

# Medicines Management Team Presentation on Specials/Unlicensed Medicines

# A Brief History of the Specials Authorisation Process

## February 2013

PCA2013(P) 4 set out new process for reimbursement of Specials. GK & SN set up authorisation process for Fife, including "Fife List".

## March 2015

RC is brought in to post to take over authorisation and clawback process.

## May 2019

Email authorisation process is implemented as the new way to submit authorisation requests to comply with GDPR.

## January 2014

contractors warned that NHS Fife will "claw back" payment where authorisation process has not been followed.

## September 2015

PCA2015(P) 17 stipulates authorisation must be given on patient by patient basis. Changes made to process and Fife List is withdrawn.

# The Authorisation Process Today



# The Pharmacy Determines Whether Health Board Authorisation Is Required...

## Generic Framework for Specials Authorisation Process across Scotland (An authorisation is required for every individual patient)

ANNEX A

Patient presents with a prescription at the community pharmacy. The GP practice system (**EMIS / INPS**) if used may have informed the prescriber that the product is unlicensed. This does not exempt the community pharmacist from undertaking the appropriate clinical checks. The pharmacy proceeds to secure supply unless the pharmacist when undertaking the clinical check deems it necessary to first contact the prescriber.

### No Health Board Authorisation Required

The product is NOT listed in  
Scottish Drug Tariff Part 7s

- Authorisation obtained for patient prescription within last 12 months with less than 20% price variation from original authorisation
- Preparation is available from an NHS manufacturing unit within Scotland/ England/ Wales
- Endorse the fixed non part 7S handling charge as a handling charge (hc)
- If other OOP expenses apply (including wholesaler handling charges) endorse as postage and packing costs (pp)

The product is listed in  
Scottish Drug Tariff Part 7s

### Health Board Authorisation Required

- The product is not listed on Scottish Drug Tariff Part 7s.
- One quote to be sourced including postage & packing, handling charges, shelf life etc.
- Reauthorisation for the same patient and product if price varies >20% from the original authorisation prescription
- Reauthorisation required after 12 months for clinical validation
- Endorse prescription electronically and on paper with invoice price, less any rebate plus any additional cost authorised e.g. OOP expenses (including wholesaler handling charge) should be endorsed as postage and packing costs (pp)
- Endorse the fixed non Part 7S handling charge of £30 as a handling charge (hc)

### Recovery by Health Boards of unauthorised expenditure e.g. where the full amount has not been authorised or the contractor has purchased at a higher price than was pre-authorised

- If a contractor sources a product at a greater price than agreed the Health Board may reclaim the difference between the agreed price and the final invoice price.
- If the contractor has not obtained authorisation the Health Board may reclaim the difference between the price that would have been approved and the invoiced price.
- If the Health Board intends to reclaim monies they will inform the contractor giving them 28 days to appeal any decision.
- All appeals will be considered on an individual basis by Health Board with a written response within 28 days

# Where Authorisation Is Required, An Authorisation Request Form Is Submitted By Email



## Special/ Unlicensed Medicine Authorisation Request Form

Please email to: [Fife-UHB.SpecialsUnlicensedMedicines@nhs.net](mailto:Fife-UHB.SpecialsUnlicensedMedicines@nhs.net)

If URGENT - follow up with a phone call to 01383 565397

Pharmacy Name & Address:	
PPD Code:	
Telephone No:	
Prescriber Name:	
Practice Name:	

Product Name:	
Strength:	
Form:	
Dose:	
Quantity:	
Indication:	
Patient CHI Number*:	
Previously been prescribed for patient:	Yes <input type="checkbox"/> No <input type="checkbox"/>
Alternative to special discussed with prescriber? Please provide example(s).	Yes <input type="checkbox"/> No <input type="checkbox"/>
Item in Scottish Drug Tariff <a href="#">Part 7S/7U?</a> <small>(download the tariff, use the tabs at the bottom to navigate to 7S/7U)</small>	Yes <input type="checkbox"/> No <input type="checkbox"/> If 'Yes', authorisation not required, refer to DT for price
Available from NHS Production Unit? <small>Glasgow Pharmacy Production Unit: (0141 451 5820) Tayside: (01382 632 052)</small>	Yes <input type="checkbox"/> No <input type="checkbox"/> If 'Yes', the order should be place with the NHS Pharmacy Production Unit, authorisation not required

**\*IMPORTANT:** You must ensure that an "@nhs.net" email address is used to submit this form to guarantee encryption of confidential patient details.

