PSNC Funding & Contract Subcommittee Agenda

For the meeting to be held on Tuesday 8th October 2013

At Devonport House, King William Walk, Greenwich, London, SE10 9JW

Starting at 13.30pm

Members: Dhiren Bhatt, Peter Cattee (Chairman), Liz Colling, Tricia Kennerley, Andrew Lane, Andy Murdock, Garry Myers, Bharat Patel, Raj Patel, Adrian Price

1. Apologies for absence

No apologies have been received.

2. Minutes

The minutes of the meeting held on 9th July 2013 were shared with subcommittee and can be downloaded from PSNC's website.

3. Matters arising

4. Work plan

The 2013 work plan is set out in **Appendix FCS 02/10/13** for review by the subcommittee. As much of the FunCon workplan relates to ongoing funding negotiations a separate confidential update is provided at **Confidential Appendix FCS 02a/10/13.**

ACTION / RATIFICATION

5. Elements of the package

The subcommittee is requested to consider the paper included as **Confidential Appendix FCS 03/10/13** which sets out the elements that the current funding package includes and potential implications for the future.

6. Margin surveys

A number of areas of contention remain for the 2012/13 survey, in particular the NIC figures used to calculate the market level result and the impact of overly influential lines.

Data is being collected and processed for Q1 2013/14.

7. Transparency Group Update

The Working Group held a conference call following July's PSNC meeting and considered in detail the proposal from DH, taking into consideration the subcommittee's responses. We presented DH with a written response to their proposal which can be seen in **Confidential Appendix FCS 04/10/13.**

REPORT

8. PAC / PRISM reports

The Pricing Audit Centre is now fully operational with PRISM and we are able to capture both efficiency and accuracy stats for the first time. Unfortunately, owing to delays with development, auditing has fallen behind so the team have been auditing fewer accounts from Oct 12. The latest results can be found in **Appendix FCS 05/10/13.** This report features 6 graphs that are based on the BSA's accuracy indicators. The first two graphs detail the Net and Absolute Cash Variance values at a batch level whereas the last four detail both NCV, ACV, total no of errors and total no of errors affecting payment at item level (therefore not taking into account any

impact on fees applied at batch level e.g. practice payment) and these are comparable to the BSA's accuracy indicators (the latest copy of which can be found at **Appendix FCS 06/10/13**.)

9. Prescriber Codes

It was requested at the last PSNC meeting for feedback on the requirement for prescriber codes and whether the number of re-subs had increased. NHSBSA have confirmed that very few prescriptions have a code missing, the majority have incorrect codes, which are dealt with internally. In the event a code is missing then payment for these prescriptions are made from centrally held funding; there should be no impact for contractors.

10. Funding distribution 2013/14

The subcommittee will be given an update on forecasts for items and the Contract Sum for 2013/14 at the meeting.

11. Category M October 2013

DH changed October Cat M prices with the aim of removing £20m quarter from reimbursement; our intial analysis of the price changes shows that this will be achieved. There will be 12 new additions to Category M in October, notable additions include Sildenafil tablets, Rivastigmine capsules, Mometasone cream and Clarithromycin oral suspension. There were 2 deletions, Nabumetone tablets and Cefalexin 125mg oral suspension.

There are now a total of 527 products in the Category M list; in October 475 of these products experienced price decreases, 49 experienced increases and 3 remained the same. The largest percentage decreases were Sildenafil tablets – these are new entries to Category M as Viagra has recently come off patent. In total, eight of the top ten price decrease products are new Category M lines.

Several of the top percentage increase products have been on concession in recent months, these include Trazodone, Indapamide and Isosorbide mononitrate. The price increases may reduce the need for concessions from October onwards; we will continue to monitor the situation regarding these lines.

12. AIV

The latest AIV analysis is shown in **Appendix FCS 07/10/13**. NHS BSA payment data shows the average AIV increased in 13/14 Q1 over the previous quarter, by 18p per item. This was made up of an 11p NIC increase and a 7p increase in fees per item. The fee increase is expected as there was an increase in the top level Practice Payment in April 2013, from 58.2p to 66.2p per item. Our preliminary analysis of PCA data shows the NIC increase of 11p per item is made up of a 15p increase in generic NIC per item, and a 3p per item decrease in brand AIV and appliance AIV. The PCA data for the final month of Q1 13/14 is not yet available so these figures may change, as NIC can vary significantly from month to month within a Cat M quarter (e.g Mar 13 NIC was 17p higher than Jan 13 NIC). So far in 13/14 Q2, NHS BSA payment data indicates a slight decrease over the previous quarter's AIV, of 4p in NIC and 2p in fees. We will gain a fuller understanding of the drivers behind the changes when PCA data becomes available.

13. Shortages

The most recent NCSO concession was granted in April (for Indapamide 2.5mg tablets). In recent months the Department have been proposing price concessions which have the benefit of reduced workload for pharmacies and on the whole have been a fair reflection of buying prices.

In the month of September 2013, 11 lines were granted a price concession by DH. By comparison in September 2012 there was only one NCSO line and two price concessions granted, demonstrating that the issue of shortages has increased substantially over the past year. Gabapentin 300mg capsules were a new addition to the price concession list in August and Propranolol 40mg has been added in September. The shortages affecting Isosorbide Mononitrate 10mg and 20mg and Trazodone 50mg, 100mg & 150mg strength

tablets and capsules continue to be problematic for contractors; however prices are only just catching up in the Drug Tariff.

Obtaining data from wholesalers has become increasingly difficult for us as they are not sharing the data as promptly as they did. This could be due to the number of products which have supply issues resulting in increased workload for them.

Shortages remain a very current issue for contractors. The office is exploring options for a more timely and reliable process to adjust reimbursement prices where shortages have lead to significant price increases as part of the funding settlement.

14. Supply Chain Issues

a. Recent Changes to Manufacturers Distribution Arrangements

As of 1st October 2013, the distribution of the Abilify product range will transfer from Bristol-Myers Squibb Pharmaceuticals Ltd (BMS) to Otsuka Pharmaceuticals (U.K.) Ltd (Otsuka).

