmacists in question (and there were numerous over the year), following our SOPs, had to resort to obtaining medications which entailed paying OOPE.

3.41 The NHSBSA have not raised any questions on these and have therefore accepted them.

3.42 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!

3.43 Sending us statistics comparing with National figures and the assertions and extrapolation process that has 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 and specific reasons why.

3.44 There are many reasons why other pharmacies nationally do not make or have not made OOPE claims or can obtain the product without incurring OOPE.

3.45 Other pharmacies may have different or no quotas with wholesalers.

3.46 Large multiples are vertically integrated so their own "wholesaler" may have separate reserved allocations of problem stocks for their stores.

3.47 Branded generics are made by smaller pharmaceutical companies, and supply can be very unreliable, and availability can be inconsistent from one region of the country to another even from depots of the same wholesaler.

3.48 Other pharmacies may have simply not endorsed their script(s) to claim OOP or may have endorsed the script(s) incorrectly and therefore not get paid. This would then not show up in the data supplied.

3.49 None of these reasons have been refuted by the NHSBSA and nor has any evidence been forthcoming from the NHSBSA that there were no supply issues.

3.50 Our primary concern was patient safety and patient welfare and ensuring that they received their medications promptly, especially during the pandemic. We make every effort to obtain medications for patients which other pharmacies may not, and they ask their patients to try elsewhere, some ending up at our doorstep.

3.51 The NHSBSA PAT have presented national data statistics and made this very general and sweeping statements with assumptions without looking at each pharmacy's individual circumstances and providing the evidence that directly relates to our claims.

3.52 And they are relying only on these broad national statistics to claim that we have not followed the DT conditions, and this too is flawed as explained.

3.53 The NHSBSA has not refuted any of our 11 or so contributing factors, and we have continually asked the PAT team to let us know why they 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 and saying they do not believe we followed them?

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

3.55 Proactive communication from the NHBSA [sic], CCG etc would have resolved these issues efficiently and saved us all this time, effort and resources 4 to 5 years on."

Letter to NHSBSA dated 16 August 2023

3.56 " You have asked us to confirm whether:

3.56.1 That the OOPE claims made between February 2019 and January 2020 period were claimed correctly and met all 3 conditions outlined in the Drug Tariff, Part II Clause 12; and that you have all the evidence in support of all of the claims identified.

3.57 The claims between February 2019 and January 2020 were correctly claimed and met all 3 conditions. We have submitted all the required evidence (as invoices) that were provided to you in February 2022.

3.58 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 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 .me, to talk to them and see if they remember/recollect the circumstances, etc.

3.59 You have not engaged with us prior and have provided no evidence or proper basis for asserting that the conditions were not met. The DT does not provide us with a definitive meaning or examples of exceptional circumstances. Can you kindly give us the interpretation of "exceptional circumstances". The assertions that have been made are unhelpful and wrong. It is not appropriate to simply say that you think that we have not followed the DT conditions, without setting out plausible reasons why. If there is any aspect of the claims or explanations that you are not sure about, please let us know and also why you think our explanations are not plausible and therefore what additional steps we should have taken within our contractual framework.

3.60 We have been providing pharmaceutical services efficiently and promptly with full duty of care to our local communities for 41 years. We are fully aware that our ordering of medicines has to be prudent not only for the effective running of the pharmacy but also because it brings DT prices down and saves the NHS money on drugs.

3.61 Our pharmacists and staff follow our Standard Operating Procedures. The pharmacist would order ethical items firstly from all our normal mainline wholesalers. Most of the time one of the wholesalers would have the item, however, if all the wholesalers were 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 normal wholesalers until in. 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 circumstances at the 2me 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. Less than 0.05% of the items are sourced from IPS and Mymed. It would be down to the pharmacist on duty’s professional judgement to decide whether it is an exceptional circumstance and to try and order from IPS or Mymed so that the patient’s needs can be met.

3.62 The NHSBSA cannot take a period in isolation and perform a desktop exercise, as it has appeared to do here. The reality and circumstances facing pharmacies with the supply of medicines during this period must be taken into consideration. Medicine shortages varied from item to item and lasted for not just a month or two but for many months. Medicine shortages existed well before 2019 but it started coming to the fore around this .me as illustrated by the sample of national articles below;

3.63 https://www.theguardian.com/politics/2019/apr/09/brexit-medicine-shortages-pharmacies-england

3.64 The Pharmaceutical Journal. ‘Confidential government documents reveal names of 209 medicine shortages in 2019’.

3.65 ‘Brexit ‘already causing medicine shortages’ at pharmacies in England’ April 2019

3.66 ‘Britain's 'unprecedented' drug shortage’ November 2019 https://www.bbc.co.uk/news/health-50465563

3.67 ‘Revealed: UK patients stockpile drugs in fear of no-deal Brexit’ January 2019

3.68 https://www.theguardian.com/politics/2019/jan/18/revealed-uk-patients-stockpile-drugs-in-fear-of-no-dealbrexit

3.69 https://www.clinigengroup.com/direct/en/insights/tackling-a-new-decade-of-medicine-shortages/

3.70 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;

3.70.1 Quotas, where the solus wholesaler restricted supply of medicines to a pharmacy, and once their quota for the month was reached they stopped supplying, which meant we had to source from other suppliers. The quotas are set arbitrarily and could be as low as zero or very low figures so if we started receiving more prescriptions (from other pharmacies too) for the same item, such as Dabigatran 110mg, we would have no choice but to try other smaller suppliers.

3.70.2 Low Spend Surcharges, where if a pharmacy does not purchase a stipulated amount monthly 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.

3.71 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.

3.72 You have given us an example where, over a period of 12 months, the pharmacy dispensed Colecalciferol (Vitamin D3) 800iu capsules on a total of 173 occasions and an OOPE claim was made against this item 56 times.

3.73 Similarly, Sukkarto SR 500mg tablets were dispensed 403 times against which 144 OOPE claims were made.

3.74 This would clearly illustrate that these items were first ordered from the normal wholesalers and available around two thirds of the time. Only when these items became unavailable from ALL our normal wholesalers that the pharmacist on duty, deemed it absolutely necessary to try from IPS first, then Mymed. This also illustrates that when there are supply issues, availability becomes very unreliable and inconsistent. Bulk ordering of these lines was not the solution and not a reasonable option, firstly, 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. For instance, Sukkarto SR 500mg tabs is prescribed as a branded generic, which could have changed overnight to the actual generic Metformin MR 500mg tablets leaving us with dead stocks of Sukkarto and a big financial loss. This is precisely what has happened as current data will corroborate how scripts for Sukkarto are a fraction of what was being prescribed before and most are now of the generic Metformin MR 500mg.

3.75 It is important to note that we are not in control of what scripts come through our door so stocking up at a possible financial loss to us is not reasonable. Nor is the option of obtaining stock from other different suppliers as in reality no supplier will want to open an account if the pharmacy does spend enough with them every month and this could be in the region of minimum £5,000 plus vat every month.