Supplier/Manufacturer:	
Product Cost:	
Additional <u>Supplier</u> Charges: <small>(Please do not include the £30 non-7S fixed handling fee here)</small>	
Total Cost For Prescribed Quantity:	
Queries to:	

Requests will be processed within 24 hours of receipt, during the office hours of 9am – 4pm Monday to Friday (except Public Holidays), e.g. If emailed at 4pm on Friday a response will be provided by 4pm on Monday. Please factor this in to supply arrangements with the patient/carer.

Please make sure that prescriptions for Specials/Unlicensed medications are endorsed both electronically and on the paper copy with the authorised price using the "SP" endorsement followed by the price in pence to ensure correct payment. More information on endorsing can be found on the [Community Pharmacy Scotland Website](#).

# Things We Consider Before Authorising a Special/Unlicensed Medicine

24 hours

Are there licensed alternatives available (e.g. licensed liquids of similar drugs)?

- Use of licensed alternatives should always be fully explored before an unlicensed medicine is considered.

Could a licensed product be used off-label (e.g. crushing tablets, opening capsules etc.)?

- Off-label use of a licensed product comes next in the MHRA Hierarchy for the use of Unlicensed Medicines.


Would input from practice team be appropriate, further discussion with the prescriber required?

- This is especially important if it is the first prescription for the patient. It is much more difficult to switch patients from any drug after it has been supplied previously.

If prescribing the Special is to go ahead, is the price acceptable or can it be sourced at a more reasonable price?

- The price of unlicensed medicine can vary immensely across different wholesalers. It is important to ensure that NHS Funds are being used in the most efficient way.

## Pharmacy feedback – since moving to email the health board takes longer to respond to special requests

- The average response time to Special Authorisation Requests in January 2020 was **52 minutes** with 100% of requests sent before 5pm receiving a response the same day.
  - We are mindful that many companies require the order to be placed by 3.30pm for next day delivery. We aim to have a response sent to the pharmacy before this time wherever possible. The best time for the pharmacy to check the inbox is through the day, **2pm – 3pm** to avoid any delays with ordering.
- 
- Decorative wavy lines in a light blue color at the bottom of the slide.

Pharmacy feedback – the price we submit is never authorised, can't we just send the form in without a price since NHS Fife obviously has a table with what they're willing to pay?

- Of the **769** authorisation requests submitted in 2019:

- 510** were approved at the price submitted

- **215** were not given immediate approval either due to a licensed/off label product being advised instead, directing pharmacies to an NHS PPU or a lower price than the one submitted being authorised

- The remaining **44** were “N/A” requests (licensed/7S/7U products or requests for authorisation to order from an NHS PPU.



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- Of the **769** authorisation requests submitted in 2019:

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These requests make up our “table” – in fact a huge spreadsheet that we use as our database to direct pharmacies to the most cost effective source and keep the amount that we authorise to every pharmacy fair. Prices for Specials are always changing, if pharmacies did not submit a price we would manually be tracking down sources and prices for 85 pharmacies submitting nearly 800 requests a year!

Pharmacy feedback – the Specials team are really helpful but we miss speaking to them since it changed to email!

We miss you too! We are looking in to different ways of keeping in touch – as ever we are only a phone call away if you need any help with Specials!

A decorative graphic at the bottom of the slide consisting of two overlapping, light blue, wavy shapes that resemble stylized waves or clouds.