Otsuka have selected an alternative distribution route for the Abilify range of products: From 1st October 2013, Alliance Healthcare will have exclusive rights to distribute the Abilify range of products.

b. Supply problems

Branded product supply obligations
PSNC wrote to the Department on two separate occasions this year highlighting the need for PPRS and its successor Value Based Pricing (VBP) to include an obligation on manufacturers to ensure there is sufficient supply to meet UK patient demand. We also responded to the Department of Health Consultation on Revisions to the Statutory Scheme to Control the Prices of Branded NHS Medicines Copies of the letters and consultation can be found in **Appendix FCS 08/10/13.** Publicising of the joint letter sent on 24th June 2013 was undertaken in early September 2013.

15. Statistics

Monthly statistics are set out in **Appendix FCS 09/10/13**.

16. Any other business

2013 Work Plan for the Funding and Contract Subcommittee

The 2013 work plan for the Funding and Contract Subcommittee covers all items agreed at the PSNC November 2012 planning meeting. It is based on the PSNC Plan for 2013, the committee's four year plan and the subcommittee's remit.

Key for RAG coding
Red – needs attention / not started / high risk
Amber – underway / in progress
Green – completed / no further attention

Target Plans	Target date	Comment / Update on progress	R/A/G
In 2013 PSNC will finalise negotiation of funding for the national contract and will develop recognition of the value and potential of community pharmacy service provision in meeting the health needs of our population. We will support development of strong and productive relationships with NHS England at local and national level and will continue to work effectively with the Department of Health on medicines pricing and reimbursement issues. We will negotiate revisions to funding distribution to minimise risk and income volatility, and continue to secure improvements to pricing accuracy through effective audit and negotiation.			
• Negotiations following the Cost of Service Inquiry will lead to levels of nationally assured funding for the pharmacy service agreed by PSNC. • As part of a funding settlement a formula for annual adjustment will be negotiated that protects the real value of funding for pharmacy contractors. • Distribution mechanisms for pharmacy funding will incentivise not only quality and service provision but also dispensing. PSNC will seek to agree reward for procurement activity and ensure protection against income volatility. • PSNC will seek to minimise opportunities for CCGs to distort contractor income, and minimise dispensing at a loss.			
Seek to negotiate the best possible outcome for national funding levels based on the results of CoSI, calling on relevant external expertise when required.	As soon as possible, subject to DH and NHS CB	Ongoing funding negotiations are confidential.	Amber
Seek to negotiate an annual adjustment mechanism for total funding to protect the contract sum and ensure stability of funding delivery to enable contractors to plan.	As soon as possible, subject to DH and	Ongoing funding negotiations are confidential.	Amber

	NHS CB		
Seek to reconcile the conflict between regulatory lag and a CoSI based contract sum. Develop arguments in support of an explicit benefit sharing mechanism.	As soon as possible, subject to DH and NCB	Ongoing funding negotiations are confidential.	Amber
Develop options for funding distribution (quality, services etc.) and discuss with DH and NHSCB.	As soon as possible, subject to DH and NHS CB	Ongoing funding negotiations are confidential.	Amber
Continue dialogue with DH about options to remove dispensing at a loss and counter contractor's lack of power in brand market, recognising the timing of latest round of PPRS negotiations.	As soon as possible, subject to DH and NHS CB	Ongoing funding negotiations are confidential.	Amber
• PSNC will continue to audit margins surveys to ensure results are reliable and will seek to improve the understanding of external stakeholders of the margins survey process.			
Maintain current focus on analysing half yearly margins survey to ensure results are reliable. For example, screening the sample, auditing the database, assessing the wholesale discount calculations, checking the calculations for reasonableness and assessing influential lines.	March 2013 Oct 2013	A paper has been submitted to DH on methodological treatment of influential lines and a meeting held to determine most appropriate way forward. Further analysis has been agreed. 2012/13 data has been submitted to DH and database auditing completed. Confidential draft results are still subject to discussion with DH. Data is being collected and processed for Q1 2013/14.	Amber
• Acceptable pricing transparency systems will be agreed and implemented. The 'pricing engine' alternative to the current method for pricing and reimbursement will continue to be promoted as an alternative if the NHS BSA cannot offer acceptable levels of information. • PSNC will continue to work with the NHS BSA to improve overall accuracy figures as well as holding it to account on addressing pricing problems at individual contractor level resulting in at least 99% accuracy in every audited account (based on errors affecting payment).			

• Progress will also be made to increase pricing transparency and payment information available for contractors. • PSNC will increase its capacity to undertake prescription pricing audit, improving the level of checking and verification and developing proactive monitoring. • PSNC will develop the capability to audit transmission and payment of electronic prescriptions.			
Respond effectively to DH's impending proposals on DT simplification.	Dec 2013	There was a meeting with DH in August to discuss outstanding areas and plan next steps. Analysis being performed by both DH and the office.	Amber
Continue to press the proposal for the pricing engine with DH.	Ongoing	Proposal shared. Awaiting next action from DH. In the meantime, commercial opportunities for use of PRISM are being considered by a group led by Kirit Patel.	Amber
Determine a usable level of transparency for contractors and seek to ensure BSA provides it.	Dec 2013	A written response to DH's proposal has been submitted following a meeting of the group in August. We are awaiting DH's response but it is anticipated that contractors will be able to view editable electronic payment schedules by q4 13/14 at the latest.	Amber
Commission report on EPS audit and determine what is needed for PRISM.	July 2013	We are actively auditing electronic prescriptions in PRISM but problems experienced with the completion of PRISM have put this work item on hold. Now that all KPI reports have been developed, we hope to be able to produce the report on EPS accuracy vs. paper and aim to discuss how best to audit data leaving the pharmacy before it arrives at the BSA (i.e. from the spine) with HSCIC.	Red
Maintain close working relationships with BSA. Utilise PRISM functionality to highlight areas of inaccuracy.	Ongoing	Relationships with BSA are improving; the Head of Processing now attends liason meetings and we have managed to get the BSA to consider PSNC as stakeholders in all future IT development and can therefore have an impact on how pricing rules are implemented in future. We are developing a new	Green