3.76 As you can see there are numerous factors to consider when purchasing medicines and many are not straightforward especially when compounded with shortages, restrictions, price increases, Covid, Brexit, reduced staff resources due to sickness etc. In each case, all reasonable steps are taken to source the problem medicine in the most efficient and cost-effective manner. Sourcing medicines from non-regular suppliers such as IPS and Mymed was neither of these, so the pharmacist on duty would have ordered these only if absolutely necessary and in exceptional circumstances.

3.77 On reviewing your appendix spread sheet (identifying less than 0.05% of the total items dispensed), over the 12 month period, the majority of the items have been ordered on average less than one a month and most of these are only one to three times in a whole year on average. Hardly an excessive number of times!

3.78 This too clearly illustrates that we had to order these items and incur a charge because we have not been able to access the medicines through our normal suppliers. With this:

3.78.1 a) In respect of Dabigatran 110mg capsules, our main line wholesaler provided a return message after ordering stating that our “MONTHLY QUOTA EXCEEDED”.

3.78.2 b) In respect of Monomil XL 60mg, which was ordered on 14 occasions, AAH provided a return message stating that “MANUFACTURER CANNOT SUPPLY”

3.79 In our view, without a clear definition, “exceptional circumstances” must be seen in the context of the pharmacy model and the actual day-to-day pharmacy workings and

being in direct contact with patients, their situation and their own expectations: our contractual obligation is to dispense medicines reasonably promptly to patients, who have been prescribed medications by a healthcare professional. If there is a risk of patient harm by not being able to dispense the medicine(s) as expected and in reasonable time due to supply issues, quotas or other restrictions, there plainly exists exceptional circumstances, and we have to source the medicines from other licensed suppliers. We could fall foul of our obligation if we did not supply the medicine if we knew it was available from elsewhere.

3.80 If the NHSBSA PAT still feels that we did not take reasonable steps to avoid claiming at the time, we would be glad to hear what they think we should have done 4 years ago under those circumstances!"

Letter to NHSBSA dated 23 September 2024

3.81 "You have asked us to confirm whether the OOPE claims made between February 2019 and January 2020 period were claimed correctly and met all 3 conditions outlined in the Drug Tariff, Part II Clause 12; and that you have all the evidence in support of all the claims identified.

3.82 The claims between February 2019 and January 2020 were correctly claimed 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.

3.83 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.

3.84 Your latest email requiring more information dated 8 July 2024 was some 11 months after our response of the 21 August 2023.

3.85 I again ask.

3.86 You have not engaged with us prior and have provided no evidence or proper basis for asserting that the conditions were not met.

3.87 The DT does not provide us with a definitive meaning or examples of exceptional circumstances, frequently supplied nor reasonable steps. Therefore, they should be given their everyday meaning. the DT is expecting the pharmacist to use his/her professional judgement in deciding depending on the specific circumstances on the ground and there can be numerous. 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!

3.88 Sending us statistics comparing with National figures and the assertions that have been made 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. There could be many reasons why other pharmacies do not make OOPE claims or can obtain the product without incurring OOPE. If there is any aspect of the claims or explanations that you are not sure about, please let us know and why you

think our explanations are not plausible and therefore what additional steps we should have taken and within our contractual framework.

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

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

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

3.90.2 Urgency of the requirement for an item.

3.90.3 Medicine shortages and supply issues as a result of Brexit and the Covid-19 pandemic.

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

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

3.90.6 Low spend surcharges, wholesale quotas.

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

3.90.8 Prescribing patterns changing (e.g. branded generic items changing to generic items and visa [sic] versa), Therefore not reasonable to bulk order these items.

3.90.9 Staff resource due to sickness.

3.90.10 Contractual obligation to dispense items reasonably promptly to patients.

3.91 One aspect of our ordering system not mentioned before but is of importance as further proof that we first exhausted checking all our normal EIGHT wholesalers was (and we still use), an automatic ordering cascade software which checks stocks and orders from all eight wholesalers one after the other until it finds the supplier that has the medicine.

3.92 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 a "exceptional" and he/she will then try and order from IPS Specials first as the OOPE fees are much less, and if out of stock, then from Mymed.

3.93 The pharmacist has also to bear in mind that his contractual duty is to dispense items reasonably promptly if available to patients.

3.94 Less than 0.05% of the items were sourced from IPS and Mymed. It would be down to the pharmacist on duty's professional judgement to decide whether it is an exceptional

circumstance (as no specific definition given in the DT) and then try and order from IPS or Mymed so that the patient's needs can be met.

3.95 The above ordering process working is evident from your own spreadsheet figures of the problem lines.

3.96 Of the top "recommended recovery" lines, 65% of the time the item was received from one of our 8 main wholesalers.

3.97 The rest of the main 3 "recommended recovery" lines, we had managed to get between 77% to 37% of the time from our 8 wholesalers.

3.98 Not only does this show that we only looked elsewhere when none of the 8 wholesalers had it in stock, but that over that year, stocks were in and out, and we had no way of gauging if or when all the wholesalers would be running out of stock.

3.99 If 8 wholesalers were not able to supply, then this would amount to be exceptional circumstances.

3.100 What else would you have expected us to do?

3.101 Sukkarto SR 500mg tabs is prescribed as a branded generic, which local prescribing teams could have changed overnight to the actual generic Metformin MR 500mg tablets leaving us with dead stocks of Sukkarto and a big financial loss. This is precisely what has happened now as current data will corroborate how scripts for Sukkarto are a fraction of what was being prescribed before and most (probably over 95%) are now of the generic Metformin MR 500mg.

3.102 Also, being a branded generic not all wholesalers stocked the line. As mentioned, supply of branded generics can be very unreliable because they tend to be manufactured by small pharmaceutical companies, and they don't get the supply and demand correct as GP prescribing can be unpredictable and at the whim of the local prescribing team.

3.103 Bulk ordering of these lines was not the solution and not a reasonable option, firstly, 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. Could the NHBSA/NHSE suggest how we could have overcome this?

3.104 In your email you interchange the words regular basis with frequently to mean the same. The DT states "frequently" meaning receiving often, or repeatedly or at short notice. Regular would mean receiving at consistent planned intervals. The scripts were not regular and predictable.

3.105 You also seem to imply that because they were frequent, they cannot be exceptional. If this was the case, it would have been given a quantifiable meaning in the DT.

3.106 Of the total of 7 "recommended recovery" lines by the NHSBSA, 3 have only been claimed once in the 12 month period.

3.107 It is plain to see from the spreadsheet received, that in the period between February 2019 and January 2020, our main supply issue was with only 1 line over the year.

3.108 Our three replies to NHSBSA, we have clearly explained why the claims are correct and met all 3 conditions outlined in the Drug Tariff, Part II Clause 12."

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 28th of February 2025 and the opportunity to provide representations on the appeal.

4.1.2 **Background**

4.1.3 An Out of Pocket Expenses (OOPE) endorsement enables community pharmacy contractors to claim payment, where in exceptional circumstances, the contractor has incurred expenses in obtaining eligible products and where the product is not required to be frequently supplied by the contractor.

4.1.4 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.