# Efficiencies on Special/Unlicensed Medicines Over The Years



# Some examples of savings made

Pharmacies Requested

We Advised

Atorvastatin 40mg/5ml  
Oral Suspension at £146

Omeprazole Oral  
Suspension at £397

Pizotifen 250mcg/5ml Oral  
Suspension at £1585

Levomepromazine 6mg  
Tablets at £585

Quetiapine 100mg/5ml  
Oral Suspension at £599

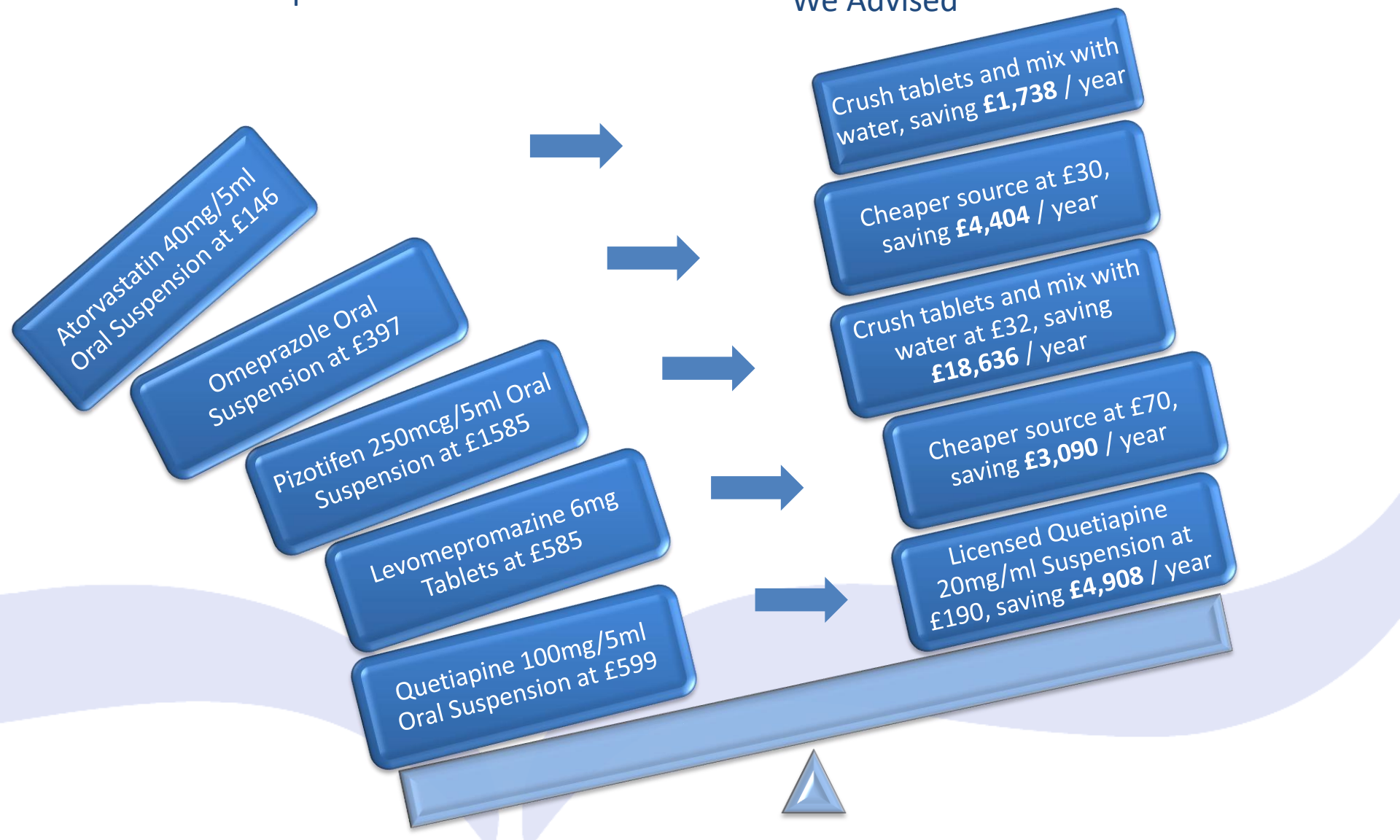
Crush tablets and mix with  
water, saving **£1,738** / year