		suite of reports to share with the BSA based on the new indicators we are capturing in PRISM and these will be on the website also.	
Maximise PAC capacity through full exploitation of the opportunities offered by PRISM and developing a prediction tool to optimise staff resources.	Oct 2013	A working group is currently considering opportunities for developing DT training programmes at the PAC and other ways of being able to utilise the data for commercial purposes. Some initial ideas have been explored but definitive workstreams and next steps need to be defined.	Amber
• PSNC will work to ameliorate problems of supply shortages, limited distribution, burden associated with securing supplies and adverse procurement terms.			
Continue to ensure robust data capture methods in margins survey covers changes in procurement terms and conditions.	March 2013 Oct 2013	This is part of the continuous assessment and improvement of the margin survey methodology and a major focus of work on wholesaler discount analysis. A number of significant 'shortage' lines were in the sample for H2 2012/13.	Amber
Ensure additional costs associated with limited distribution models are reflected in funding arrangements, along with implications of these arrangements of reduced competition in the wholesale market.	March 2013 Oct 2013	This forms part of negotiations on Margins Surveys and Regulatory Burdens.	Amber
Seek to ensure funding reflects full costs of securing supplies e.g. basing calculations on updated survey data.	March 2013 Oct 2013	This forms part of negotiations on CoSI and Regulatory Burdens.	Amber
Monitor NCSO and price concession lines and ensure DH applies most appropriate reimbursement mechanism to shortage lines in a timely fashion.	On-going	Observed trends are continuing to be reported to DH, along with earlier applications for long-term shortages. This was a substantive agenda item for May 2013.	Amber

Pricing Accuracy Report

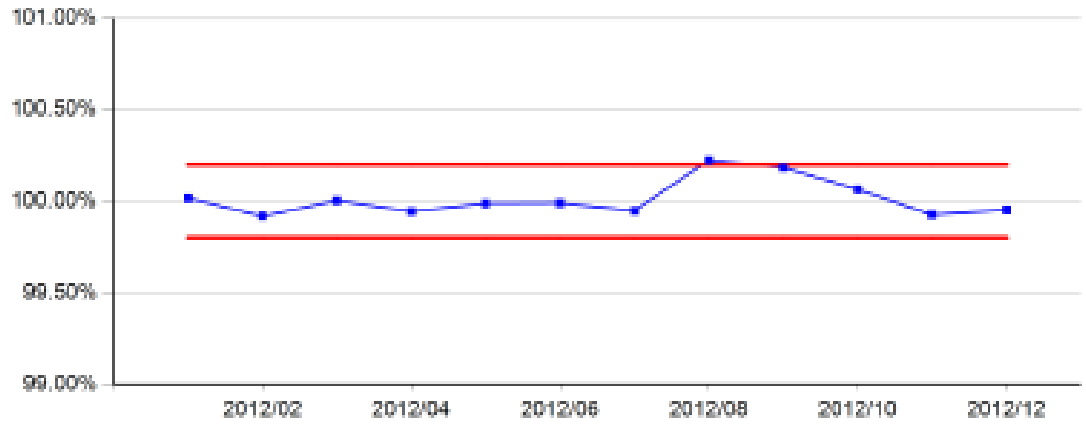
Period: 2012/01 to 2012/12
Jurisdiction: England
Types: Routine, Routine EPS

Batch based charts

Batch Net Cash Variance

Lower Tolerance: 99.80% - Upper Tolerance: 100.20%

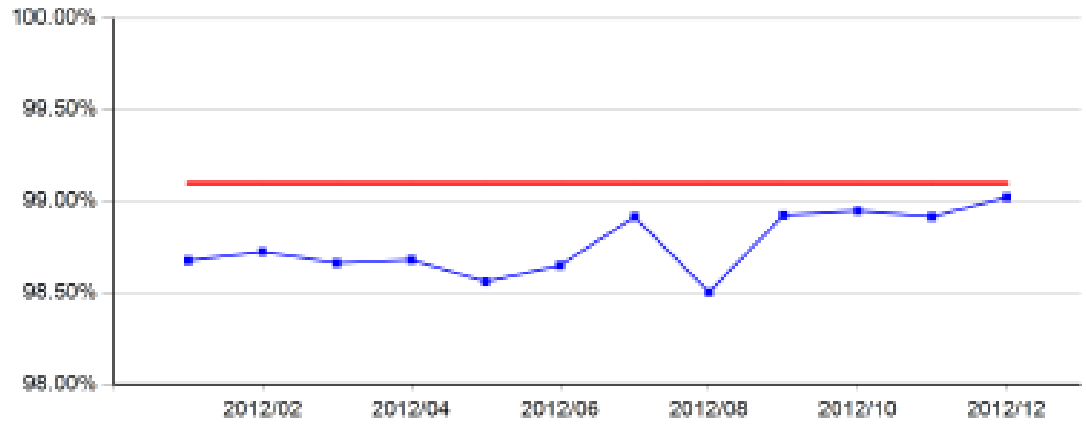
Rolling Average: 100.02%



Batch Absolute Cash Variance

Target: 99.10% by Mar 2013

Rolling average: 98.74%



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Pricing Accuracy Report

Period: 2012/01 to 2012/12

Jurisdiction: England

Types: Routine, Routine EPS

Batch based values

		Overpaid			Underpaid		
Period	Batches	#	£	£/#	#	£	£/#
2012/01	11	5	-£962.71	-£192.54	6	£885.04	£147.51
2012/02	27	10	-£1,355.90	-£135.59	17	£2,529.52	£148.80
2012/03	23	12	-£1,582.60	-£131.88	11	£1,541.11	£140.10
2012/04	18	8	-£1,142.22	-£142.78	10	£1,756.51	£175.65
2012/05	30	13	-£2,483.09	-£191.01	17	£2,679.81	£157.64
2012/06	23	13	-£2,190.41	-£168.49	10	£2,308.79	£230.88
2012/07	21	8	-£1,566.14	-£195.77	12	£2,383.68	£198.64
2012/08	22	13	-£4,841.97	-£372.46	9	£1,969.94	£218.88
2012/09	21	13	-£3,392.27	-£260.94	8	£1,039.92	£129.99
2012/10	14	8	-£922.60	-£115.33	6	£412.64	£68.77
2012/11	15	9	-£437.91	-£48.66	6	£883.66	£147.28
2012/12	10	5	-£662.10	-£132.42	5	£887.14	£177.43
	235	117	-£21,539.92	-£184.10	117	£19,277.76	£164.77