4.1.5 Part II, Clause 12 of the Drug Tariff sets out the 3 conditions which must be met when submitting a claim for OOPE:

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

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

4.1.7.1 Part VIIIA Category C

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

4.1.7.3 Part IXB

4.1.7.4 Part IXC

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

4.1.8.1 Postage and Packaging

4.1.8.2 Handling

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

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

4.1.10 **February 2019 – January 2021 OOPE PPV**

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

4.1.12 The Counter Fraud Authority (CFA) also raised concerns around how the allowance was being claimed by a small number of pharmacy contractors following these high-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.

4.1.13 PAT began the assurance activity by reviewing OOPE claims over a two-year period, from February 2019 to January 2021. To define and limit the scope of 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:

4.1.13.1 Contractors with claims over £10,000 in both years were reviewed over a 24-month period February 2019 to January 2021 (referenced as Sample One)

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

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

4.1.14 Simmons Chemist was included in Sample Two which covered February 2019 to January 2020 as their total reimbursement for OOPE claims for the period was £25,790.29.

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

4.1.15.1 Claims were made only in 'exceptional circumstances'.

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

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

4.1.16 NHSE and PAT understood that these 3 conditions were cumulative conditions and that each needed to be met for an OOPE to be considered valid. However, the PAT also recognised that the 3 conditions were not quantified and were therefore subject to individual circumstances for each pharmacy. This therefore required contractor engagement in the assurance activity and an opportunity for them to provide information and detail in support of their submitted OOPE claims.

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

4.1.18 As part of the proposed reengagement, it was decided that the PAT would also show a recommended recovery value for any items which fell into the below categories, as the data did not suggest that the items warranted the OOPE claims; these were:

4.1.18.1 **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.

4.1.18.2 **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.

4.1.18.3 **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.

4.1.19 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 Simmons Chemist with an overview, containing all the pharmacy's claiming data, alongside the national data.

4.1.20 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 Feb 2022 while the following phase lasted from July 2023 to September 2024. The goal of the engagement was for the contractor to show that they had evidence to support their claims or agreed to the proposed recovery. If neither was achieved, the case details would then be passed to the NHS England regional team for their Pharmacy Services Regulations Committee (PSRC) to review for a final decision on whether the claims met the DT tests for claiming OOPE, and if not to recover the overpayments from the contractor.

4.1.21 **Simmons Chemist – Individual Contractor Timeline**

4.1.22 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.flh33@nhs.net) as required by NHSE. PAT also shared correspondence with the following email addresses simmons.pharmacy@nhs.net and patelnx4@aol.com at the request of the contractor.

4.1.23 During the initial phase of correspondence, the intended deadline for Simmons Chemist to complete the required OOPE self-review was January 31st, 2022. Follow up emails were sent to Simmons Chemist on the 26th of November 2021, 15th December 2021 and the 10th of January 2022 reminding them of the deadline. Simmons Chemist responded on the 13th of February 2022, after the initial deadline, with a completed self-review. PAT sent an email to the contractor on 15th February 2022 to advise the information would be reviewed and they would be contacted if any further action was required.

4.1.24 PAT emailed the pharmacy on the 1st of December 2022 [sic] apologising for the delay and advising the PAT were reviewing the information with NHS England.

4.1.25 During the second phase of engagement, Simmons 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 Meera, the pharmacy manager, was made on the 31st of July 2023 and she advised that she would look into it could we send the email to simmons.pharmacy@nhs.net. PAT forwarded the email onto the email provided. On the 17th of August 2023 PAT emailed the contractor with a reminder to complete the review by the 31st of August 2023.

4.1.26 Simmons Chemist responded on the 21st 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.

4.1.27 In their response on 21st August 2023, Simmons Chemist state "*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 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 .me, to talk to them and see if they remember/recollect the circumstances, etc*.

4.1.28 The PAT responded to FLH33 on 6th September 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.

4.1.29 FLH33 state "*Our pharmacists and staff follow our Standard Operating Procedures. The pharmacist would order ethical items firstly from all our normal mainline wholesalers. Most of the time one of the wholesalers would have the item, however, if all the wholesalers were 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 normal wholesalers until 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 circumstances 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. Less than 0.05% of the items are sourced from IPS and Mymed. It would be down to the pharmacist on duty's professional judgement to decide whether it is an exceptional circumstance and to try and order from IPS or Mymed so that the patient's needs can be met."*

4.1.30 In the 6th September response, PAT went on to address the frequency of items, using Sukkarto SR 500mg tablets as an example, 164 claims were submitted nationally for the item, FLH33 contributed to 144 of those. Therefore the 20 additional claims were submitted by only 11 other pharmacies, at an average of 1.82 occasions for the other pharmacies. This is drastically different from the 144 FLH33 submitted. Therefore, the item was required frequently. The pharmacy gave the above explanation of their ordering process; however, it doesn't show how their circumstances were any different to the other pharmacies claiming OOPE on significantly less occasions. Nor does it support what additional measures were taken to avoid claiming.

4.1.31 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".

4.1.32 PAT would also like to highlight, that, although FLH33 used supply issues caused by the Covid-19 Pandemic as part of their reasoning, the sample period under review for FLH33 (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.

4.1.33 Although PAT appreciate the engagement and information provided by Simmons Chemist PAT would also suggest that the circumstances expressed by FLH33 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.

4.1.34 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 Simmons Chemist did not demonstrate how the claims met the cumulative conditions required before an OOPE claim should be considered.

4.1.35 After reviewing the data and information FLH33 had provided alongside the National data, the PAT found that four items had been claimed on more than 12 occasions over the 12 months reviewed. The PAT had received no evidence or information from the contractor to support that these claims were not required to be frequently supplied, nor that 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 £11,376.00 for these items (144 claims).

4.1.36 The data also highlighted that FLH33 were the only pharmacy nationally to submit OOPE claims for the following items:

4.1.36.1 Estradiol 1mg/Norethisterone acetate 500microgram tablets

4.1.36.2 Macrogol compound oral liquid NPF sugar free

4.1.36.3 Lacosamide 200mg tablets

4.1.37 FLH33 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 or outlined how they differed from other pharmacies claiming for the item without the need for OOPE claims, it was determined that the three claims for these items were also unnecessary, and that the pharmacy had received an overpayment of £237.00 for these claims.

4.1.38 PAT therefore concluded that a total recommended recovery figure of £11,613.00 should be reclaimed for OOPE claims not meeting the three conditions of the Drug Tariff.

4.1.39 The PAT sent an email to the pharmacy on 8th July 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 7 separate items and 147 OOPE claims. Any further information the pharmacy wished to include in this referral was required to be submitted to PAT by 5th August 2024 prior to it being referred to PSRC for consideration.

4.1.40 FLH33 responded on the 5th of August 2024 asking for a 14-day extension due to being on annual leave the date PAT sent the initial email. PAT emailed on the 6th of August 2024 granting the extension until the 21st of August 2024.

4.1.41 FLH33 responded on the 20th of August 2024 asking for a further extension until the 23rd of September 2024. PAT emailed on the 21st of August also granting the extension until the 23rd of September 2024.

4.1.42 Simmons Chemist responded on the 24th of September 2024 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. In their email, they provided any further information they wished to be considered by PSRC.