Cheaper source at £30,  
saving **£4,404** / year

Crush tablets and mix with  
water at £32, saving  
**£18,636** / year

Cheaper source at £70,  
saving **£3,090** / year

Licensed Quetiapine  
20mg/ml Suspension at  
£190, saving **£4,908** / year

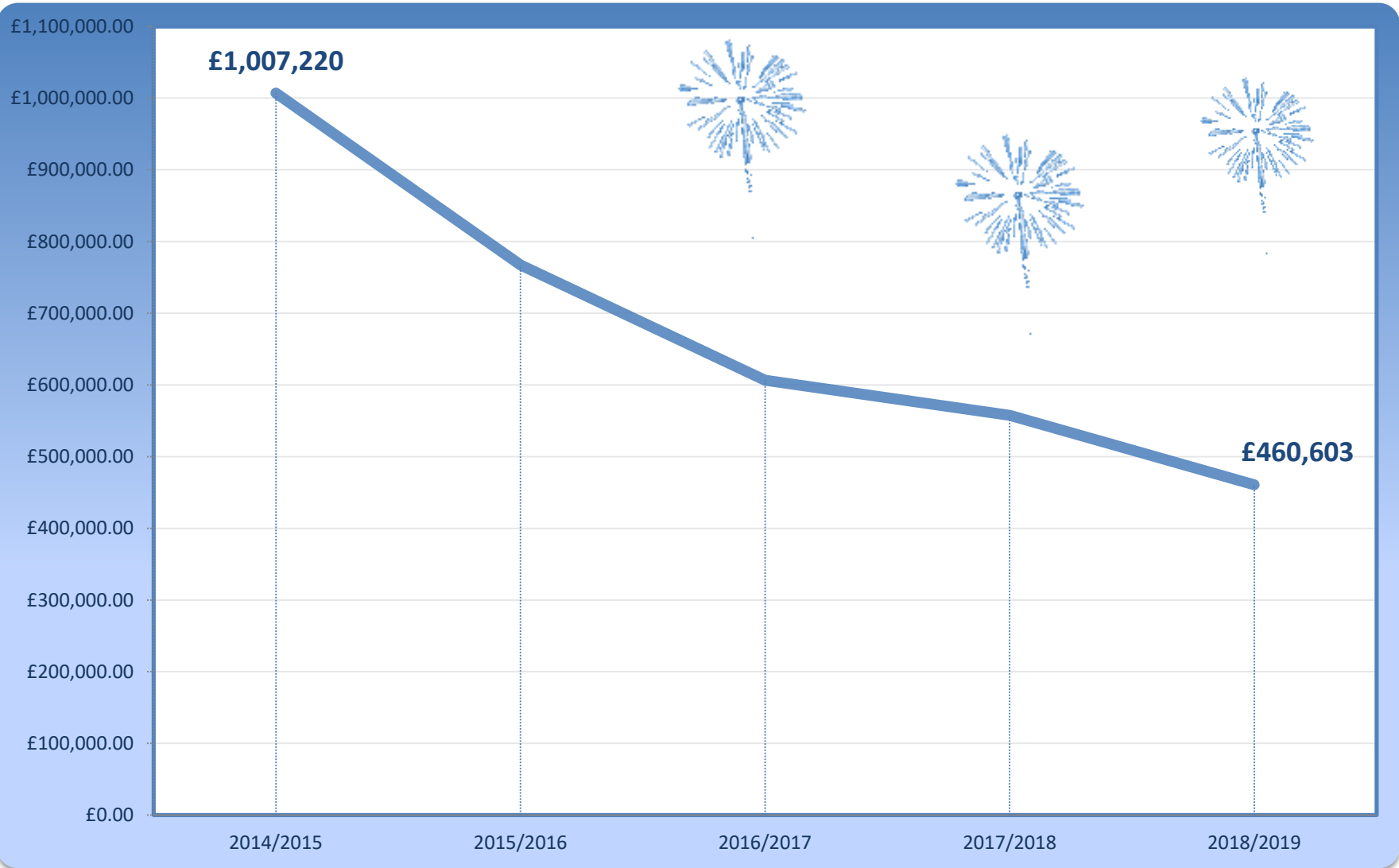


With the cooperation of  
Community Pharmacies,  
NHS Fife avoided spending an  
additional