Key

#: Number of batches

£: Total net value of batch adjustments (overpaid or underpaid)

£/#: Average net value of batch adjustments (overpaid or underpaid)

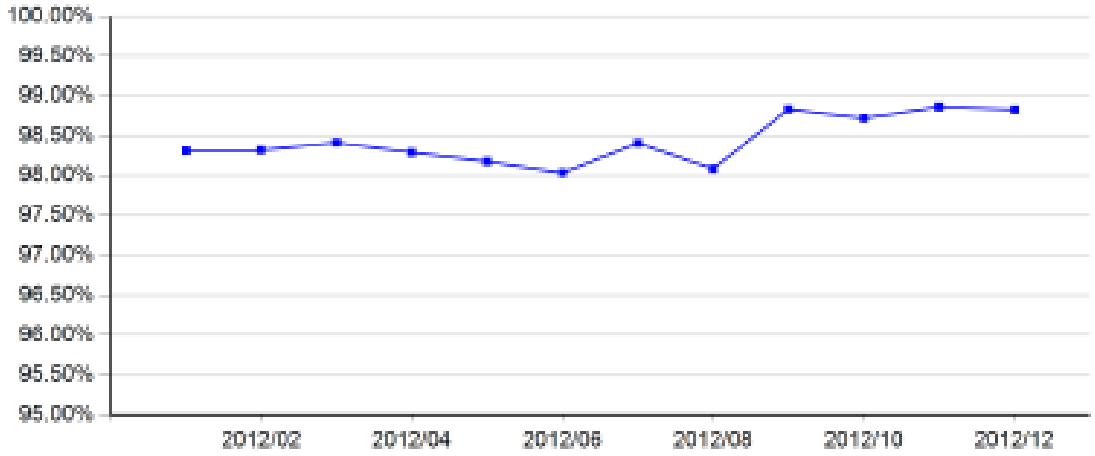
Pricing Accuracy Report

Period: 2012/01 to 2012/12
Jurisdiction: England
Types: Routine, Routine EPS

Item Based Statistics

Prescription Pricing Overall Accuracy (PPOA)

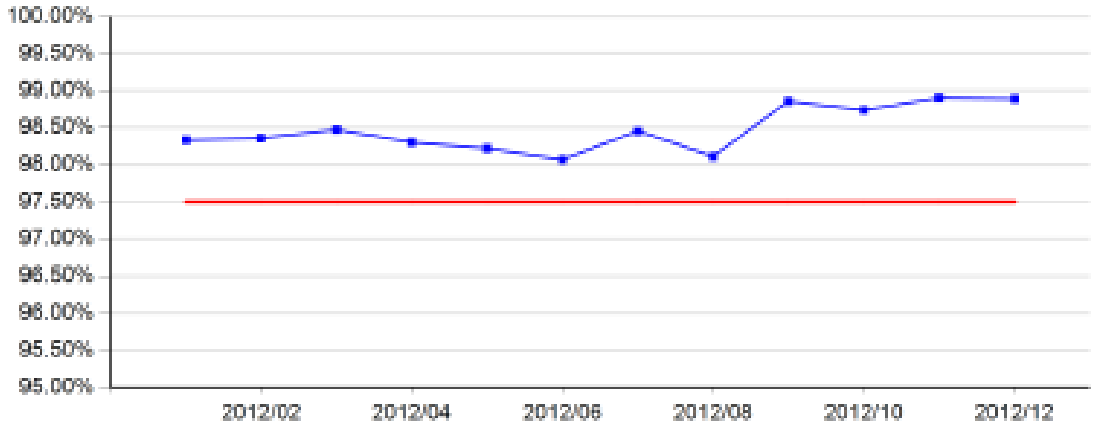
Rolling Average: 98.39%



Prescription Pricing Accuracy Affecting Payment (PPAAP)

Target: 97.50%

Rolling Average: 98.42%



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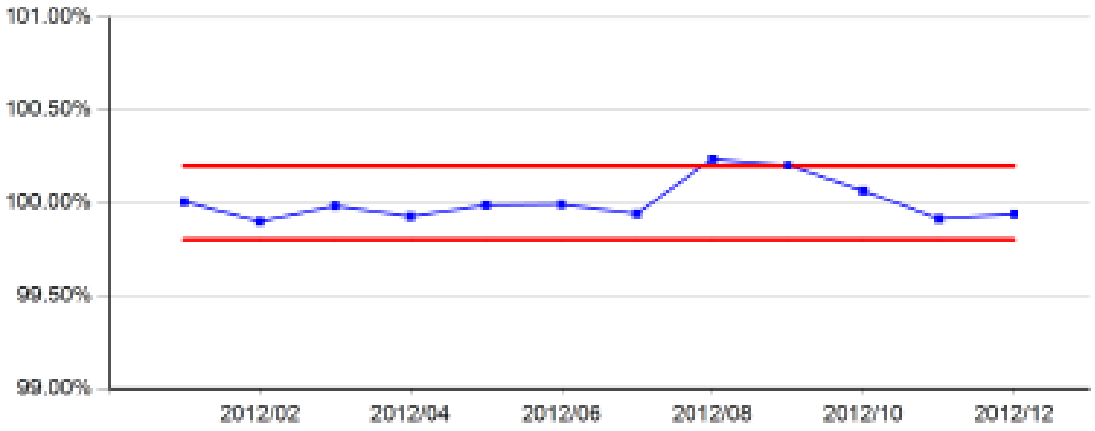
Net Cash Variance (NCV)