4.1.43 Simmons chemist also states that *"The DT does not provide us with a definitive meaning or examples of exceptional circumstances, frequently supplied nor reasonable steps. Therefore, they should be given their everyday meaning. the DT is expecting the pharmacist to use his/her professional judgement in deciding depending on the specific circumstances on the ground and there can be numerous. 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!"*

4.1.44 Pre-payment validation would involve a much greater volume of work and currently that is not the request that PAT have been asked to action. NHSE have asked PAT to perform post payment verification to provide assurance that claims are following the Drug Tariff correctly. We would suggest any pharmacy that is unsure around whether a claim is following the Drug Tariff is advised to reach to either Pharmacy Provider Assurance or the ICB and advice would be given.

4.1.45 The appellant goes on to state "*Sending us statistics comparing with National figures and the assertions that have been made 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. There could be many reasons why other pharmacies do not make OOPE claims or can obtain the product without incurring OOPE. If there is any aspect of the claims or explanations that you are not sure about, please let us know and why you think our explanations are not plausible and therefore what additional steps we should have taken and within our contractual framework."*

4.1.46 PAT have engaged multiple times with the contractor and identified the issues with FLH33's OOPE claims. As previously stated, four of the seven items considered in the recommended recovery were deemed to be frequently supplied. The pharmacy specified that they would first utilise their main wholesaler, if the item was not available and the patient required the medication quickly, they would use IPS or Mymed. However, they do not

specify if they try multiple wholesalers prior to resorting to IPS or Mymed. They also have not given any indication to what other steps they have taken to avoid claiming. For instance, if the patient was presenting at the pharmacy requiring the medication urgently, did the pharmacy provide education to the patient to order their repeat prescription with enough time to source it with no additional costs? This was a regular occurrence throughout the year, however, the pharmacy continued to claim for these items repeatedly in the majority of months and have not demonstrated what steps were taken to avoid doing so.

4.1.47 Simmons 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 eight normal wholesalers through the cascade software before going to IPS or Mymed. Having stated they tried wholesalers, in their opinion, evidence they tried all reasonable steps to obtain drugs without the need to claim OOPE.

4.1.48 Simmons chemist also state "*Sukkarto SR 500mg tabs is prescribed as a branded generic, which local prescribing teams could have changed overnight to the actual generic Metformin MR 500mg tablets leaving us with dead stocks of Sukkarto and a big financial loss. This is precisely what has happened now as current data will corroborate how scripts for Sukkarto are a fraction of what was being prescribed before and most (probably over 95%) are now of the generic Metformin MR 500mg.*

4.1.49 Whilst we appreciate prescribing habits can change, the data shows that Sukkarto SR 500mg tabs, were claimed for in 11 of the 12 months sampled, on a total of 144 occasions. Therefore, it is highly likely that any stock procured would be used in a short space of time. The pharmacy should be monitoring this on an ongoing basis, and if required month after month, they should be looking for different options to source the item without additional costs.

4.1.50 FLH33 go on to advise "*Also, being a branded generic not all wholesalers stocked the line. As mentioned, supply of branded generics can be very unreliable because they tend to be manufactured by small pharmaceutical companies, and they don't get the supply and demand correct as GP prescribing can be unpredictable and at the whim of the local prescribing team."*

4.1.51 Again, the information provided does not demonstrate the individual circumstances of this pharmacy. The statement above confirms that this would be the case for all pharmacy contractors, and the data simply does not support that this rational was a contributing factor.

4.1.52 After reviewing all the details given from Simmons Chemist and reviewing all the NHSBSA data for the period under review, PAT were unable to validate the OOPE claims claimed by Simmons Chemist during the designated sample period, an amount to be recovered was calculated for the 7 items it was felt were not meeting those conditions, rather than every claim submitted by the pharmacy. However, Simmons 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 7 identified items did not meet the cumulative conditions and therefore should be recovered under regulation 94 (1) (a) as an overpayment.

4.1.53 **The PSRC decision**

4.1.54 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 Simmons Chemist for review. These timelines have been provided to you in addition to this information.

4.1.55 The engagement showed that despite repeated requests by PAT, Simmons 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.

4.1.56 Consequently, the PSRC concluded that PAT had been unable to find any evidence to demonstrate that the 7 items (147 claims) claimed by Simmons 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 Simmons Chemist was not entitled to the payment made for which it had received.

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

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

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

4.1.60 Each of the points highlighted are conditions that need to be met before an OOPE claim should be submitted. For the 7 items (147 claims) highlighted in PAT's recommended recovery, Simmons Chemist have not provided any evidence to support that these conditions were met prior to submitting the claims.

4.1.61 FLH33 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. Simmons 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.

4.1.62 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.

4.1.63 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 7 items (147 claims) highlighted in the provided data overview, met the three conditions of the Drug Tariff.

4.1.64 In their appeal statement Simmons 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 as OOPE.

4.1.65 FLH33 state "*Regarding Sukkarto (for diabetes), over the 12-month period of the 403 occasions we dispensed, We claimed OOPE 144 times (36%). 259 occasions ordered from normal wholesalers. Regarding Monomil (for angina and heart), of the 60 occasions, we claimed OOPE 14 times (23%). 46 occasions ordered from normal wholesalers. Regarding EpiPen (for emergency anaphylaxis), of the 27 occasions, we claimed OOPE 17 times (63%), 10 occasions ordered from normal wholesalers, and Regarding Dabigatran, of the 51 occasions, we claimed OOPE 17 times (33%), 34 occasions ordered from normal wholesalers.*"

Table 1 (excerpt from PAT Data Overview for FLH33 – Simmons Chemist)

Item/ Product	**Sukkarto SR 500mg tablets**	**Dabigatran etexilate 110mg capsules**	**EpiPen 300micrograms/0.3ml (1 in 1,000) inj auto-injectors**	**Monomil XL 60mg tablets**
FLH33 Dispensed Occasion Total (19-20)	403	51	27	60
FLH33 OOPE Claim Occasion Total (19-20)	144	17	17	14
National Claims for the item	164	136	305	31

Number of pharmacies claimed for item nationally	12	30	68	5
Percentage of National claims made by FLH33	87.80%	12.50%	5.57%	45.16%
National Dispensed Occasion Total	1741830	211752	165439	1224290
Number of pharmacies who dispensed the item nationally	9236	7573	11075	9478

4.1.66 Above is an excerpt (*Table 1*) from the PAT's data overview that shows these 4 items, Sukkarto SR 500mg tablets, Dabigatran etexilate 110mg capsules, EpiPen 300micrograms/0.3ml (1 in 1,000) inj auto injectors and Monomil XL 60mg tablets that PAT have recommended for recovery as the data suggests these items were frequently supplied. FLH33 submitted OOPE claims for Sukkarto SR 500mg tablets on 144 occasions over a 12 month sample period. The claims submitted by Simmons Chemist account for 87.80% of the national claims for this item. It also shows that nationally, Sukkarto SR 500mg tablets were dispensed on 1,741,666 occasions by 9,224 pharmacies without any of these occasions requiring the pharmacies to submit a OOPE claim. Only 12 pharmacies nationally submitted 164 claims for this item, 144 of those were submitted by FLH33. The data also shows that Dabigatran etexilate 100mg capsules were submitted on 17 occasions in 12 months which equates to 12.50% of the national claims. It was also dispensed on 211,616 occasions by 7,543 pharmacies without a OOPE claim. EpiPen 300micrograms/0.3ml (1 in 1,000) inj auto injectors were submitted on 17 occasions, 5.57% of national claims. Dispensed on 165,134 occasions by 11,007 pharmacies without a need for OOPE claim. And finally, Monomil XL 60mg tablets which was submitted on 14 occasions in 12 months 45.16% of the national claims. It was dispensed on 1,224,259 occasions by 9,473 pharmacies without a claim.