**£211,734**

on Specials last year because of  
switches like these!

# Overall Spend on Specials – 2014 - 2019



# The Scottish Government Process – Clawbacks on Specials



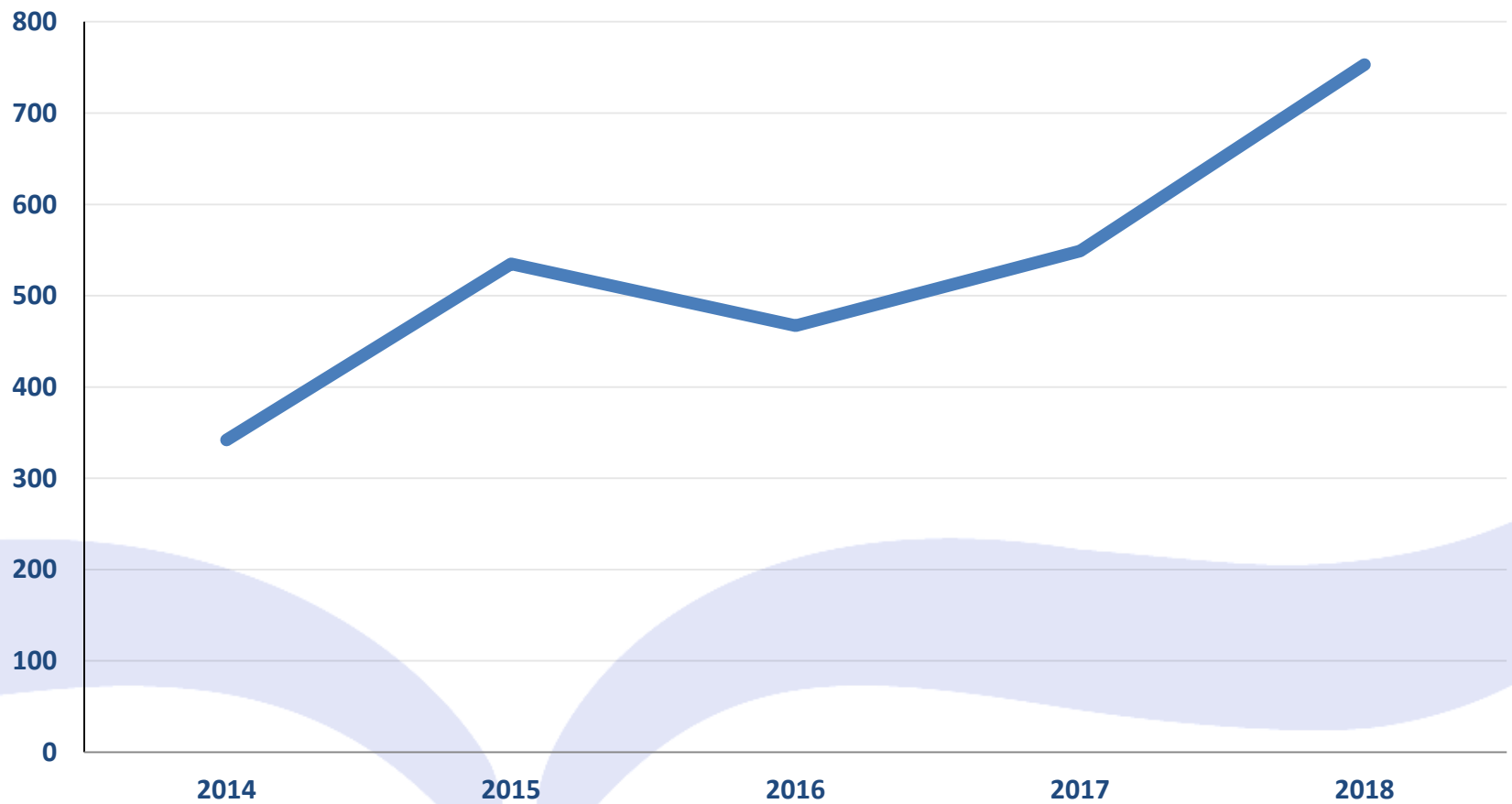
When the Scottish Government authorisation process is not followed, the Health Board should take steps to recover the unauthorised payments. From 2014 to 2019 this amounted to...