Lower Tolerance: 99.80% - Upper Tolerance: 100.20%

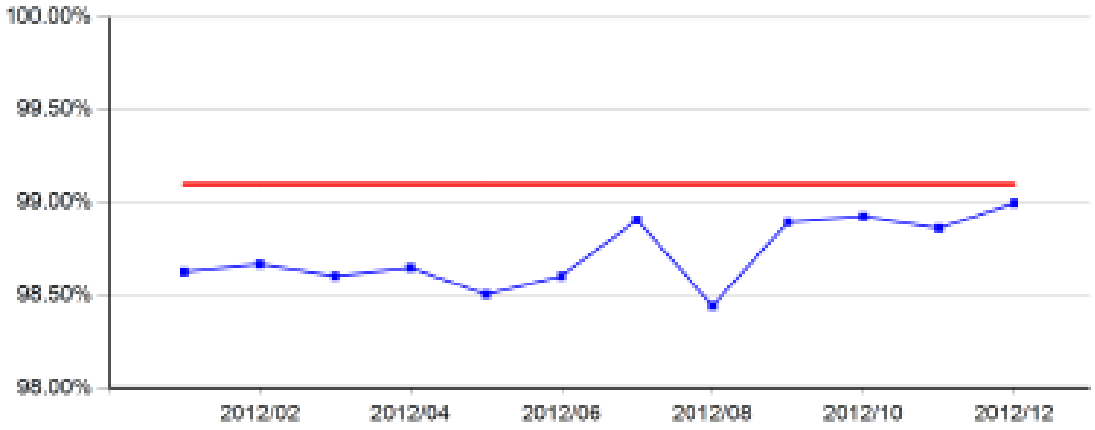
Rolling Average: 100.01%



Absolute Cash Variance (ACV)