4.1.67 The data also demonstrates that the pharmacy was able to obtain these items without resorting to OOPE on some occasions but also that the pharmacy had a consistent claiming behaviour resorting to claiming OOPE frequently on the item. No information provided by Simmons Chemist allowed PAT (and therefore NHSE or the ICB) to understand the conditions behind these OOPE claims. PAT would also question what the pharmacy did to avoid claiming OOPE on these items if they continued to claim OOPE most months. PAT also question how the claims meet the other cumulative conditions of not being frequently supplied and being claimed only in exceptional circumstances as, again, nothing in the response from Simmons Chemist allows the PAT to

understand the reasoning behind those claims and how they were adhering the Drug Tariff conditions.

4.1.68 Simmons Chemist go on to detail their ordering process:

4.1.69 "*Our electronic ordering cascade system (which is operational currently too) which checks live stocks was further proof that we would have first exhausted checking and ordering from all our normal 8 wholesalers, one after the other until it finds the supplier that has the medicine and orders."*

4.1.70 *Most of the time, as indicated above, one of the wholesalers would have the item, however, if all 8 of 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 from IPS, then from Mymed.*

4.1.71 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.

4.1.72 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. Prescribing teams or doctors would without notice, change from prescribing branded generics to just generics and visa [sic] versa. Practically and financially, we cannot hold excess stocks of lines such as Sukkarto as we have no way of knowing what 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 items 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 Items. The pharmacy were dispensing Sukkarto in 11 of the 12 months, therefore it is likely that these would go on to be dispensed within a reasonable timeframe.

4.1.73 Simmons Chemist confirm their stance that *"I would say that these actions and circumstances met ALL three conditions as laid out in the DT and would again challenge you to specify how it does not and how we could have overcome that!"*

4.1.74 The PAT disagrees with this conclusion. The pharmacy argue that they obtained Sukkarto SR 500mg tablets, Dabigatran etexilate 110mg capsules,

EpiPen 300micrograms/0.3ml (1 in 1,000) inj auto injectors and Monomil XL 60MG tablets 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 these items in 11 of the 12 months for Sukkarto, 9 in 12 months for Dabigatran, 8 in 10 months for EpiPen and 9 in 12 months for Monomil reviewed and dispensed. PAT acknowledge that there may be times when the pharmacy did need to claim for these items. However, due to the frequency of the claims, the pharmacy should have looked for other solutions to obtain these items 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.

4.1.75 In reference to the recommended recovery for the three items highlighted in orange on the data overview, FLH33 indicate that "*over the **12 months** in question, all 3 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 Simmons 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, Lacosamide 200mg tablets were dispensed by 2,888 pharmacies on 36,515 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, 100 times per day nationally.

4.1.76 FLH33 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 state "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*" 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, FLH33 has been updated with progress and the reasons behind any delays. 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.

4.1.77 For the avoidance of doubt, the PAT recognise that "*The DT does not intentionally provide 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 Simmons 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 FLH33, and the national data supports that other pharmacies did not encounter these issues.

4.1.78 FLH33 state "*The DT does not stipulate that records (apart from invoices) must be kept of each OOP supply with their "specific circumstances and evidence" as the NHSBSA PAT are 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).

4.1.79 Simmons Chemist explain "*There are many reasons why other pharmacies nationally 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 with wholesalers. Large multiples are vertically integrated so their own "wholesaler" may have separate reserved allocations of problem stocks for their stores."*

4.1.80 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 Simmons Chemist could not.

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

4.1.82 It is worth noting that the information provided by Simmons 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.

4.1.83 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
Sukkarto SR 500mg tablets	£10,428.00
Dabigatran etexilate 110mg capsules	£395.00
EpiPen 300micrograms/0.3ml (1 in 1,000) inj auto-injectors	£395.00
Monomil XL 60mg tablets	£158.00
Estradiol 1mg / Norethisterone acetate 500microgram tablets	£79.00
Macrogol compound oral liquid MPF sugar free	£79.00

Lacosamide 200mg tablets	£79.00
Total of PSRC recovery	**£11,613.00**

4.1.84 NHSE and PAT maintain that the contractor has not provided sufficient evidence to support that the claims for the 7 items (147 claims) highlighted in the data overview met the conditions outlined in the Drug Tariff, so the decision to recover £11,613.00 is correct.

4.1.85 **Key points for consideration**

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

4.1.87 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:

4.1.87.1 Claims were made only in 'exceptional circumstances'

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

4.1.87.3 The contractor took all reasonable steps to avoid claiming OOPE

4.1.88 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. Simmons 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.

4.1.89 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.

4.1.90 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.

4.1.91 The NHSBSA data does not corroborate the contractor's statement about supply concerns; there was no notable increase in OOPE claims nationally for the disputed items.

4.1.92 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.

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

4.1.94 The contractors' appeal provides no details specific for Simmons 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.

4.1.95 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 £11,613.00 overpayment recovery from Simmons Chemist was fair and in accordance with the regulations."

5 OBSERVATIONS

5.1 THE APPELLANT

5.1.1 "It is not appropriate for the NHSBSA PAT to simply state that not enough evidence has been given to them when we have provided invoice copies, as required by the DT and given full and thorough explanations as to the circumstances of supplying and claiming OOPE on these few specific lines.

5.1.2 NHSBSA PAT's reasoning is flawed (their desktop hindsight statistical analysis is not taking account of the circumstances at the time nor local conditions.

5.1.3 Please also refer to our previous responses dated 16th August 2023 and 23rd September 2024 (both attached), to save us repeating everything again.

5.1.4 We have already highlighted some of the circumstances below to be contributing factors to the claims which PAT have noted and Accepted:

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

5.1.4.2 Supply of 'branded generics' can be very unreliable and even availability can be inconsistent from one region of the country to another even if same wholesaler.

5.1.4.3 Urgency of the requirement for an item.

5.1.4.4 Medicine shortages and supply issues (see RPSGB article attached as evidence).

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

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

5.1.4.7 Low spend surcharges and wholesale quotas on medicines.

5.1.4.8 Government guidelines did not allow for bulk ordering of problem lines to prevent shortages elsewhere.

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

5.1.4.10 Staff resource due to sickness.

5.1.4.11 Contractual obligation to dispense items reasonably promptly to patients.

5.1.5 We are surprised that, 5 years on, the NHSBSA 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. They have undertaken a desktop National statistical analysis of data 4 to 5 years on, clearly ignoring our evidence, explanations and circumstances on the ground at the time.