**£420,556**

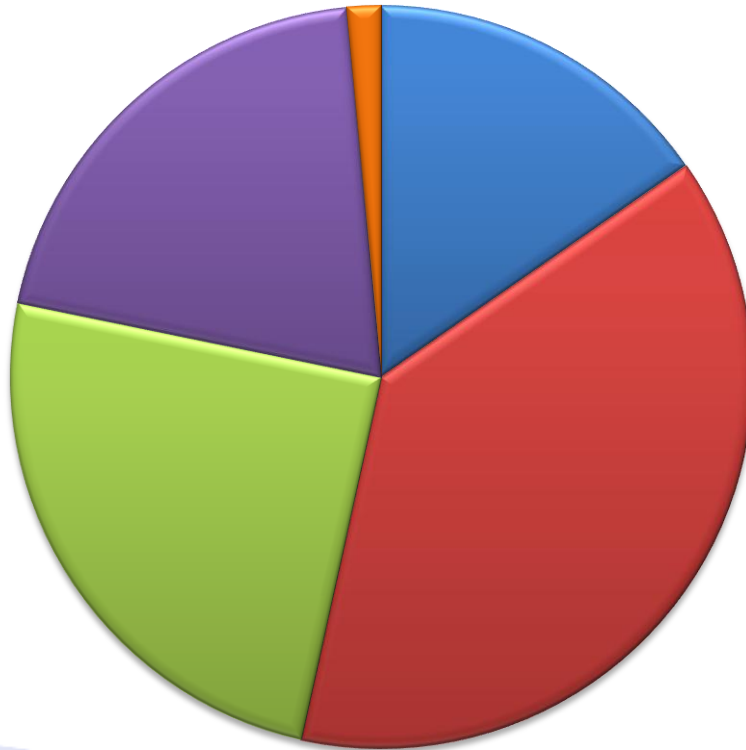
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Despite an increase in compliance with the authorisation part of the Scottish Government process, the number of claw back letters issued continues to rise...



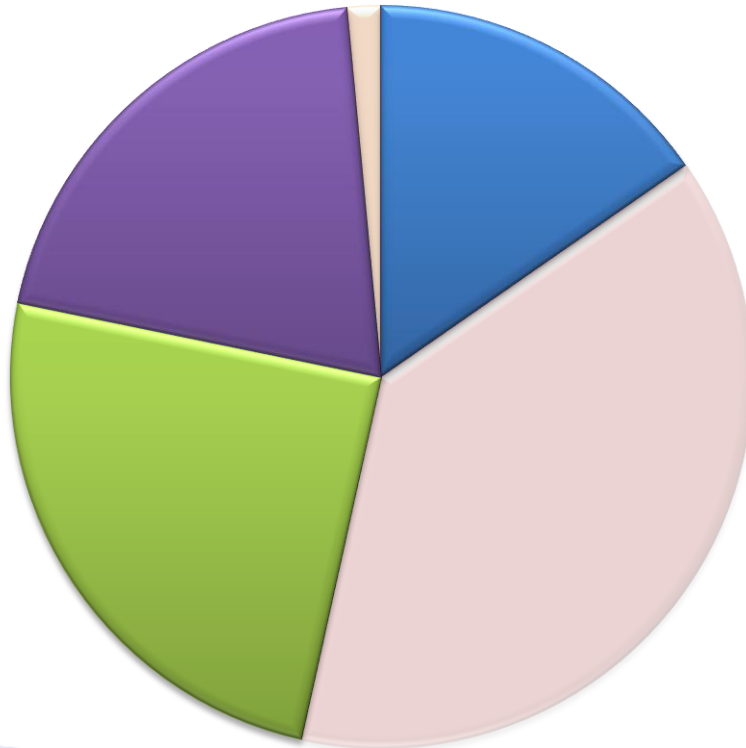
# How Can We Tackle The Issue Of Clawbacks? Let's take a look at the numbers...