Target: 99.10% by Mar 2013

Rolling average: 98.70%



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Pricing Accuracy Report

Period: 2012/01 to 2012/12

Jurisdiction: England

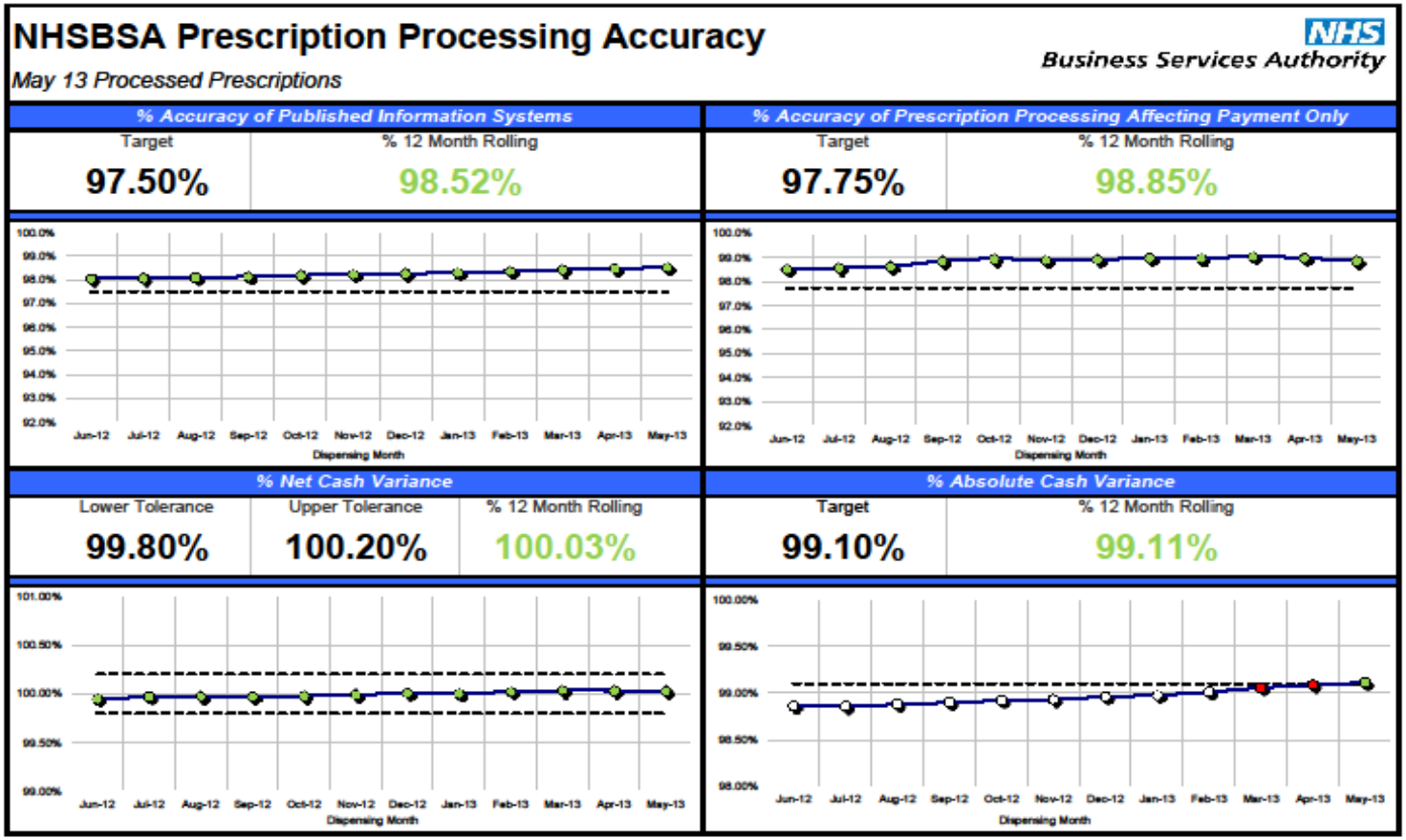
Types: Routine, Routine EPS

Item Based values

	PPOA	PPPAP		NCV			ACV	
Period	Actual	Actual	T	Actual	L/T	U/T	Actual	T
2012/01	98.31%	98.33%	97.50%	100.00%	99.80%	100.20%	98.63%	99.10%
2012/02	98.32%	98.36%	97.50%	99.90%	99.80%	100.20%	98.67%	99.10%
2012/03	98.41%	98.47%	97.50%	99.98%	99.80%	100.20%	98.60%	99.10%
2012/04	98.29%	98.30%	97.50%	99.93%	99.80%	100.20%	98.65%	99.10%
2012/05	98.18%	98.22%	97.50%	99.99%	99.80%	100.20%	98.51%	99.10%
2012/06	98.03%	98.07%	97.50%	99.99%	99.80%	100.20%	98.60%	99.10%
2012/07	98.41%	98.45%	97.50%	99.94%	99.80%	100.20%	98.91%	99.10%
2012/08	98.09%	98.11%	97.50%	100.24%	99.80%	100.20%	98.44%	99.10%
2012/09	98.83%	98.86%	97.50%	100.20%	99.80%	100.20%	98.89%	99.10%
2012/10	98.72%	98.74%	97.50%	100.06%	99.80%	100.20%	98.93%	99.10%
2012/11	98.86%	98.90%	97.50%	99.92%	99.80%	100.20%	98.86%	99.10%
2012/12	98.83%	98.89%	97.50%	99.94%	99.80%	100.20%	99.00%	99.10%

Key:

- PPOA: Prescription Pricing Overall Accuracy
- PPPAP: Prescription Pricing Accuracy Affecting Payment
- NCV: Net Cash Variance
- ACV: Absolute Cash Variance
- *Actual*: Actual value
- *T*: Target value
- *L/T*: Lower tolerance value
- *U/T*: Upper tolerance value

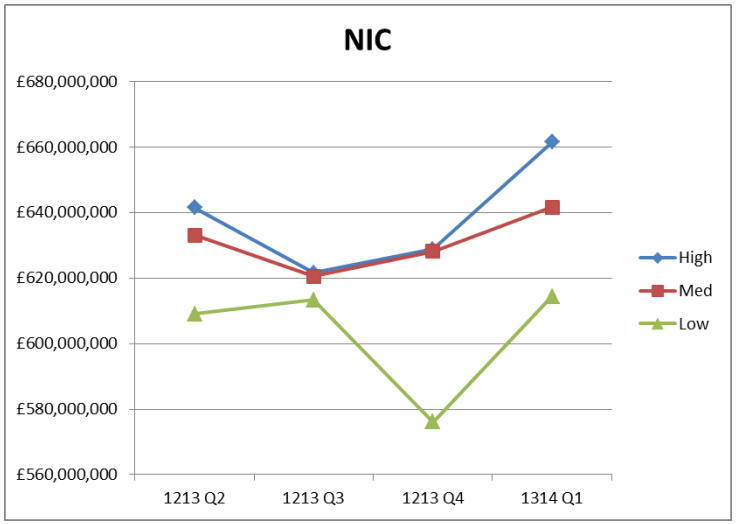

NHSBSA Prescription Processing Accuracy
May 13 Processed Prescriptions
NHS
Business Services Authority
% Accuracy of Published Information Systems
Target
97.50%
% 12 Month Rolling
98.52%
% Accuracy of Prescription Processing Affecting Payment Only
Target
97.75%
% 12 Month Rolling
98.85%
100.0%
99.0%
98.0%
97.0%
96.0%
95.0%
94.0%
93.0%
92.0%
Jun-12 Jul-12 Aug-12 Sep-12 Oct-12 Nov-12 Dec-12 Jan-13 Feb-13 Mar-13 Apr-13 May-13
Dispensing Month
% Net Cash Variance
Lower Tolerance
99.80%
Upper Tolerance
100.20%
% 12 Month Rolling
100.03%
% Absolute Cash Variance
Target
99.10%
% 12 Month Rolling
99.11%
101.00%
100.50%
100.00%
99.50%
99.00%
98.50%
98.00%

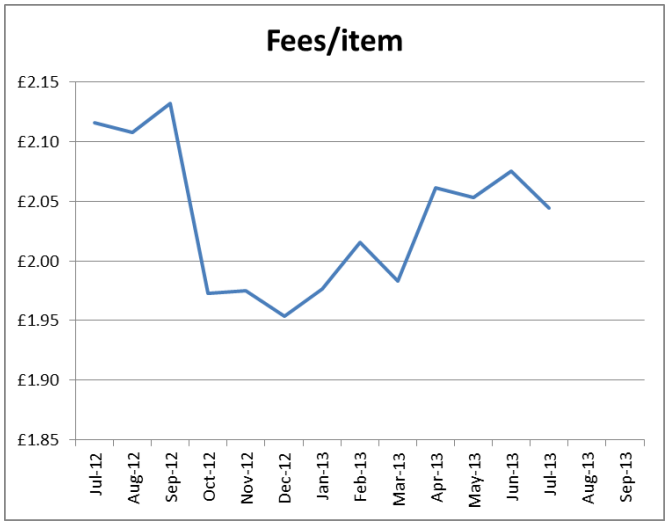
Average Item Value

AIV comparison

(Source: BSA PD1 data)

	Fees (Items)	Fees (£)	NIC	Disc		Fees/item	NIC/item	CB/item		Reimb/item					
Jan-13	80,238,908	158,611,354	628,753,945	49,314,100		1.98	7.84	0.61		7.22					
Feb-13	73,161,789	147,465,556	576,042,653	44,611,097		2.02	7.87	0.61		7.26		**Q4 results**			
Mar-13	78,282,406	155,217,069	628,141,556	49,514,498		1.98	8.02	0.63		7.39		0.12	NIC difference v previous 3 month avg		
Total	**231,683,103**	**461,293,979**	**1,832,938,155**	**143,439,696**		**1.99**	**7.91**	**0.62**		**7.29**		0.02	fee difference v previous 3 month avg		
Apr-13	79,485,591	163,848,875	641,639,925	50,864,900		2.06	8.07	0.64		7.43					
May-13	82,500,614	169,397,557	661,513,991	52,630,765		2.05	8.02	0.64		7.38		**Q1 results**			
Jun-13	76,640,588	159,070,838	614,441,285	48,432,334		2.08	8.02	0.63		7.39		0.11	NIC difference v previous 3 month avg		
Total	**238,626,793**	**492,317,270**	**1,917,595,201**	**151,927,999**		**2.06**	**8.04**	**0.64**		**7.40**		0.07	fee difference v previous 3 month avg		
Jul-13	83,636,084	170,989,277	668,368,526	52,961,073		2.04	7.99	0.63		7.36					
Aug-13												**Q2 results**			
Sep-13												-0.04	NIC difference v previous 3 month avg		
Total	**83,636,084**	**170,989,277**	**668,368,526**	**52,961,073**		**2.04**	**7.99**	**0.63**		**7.36**		-0.02	fee difference v previous 3 month avg		