5.1.6 Furthermore, NHSBSA have not engaged with us during this period, nor suggested where we may obtain the relevant medicines from, nor made any suggestions of how our ordering could have been improved!

5.1.7 There are 7 items that they are looking to recover OOPE claimed. From them, 2 are branded generics (Sukkarto and Monomil) and 1 is EpiPen where there was well-documented evidence of National shortages and the MHRA even authorised extension of expiry dates to try and overcome the supply issue (see attached notice). It is also important to bear in mind that these medicines are of vital importance and patients need to take regularly and cannot be without therefore it was imperative that patients received them promptly.

5.1.8 Regarding Sukkarto (for diabetes), over the 12-month period of the 403 occasions we dispensed, we claimed OOPE 144 times (36%). Thus, 259 occasions were ordered from normal wholesalers.

5.1.9 Regarding Monomil (for angina and heart), of the 60 occasions, we claimed OOPE 14 times (23%). Thus, 46 occasions we ordered from normal wholesalers. Regarding EpiPen (for emergency anaphylaxis), of the 27 occasions, we claimed OOPE 17 times (63%), Thus 10 occasions we ordered from normal wholesalers, and Regarding Dabigatran, of the 51 occasions, we claimed OOPE 17 times (33%), Thus, 34 occasions we ordered from normal wholesalers.

5.1.10 That we should have predicted and stocked up on items such as Sukkarto and Monomil, that we have no control over and went against government guidelines, is not a sensible suggestion, as explained below.

5.1.11 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.

5.1.12 It would be very helpful if the NHBSA/NHSE could have suggested at the time or even now, how we could/can overcome this or is the NHSBSA saying that we should have gone against government guidelines?

5.1.13 We put to you that your statistical analysis, methodology and assumptions (not evidence) is totally flawed in its sampling and being one dimensional and does

not look at circumstances on the ground and does not prove that the evidence or basis of our claims is wrong.

5.1.14 Bulk ordering and stocking of these lines was not the solution and not a reasonable option Government guidelines were that pharmacies should not hoard stocks of problem lines (although I am sure many did).

5.1.15 Also, prescribing patterns change without warning. Prescribing of Sukkarto dropped significantly and subsequently over 97% of the scripts are changed and written generically as Metformin MR 500mg tablets.

5.1.16 Even now, over the last 6 months or so, Monomil is in very short supply and has Serious Shortage Protocol (SSP) for it. SSP's was introduced recently for the precise reasons to allow for substitutions of lines in short supply.

5.1.17 Dabigatran was new and only available as the brand Pradaxa which was stocked by only 1 or 2 wholesalers (due to the restricted distribution agreements that manufacturers have) and they also operated quotas of only supplying 3 a month to us, if they had them in stock.

5.1.18 Regarding the others 3 lines (in orange) that the NHSBSA want to recover OOPE, we claimed OOPE only once over the 12-month period. NHSBSA have not given us any evidence why it does not consider these lines to be claimed.

5.1.19 This clearly indicates that the NHSBSA PAT's approach to this whole verification process is defective as it does not consider the OOPE claim individually and adopts a broad-brush approach which does not consider the various complex circumstances in play. It does not look at any other mitigating factors such as the ones already explained like limited stock in local depots, differing quota restrictions, shortages, vertical integration of multiples etc.

5.1.20 From the spreadsheet data that the NHSABSA has provided, of the nearly 60 lines, there is no explanation of methodology or reasoning provided of why these 7 lines are picked to reclaim the OOPE.

5.1.21 As explained in previous emails, the pharmacists had clearly followed our SOP's which is why most of the time we were able to obtain the stocks from our main suppliers as indicated above from the NHSBSA data.

5.1.22 Our electronic ordering cascade system (which is operational currently too) which checks live stocks was further proof that we would have first exhausted checking and ordering from all our normal 8 wholesalers, one after the other until it finds the supplier that has the medicine and orders. Most of the time, as indicated above, one of the wholesalers would have the item, however, if all 8 of 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 from IPS, then from Mymed.

5.1.23 I am sure they would agree that it is exceptional circumstances if none of the 8 main wholesalers have the medication available. I would also say that having 8 normal wholesalers (which is more than what most pharmacies have) is more than sufficient to indicate that we always take reasonable steps to obtain medicines without claiming OOPE.

5.1.24 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 are not getting their vital medicine or when will they have their medication as they will be running out, especially due to patients not wanting to venture out or too far even after the Covid pandemic.

5.1.25 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. Prescribing teams or doctors would without notice, change from prescribing branded generics to just generics and vice versa. Practically and financially, we cannot hold excess stocks of lines such as Sukkarto and Monomil, as we have no way of knowing what we will receive during the same month let alone next few months.

5.1.26 I would say that these actions and circumstances met ALL three conditions as laid out in the DT and would again challenge you to specify how it does not and how we could have overcome that!

5.1.27 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.

5.1.28 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"

5.1.29 NHSBSA 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.

5.1.30 **DT - CLAUSE 12 OUT OF POCKET EXPENSES**

5.1.31 *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 VIIID, 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. An exception to this will be made for Cefuroxime 5% preservative free eye drops, for which there will be an additional fixed out-of-pocket expense payment of £50 automatically applied without the need for any 'XP' or 'OOP' endorsements. This payment will also be retrospectively applied to all prescriptions for this item dispensed between the months of April 2023 to February 2024. Other applicable fees and allowances will continue to be paid as usual.

5.2 The DT does not intentionally provide us with a definitive meaning nor examples of what is exceptional circumstances, frequently supplied or reasonable steps. One can only conclude that these unquantified expressions are deliberate by those drafting the DT to enable specific circumstances to be considered and implemented according to the pharmacist's professional judgement. I can only presume this is why the NHSBSA PAT are unable to provide specific reasons why they think we have not met the 3 DT conditions.

5.3 Therefore, these conditions should be given their everyday meaning, and the DT is expecting the pharmacist to use his/her professional judgement in line with the DT and SOPs to make decisions based on the specific circumstances at the time.

5.4 We have complied with the DT with what evidence is required. The DT does not stipulate that records (apart from invoices) must be kept of each OOP supply with their "specific circumstances and evidence" as the NHSBSA PAT are requiring.

5.5 We have provided the PAT with sufficient evidence as is required in the form of invoices (which we have paid) and numerous factual plausible explanations of why the pharmacists in question (and there were numerous over the year), following our SOPs, had to resort to obtaining medications which entailed paying OOPE. The NHSBSA have not raised any questions on these and have therefore accepted them.

5.6 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!

5.7 Sending us statistics comparing with National figures and the assertions and extrapolation process that has 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 factual, plausible and specific reasons why.

5.8 There are many reasons why other pharmacies nationally 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 with wholesalers. Large multiples are vertically integrated so their own "wholesaler" may have separate reserved allocations of problem stocks for their stores. Branded generics are made by smaller pharmaceutical companies, and supply can be very unreliable, and availability can be inconsistent from one region of the country to another even from depots of the same wholesaler. From our experience, this would apply to other branded lines too.