- Special should have been ordered from NHS Manufacturing Unit
- Authorisation granted but reimbursement was over the authorised price
- Authorisation not sought but lower price would have been authorised
- Authorisation not sought & alternative would have been advised
- Prescription hand endorsed ND but electronic claim was made

Types of Clawback Letters sent from January to April 2019

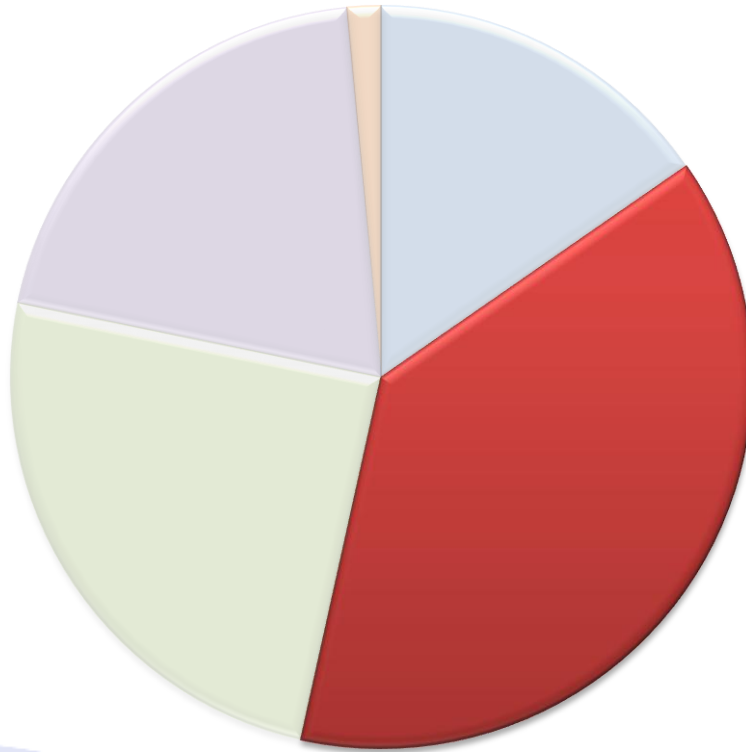
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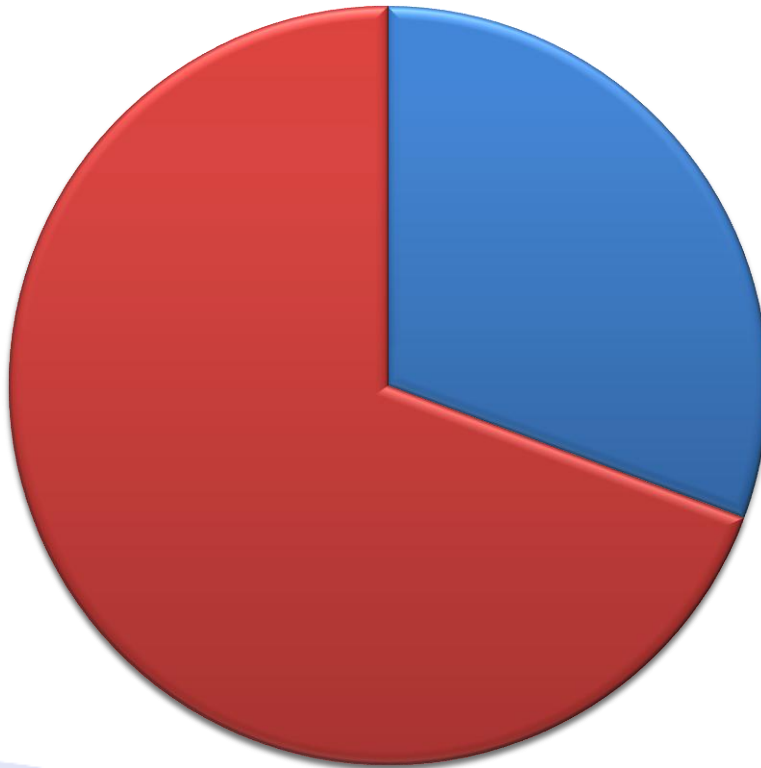
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Types of Clawback Letters sent from January to April 2019