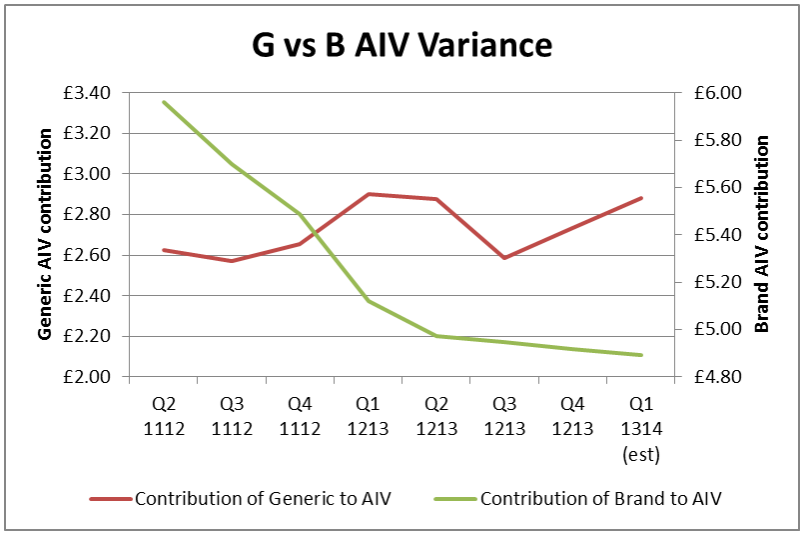




Average Item Value – Variance Analysis

(Source: BSA PCA data. NB June 2013 PCA data is not yet available)

	AIV	Contribution of Generic to AIV	Contribution of Brand to AIV	Contribution of Appliances to AIV
Q2 1112	£9.31	£2.63	£5.96	£0.73
Q3 1112	£8.99	£2.57	£5.70	£0.72
Q4 1112	£8.86	£2.65	£5.49	£0.72
Q1 1213	£8.74	£2.90	£5.12	£0.72
Q2 1213	£8.59	£2.88	£4.97	£0.74
Q3 1213	£8.25	£2.58	£4.95	£0.73
Q4 1213	£8.39	£2.73	£4.92	£0.74
Q1 1314 (est)	£8.49	£2.88	£4.89	£0.72



12/13 Q4 v 13/14 Q1 (estimated) comparison

(Source: BSA PCA data. NB June 2013 PCA data is not yet available)

	G NIC/ITE	G Items			B NIC/ITE	B Items			A NIC/ITE	A Items			Mvmt
Q4Q4	3.77	72%	2.73		20.20	24%	4.92		23.29	3%	0.74		
Q4Q1	3.77	73%	2.74	0.01	20.20	24%	4.87	-0.05	23.29	3%	0.73	-0.01	
Q1Q1	3.96	73%	2.88	0.14	20.30	24%	4.89	0.03	22.81	3%	0.72	-0.02	
			0.15	0.15			-0.03	-0.03			-0.03	-0.03	0.10

Earl Howe
Parliamentary Under Secretary of State (Quality)
Department of Health
Richmond House
79 Whitehall
London SW1A 2NS

18 March 2013

Dear Minister,

PPRS negotiations.

The Department's negotiations with members of the ABPI on prescription pricing began last year, and we expect that they will lead to a revised scheme to be implemented from 1 January 2014. Both BAPW and PSNC have already written to Katy Peters to highlight the problems this implementation date implies for the supply chain.

We understand that the negotiations on PPRS are bilateral, between manufacturers and the Department, but as distributors of the products covered by the scheme, we have a substantial interest in ensuring that it addresses obligations not simply restricted to pricing, but also ensuring that medicines are supplied promptly and reliably to the pharmacies that need them to fulfil prescriptions for patients in the community.

In the course of consultations before the last PPRS was agreed in 2009, PSNC wrote to press for the scheme to include arrangements to monitor supplies. Sadly this was not adopted, and, in the absence of any effective provisions in the scheme to *require* manufacturers to ensure good distribution of medicines, we have suffered longstanding problems, of which I know you are well aware. These have led to numerous initiatives, including the All Party Pharmacy Group inquiry, but they have had negligible success. We have articulated the costs in terms of work to pharmacies and the adverse impact on their ability to provide a reliable service for their patients. The associated impact on distributors of managing limited stocks, sometimes well below established market need, are less well known.

BAPW and PSNC are therefore writing to you jointly to urge that this time, the Department of Health takes the opportunity given by the current PPRS negotiations and addresses the resilience of the supply arrangements for medicines covered by the scheme. We believe this can only work if our organisations are fully involved in that specific part of the negotiations. BAPW and PSNC both have recent track records of working with the Department on issues of medicines supply and patient safety, and experience has shown that failure to address this problem in the past has been a serious weakness of the PPRS which both our organisations believe the government cannot afford to ignore.

Yours faithfully,

Sue Sharpe
Chief Executive
PSNC

Martin Sawer
Executive Director
BAPW

Ms Katy Peters
Deputy Director - Pricing, Prescriptions and Supply
Medicines, Pharmacy and Industry
Department of Health
Skipton House
80 London Road
London
SE1 6LH

Dear Katy

24th June 2013

Following our meeting two weeks ago we are writing, as you requested, to set out what we would wish to see incorporated into the PPRS, and why we believe it is important in our efforts to ensure that patients have prompt and assured access to medicines prescribed for them in primary care.