5.9 Other pharmacies may have simply not endorsed their script(s) (unknowingly), to claim OOP or may have endorsed the script(s) incorrectly and therefore not get paid. This would then not show up in the data supplied.

5.10 IT IS VERY EASY, SIMPLISTIC AND NAÏVE OF THE NHSBSA TO COMPARE EVERY SITUATION WITH NATIONAL STATISTICS WITHOUT GIVING SPECIFIC LOCAL COMPARABLE EVIDENCE TO SUBSTANTIATE THEIR POSITION.

5.11 None of these reasons have been refuted by the NHSBSA and nor has any evidence been forthcoming from the NHSBSA that there were no supply issues. Our primary concern was patient safety and patient welfare and ensuring that they received their medications promptly, especially during the pandemic. We make every effort to obtain medications for patients which other pharmacies may not, and they ask their patients to try elsewhere, some ending up at our doorstep.

5.12 The NHSBSA PAT have presented national data statistics and made this very general and sweeping statements with assumptions without looking at each pharmacy's individual circumstances and providing the evidence that directly relates to our claims. And they are relying only on these broad national statistics to claim that we have not followed the DT conditions, and this too is flawed as explained.

5.13 The NHSBSA has not refuted any of our 11 or so contributing factors, and we have continually asked the PAT team to let us know why they 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 and saying they do not believe we followed them?

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

5.15 Proactive communication from the NHBSA, CCG etc would have resolved these issues efficiently and saved us all this time, effort and resources 4 to 5 years on.

5.16 To reclaim such a large amount when medicines were dispensed in accordance with the DT and in the patient's interest, and we have paid for all of it, will impact on our pharmacy resources greatly. The most obvious impact will be on our staffing."

6 CONSIDERATION

6.1 Direction 2 of the Payment Disputes Directions directs me to determine a dispute in respect of the recovery of an overpayment from an NHS pharmacist under regulation 94(1) of the NHS (Pharmaceutical and Local Pharmaceutical Services Regulations) 2013 (the "Regulations") which is in the nature of an appeal against a decision of NHS England that there has been an overpayment.

6.2 Direction 4 of the Payment Disputes Directions requires me to determine the appeal by dismissing it if:

6.2.1 NHS England has advised that an appeal must be brought within 30 days of the date the Appellant was notified of NHS England's decision and the appeal was not brought within that timescale; or

6.2.2 I am of the opinion that notification of the appeal contains no valid grounds of appeal (for example because it amounts to a challenge to the legality or reasonableness of the Payment Disputes Directions, the Regulations or the Drug Tariff).

6.3 I consider that I am not required to dismiss the appeal pursuant to Direction 4 as:

6.3.1 the NHS BSA advised the Appellant of a 30 days' timescale for appeal and the appeal was received within that timescale; and

6.3.2 the grounds of the appeal are valid.

6.4 Direction 6 of the Payment Disputes Directions states that I may determine the appeal without hearing any oral representations but if an appellant asks to make oral representations a hearing must be arranged unless I am satisfied that:

6.4.1 a hearing is unnecessary; or

6.4.2 I must dismiss the appeal by virtue of Direction 4.

6.5 The Appellant has not requested a hearing. On the basis of the information before me I have considered that it is unnecessary to hold an oral hearing.

6.6 I have before me the papers considered by the NHS BSA. I also have before me the responses to NHS Resolution's own statutory consultations.

6.7 I note the NHS BSA's 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 May 2020 through to the current Drug Tariff (June 2025) could be found. It is noted that earlier back copies of the Drug Tariff can be found through the search function. I further note that the Drug Tariff has not been disputed by the Appellant.

6.8 The appeal relates to payments made to the Appellant in respect of claims for Out of Pocket Expenses ("OOPE"). The NHS BSA states that "*An 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.*

6.9 *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."*

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 NHS BSA states that the Appellant falls into sample two "*Contractors with claims over £10,000 over a 12 month period from February 2019 to January 2020"* as the total OOPE for the Appellant for this period totalled £25,790.20.

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 August 2024 the pharmacy was contacted 11 times by the NHS BSA. The NHS BSA contacted the

Appellant reminding them of the deadline and the Appellant engaged with the NHS BSA and this has not been disputed.

6.18 It is noted that the Appellant's pharmacy submitted 335 OOPE claims totalling £25,790.29 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 147 claims totalling £11,613.00. 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"*.

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 that would have been in force at the beginning of 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 chemist reagents" Clause 12 with regard to "Out of Pocket Expenses" states:

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

6.21 I next consider the OOPE claims for the seven items identified by the NHS BSA (Sukkarto SR 500mg tablets, Dabigatran etexilate 110mg capsules, EpiPen 300 micrograms/0.3ml (1 in 1,000) inj auto-injectors, Monomil XL 60mg tablets, Estradiol 1mg / Norethisterone acetate 500microgram tablets, Macrogol compound oral liquid NPF sugar free and Lacosamide 200mg tablets). In doing so, I have considered the wording of Part II Clause 12 of the Drug Tariff and consider that the NHS BSA is correct in that is makes clear that for an OOPE claim to be successfully made, there are certain criteria that need to be met:

6.21.1 That there are exceptional circumstances;

6.21.2 That the product is a type of product for which an OOPE claim can be made, with reference to parts and categories of the Drug Tariff;

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

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

6.22 I also concur with the NHS BSA that Part II Clause 12 makes clear that these are cumulative conditions – all must be met in order for a claim for OOPE to be successfully made.

6.23 I note that there are no definitions for 'exceptional circumstances', '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. I note that 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.

6.24 I first consider exceptional circumstances.

6.25 I consider that this condition shares some similarity to the "not required to be frequently supplied" condition in that both can be read as relating to the extent to which it is usual for the drug to be supplied. I do consider, however, that "exceptional circumstances" can be read more widely than simple frequency of supply to encompass other circumstances that may make such ordering very unusual. I would consider "exceptional" to indicate that such circumstances are very unusual rather than simply unusual.

6.26 I note the Appellant's comment that "*Medicines shortages and supply issues because of Brexit and the Covid-19 pandemic*" contributed to the exceptional circumstances experienced. The Appellant then goes on to state *"shortages due to restricted supply of medicines due to wholesale quotas"* also contributed to the high volume of OOPE claims.

6.27 The NHS BSA highlights that "*…although FLH33 used supply issues caused by the Covid-19 pandemic as part of their reasoning, the sample period under review for FLH33 (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 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."*

6.28 Given the timeframe for Brexit (31 January 2020) and the first Covid lockdown (March 2020) post dated the sample period, I am not satisfied, nor have I been provided with evidence to support the fact, that these occurrences contributed to medicines shortages and supply issues. Whilst I accept that there could have been a period of medication shortages ahead of Brexit, I have not been provided with any information to show a link between this particular occurrence and the medicines the Appellant was sourcing.

6.29 In any event, as it became apparent that this medication was being prescribed on a regular basis, as indicated by the figures in Table 1 above, I am not of the view that this continued to be exceptional. If the Appellant was aware that the medication was being prescribed with relative regularity then I am of the view that it is not "exceptional".