# Let's take a look at endorsing



- Paper copy included endorsed price but it was higher than was/would have been authorised
- Paper copy did not include endorsed price

Level of endorsing from the same sample, January – April 2019

# 2020 – The Year of Endorsing!




**NHS**  
Fife

HELLO  
I AM...  
**ENDORSED**

**S P**




## How can we improve authorisation compliance and awareness of the “SP” endorsement?

A silver paperclip icon is positioned at the top left corner of the green box.

It looks like this item does not have valid authorisation. It could be that authorisation has not been sought or a previously valid authorisation has expired.

If continuing to supply this item please submit an authorisation request form to [Fife-UHB.specialsunlicensedmedicines@nhs.net](mailto:Fife-UHB.specialsunlicensedmedicines@nhs.net) for the next dispensing.

A silver paperclip icon is positioned at the top left corner of the blue box.

It looks like this item may not have been endorsed appropriately, leading to an overpayment. If continuing to supply this item make sure to use the “SP” endorsement both electronically and on the paper copy. More information on endorsing can be found on the Community Pharmacy Scotland website.



## A Special Report



Would you like a personalised report on Specials for ***“Fife Pharmacy, Fife?”***

NHS Fife are on a mission to reduce the number of clawbacks this year. To help we are offering pharmacies a personalised report on their specials and clawbacks. We will let you know how many clawback letters have been sent to the pharmacy in the previous 3 months, whether these Specials had authorisation and what could be done to avoid receiving a clawback on these Specials in future.

To request a personalised report, simply email [Fife-UHB.SpecialsUnlicensedMedicines@nhs.net](mailto:Fife-UHB.SpecialsUnlicensedMedicines@nhs.net) with the pharmacy details. If you have any specific queries regarding Specials please also note these and we will address them. We will get back to you within a few days with your personalised report and we are happy to discuss things further if required.

Let's work together to reduce clawbacks in 2020!

What else is the Health Board doing to improve Specials for community pharmacies?



# Take Away Messages

- Let's spread the word about the **SP endorsement** and get all prescriptions for Specials **endorsed both electronically and on the paper copy!**
- By improving compliance with the **authorisation** process and spreading awareness of the importance of **endorsing** we can reduce the number of clawbacks **significantly**.
- Any money clawed back comes at a cost... whether it's the actual cost of stationary and postage to send the letters, salaries, time or the cost to the working relationship between the pharmacy and the Health Board. NHS Fife would ultimately prefer not to issue clawback letters and we are sure the feeling is mutual about receiving them!
- Please do direct pharmacies to the article in the Xmas edition of Fife Pharmacy News and feed back our appreciation for contributing to the tremendous savings made! More information on endorsing and it's role in Specials/Clawbacks is also included in this article.
- If in doubt, please do get in touch!

# Are There Any Questions or Feedback?



# Contact Details

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