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

6.31 I have also not been provided with any information from the Appellant to rebut the NHS BSA's assertion that the products in question were "*not required to be frequently supplied"*. The NHS BSA has provided information confirming the frequency of supply throughout the sample period and the Appellant has not provided any response to this either on appeal or in subsequent representations.

6.32 I note that, from the undisputed information provided by the NHS BSA and set out in Table 1 above, the Appellant dispensed Sukkarto SR 500mg tablets 403 times in 2019-2020 and claimed OOPE 144 times. Whilst I have not been provided with a breakdown of how many times per month the medication was claimed for during the sample period,

I note from the NHS BSA information that the Appellant's pharmacy made up 87.80% of the national claims for this medication. Based on the information before me, I am of the view that Sukkarto SR 500mg tablets was frequently supplied during the period February 2019 to January 2020.

6.33 I note that, from the undisputed information provided by the NHS BSA and set out in Table 1 above, the Appellant dispensed Dabigatran etexilate 100mg capsules 51 times in 2019-2020 and claimed OOPE 17 times. Whilst I have not been provided with a breakdown of how many times per month the medication was claimed for during the sample period, I note from the NHS BSA information that the Appellant's pharmacy made 12.50% of the national claims for this medication. Based on the information before me, I am of the view that Dabigatran etexilate 100mg capsules was frequently supplied during the period February 2019 to January 2020.

6.34 I note that, from the undisputed information provided by the NHS BSA and set out in Table 1 above, the Appellant dispensed EpiPen 300micrograms /0.3ml (1 in 1,000) inj auto-injectors 27 times in 2019-2020 and claimed OOPE 17 times. Whilst I have not been provided with a breakdown of how many times per month the medication was claimed for during the sample period, I note from the NHS BSA information that the Appellant's pharmacy made up 5.57% of the national claims for this medication. This does not appear excessive and I therefore consider it reasonable to conclude that this product was not required to be frequently supplied.

6.35 I note that, from the undisputed information provided by the NHS BSA and set out in Table 1 above, the Appellant dispensed Monomil XL 60mg tablets 60 times in 2019-2020 and claimed OOPE 14 times. Whilst I have not been provided with a breakdown of how many times per month the medication was claimed for during the sample period, I note from the NHS BSA information that the Appellant's pharmacy made up 45.16% of the national claims for this medication. Based on the information before me, I am of the view that Monomil XL 60mg tablets were frequently supplied during the period February 2019 to January 2020.

6.36 I note that, from the undisputed information provided by the NHS BSA in its representations, the Appellant claimed OOPE for Estradiol 1mg/ Norethisterone acetate 500 microgram tablets, Macrogol compound oral liquid NPF sugar free and Lacosamide 200mg. I note the statement from the NHS BSA that "*FLH33 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 or outlined how they differed from other pharmacies claiming for the item without the need for OOPE claims, it was determined that the three claims for these items were also unnecessary*".

6.37 I note from the information provided by NHS BSA that these were dispensed by the Appellant 24, 12 and 10 times respectively during 2019-2020. Whilst these figures do not appear to be excessive and I consider it reasonable to conclude that these products were not required to be frequently supplied, I note that the Appellant was the only pharmacy to claim OOPE for these products in 2019-2020. No information has been provided by the Appellant to demonstrate that these products necessitated claiming OOPE.

6.38 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 that 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 that apart from reference to the supply chain issues and the urgency to supply items, I have been provided with limited information as to the steps that the Appellant went to in order to avoid claiming.

6.39 I note the statement from the Appellant that:

6.40 "*… the pharmacists had clearly followed our SOP's which is why most of the time we were able to obtain the stocks from our main suppliers as indicated above from the NHS BSA data.*

Our electronic ordering cascade system (which is operational currently too) which checks live stocks was further proof that we would have first exhausted checking and ordering from all our normal 8 wholesalers, one after the other until it finds the supplier that has the medicine and orders.

Most of the time, as indicated above, one of the wholesalers would have the item, however, if all 8 of 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 from IPS, then from Mymed."

6.41 I am of the view that if the Appellant was following its SOPs and utilising an electronic ordering cascade system then there must have been some contemporaneous record kept of this which the Appellant should have been able to provide to the NHS BSA. I note no information has been provided as to which supplier the Appellant contacted in the first instance and no evidence has been provided to demonstrate that other suppliers were also contacted.

6.42 Regarding the supply chain issues and urgency to supply point, I also note the NHS BSA's data regarding other pharmacies. I consider that if there were supply chain issues or a real urgency to supply these items, then this should have been felt elsewhere as well. Looking at each items in turn, the NHS BSA indicates that during the period in question 12 pharmacies nationally claimed for Sukkarto SR 500mg tablets; 30 pharmacies nationally claimed for Dabigatran etexilate 110mg capsules; 68 pharmacies nationally claimed for EpiPen 300micograms/0.3ml (1 in 1,000) inj auto-injectors; 5 pharmacies nationally claimed for Monomil XL 60mg tablets. However, the Appellant made up 87.80%, 12.50%, 5.57% and 45.16% of these claims respectively. Whilst it is possible that the Appellant had a noteworthy number of patients requiring these items, these numbers suggest that it was a significant outlier. This would either suggest that the supply chain/urgency issues were less impactful than the Appellant suggests, or that, if they were, then other pharmacies found solutions. Accepting the Appellant's statements on that matter, that there were significant issues, then I must conclude that not every reasonable step was being taken, as other pharmacies were able to resolve the issues and make less claims.

6.43 Further to this, I note that the NHS BSA's data indicates that on at least ten occasions all items were dispensed without an OOPE claim. In particular, I note that Sukkarto SR 500mg tablets were dispensed 259 times without an OOPE claim.

6.44 I note the Appellant's comments regarding "bulk ordering" and how doing so would have been against the government guidelines in relation to 'problem' lines. I further

note the comment that it is unable to store excess stock due to the inability of knowing what prescriptions will be received in the following month. Whilst I accept that there may have been challenges for the pharmacy in managing stock levels, I note that this trend is not reflected nationally and therefore other pharmacies were finding ways around the challenges. Further, whilst I note the comment from the Appellant relating to storage space for excess stock, I am mindful that no information has been provided to expand on this issue and how they have taken reasonable steps in this regard.

6.45 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 need to be provided in order for a claim to be successfully made. It is not sufficient to claim exceptional circumstances without also providing sufficient evidence regarding the frequency of the supply and how all reasonable steps have been taken to avoid claiming.

6.46 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.

6.47 I also note the comments from the Appellant with regard to the length of time that has passed since the OOPE for the period February 2019 to January 2020, however I am mindful that the NHS BSA initially contacted the Appellant in November 2021. I am of the view that the Appellant should have been able to provide the initial information and supporting evidence as requested by the NHS BSA at this time. Given that the Appellant was first contacted in November 2021, I am of the view that it was aware from this date that they were subject to a PPV and records should have therefore been retained along with any further information that it had with regard to OOPE for those medications.

6.48 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 £11,613.00.

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