We clarified to you that our proposals did not amount to a request to be involved in the negotiations and were not focused on parallel trade. Our motivation is to ensure that patients can get the medicines they need promptly from the pharmacy they choose, supporting the framework for supply of medicines found in NHS legislation, and in particular the legal duty on the pharmacy to supply any medicine prescribed on an NHS prescription form with "reasonable promptness".

In the course of our discussions you explained your concern to ensure that the PPRS avoided the use of 'non-deliverable aspirational language', and we understand and support this. Indeed we have experienced, to our cost, the dangers of this in our work with you and other partners on the Supply Chain Group. Despite all our endeavours to agree good distribution practice, culminating in guidance accepted by all participants, it soon became evident that interpretation of the wording by some manufacturers nullified the impact of the guidance, and did nothing to improve the adverse consequences for pharmacies, and of course the patients they serve, of some of the worst practices adopted by manufacturers.

We identified to you the risks that, unless action is taken to reinforce and protect the arrangements for access to medicines, further changes, such as manufacturers' direct supply to patients, could well develop. This happens today with some appliances. Such a development would fundamentally undermine the aim of the legislation. You referred to the NPA study of shortages as indicating that supply and access problems were not significant; we warned of the dangers of relying on a snapshot survey and figures of overall supply levels in this particularly sensitive market. We also spoke about the increased costs to the NHS, associated with practices adopted by manufacturers in the last seven years, and gave as an example just one of these elements of increased costs: the lost discount to pharmacies attributable to medicines that are supplied to pharmacies directly by the manufacturer, bypassing normal distribution routes. This alone we estimate as costing £70m per annum. The NHS pays for this of course. You responded that for you the security of supply concerns were less persuasive than the costs.

The Supply Chain Group has been meeting for over three years, and its fore-runner, that we instituted prior to the ministerial summit in February 2010, began two years before that. Whilst some manufacturers have over time recognised the virtues of our joint buffer stocks proposals, many have not, and nothing in the PPRS or elsewhere provides a firm basis for requiring them to ensure prompt supply to pharmacies. As you know the BAPW has advocated a 24 hour requirement, and PSNC supports this.

We propose inclusion of a provision in the PPRS that obliges a manufacturer covered by the scheme to ensure that it has effective arrangements to ensure the supply of medicines required by a dispenser for supply, to meet an NHS prescription, within 24 hours of the request being made. The obligation should specify the exceptions, which would include some provision for requests made over weekends, and when manufacturing problems make compliance impossible. We would like to see the provisions include an obligation to submit to adjudication of complaints of a breach of this obligation. In practice we would expect to have few, if any adjudications because such a requirement would change the behaviours of those manufacturers that, at present, rely on the total absence of any standards regulating their supply arrangements.

We hope this is helpful in clarifying our request and why we believe it is both necessary and appropriate.

Yours sincerely,

Sue Sharpe
Chief Executive
PSNC

Martin Sawer
Executive Director
BAPW

T 0844 381 4180
E info@psnc.org.uk
www.psnc.org.uk

The Pharmaceutical Services

Negotiating Committee

Response to:

Department of Health Consultation on

Revisions to the Statutory Scheme to Control the Prices of Branded NHS Medicines

PHARMACY
the Heart of our Community

July 2013

Sue Sharpe
CEO, PSNC
Times House
5 Bravingtons Walk
London
N1 9AW

PSNC promotes and supports the interests of all NHS community pharmacies in England. We are recognised by the Secretary of State for Health as the body that represents NHS pharmacy contractors. Our goal is to develop the NHS community pharmacy service, and to enable community pharmacies to offer an increased range of high quality and fully funded services; services that meet the needs of local communities, provide good value for the NHS and deliver excellent health outcomes for patients.

PSNC's response is confined to questions where we believe our knowledge is valuable to the consultation. We have focused on three issues: the exploitation of the current pricing systems to increase costs to the NHS, and how this could be addressed; the adverse impact on security of supply and patient access of introducing price changes on 1st January; and the need to incorporate obligations on manufacturers to ensure speedy supply to patients through their chosen dispenser.

Scope of the scheme

The proposed scope of the scheme is 'branded medicines'. It is intended to make provisions for the pricing of medicines eligible for control under the voluntary PPRS, where the manufacturer does not consent to be bound by the PPRS. Although primarily seeking to control the prices of medicines with patent protection, the definition in both the draft regulations and in the PPRS allows the inclusion of medicines that are out of patent protection, where a manufacturer chooses to apply a brand name. It excludes medicines marketed under a generic name, even where patent protection applies.

This, as a consequence of features of pharmacy funding mechanisms, enables manufacturers to sell branded generic medicines on terms that result in higher cost to the NHS than the net cost of the true generic, with transfer of costs away from the prescribing budget. We comment on this under question 16, below and would be happy to explain the operation of the arrangements.

As presently proposed, the scheme does not apply to 'divestments' that are marketed under a generic name, even where they remain covered by patent protection. In practical terms, the specialist nature or limited demand for these products means that there is no stimulus to other entrants into the market, and even on patent expiry, excessive prices can continue to be charged.

Recent activity has highlighted the failure of current pricing schemes for medicines prescribed in primary care to prevent exploitation of loopholes. We believe there is an urgent need to re-examine the scope of the scheme to ensure that mechanisms are in place to limit opportunities for businesses to make excessive profits from NHS and taxpayer funds.

We suggest that the scheme should apply to all medicines where there is only one person placing product on the market, and should not seek to regulate by reference to the application of a brand name, which is an inappropriate definition. We recognise that this requires significant amendment to the draft regulations to re-define "branded health service medicine", add definitions to cover branded generics and 'divested' medicines, and make provision for their pricing. New paragraphs would be required for the two new categories that require control, but within the current draft regulations, relevant criteria to be applied in determining prices can be found, and we are happy to explain our proposals separately.

5) Is the proposed £5 million small firms exemption needed?

As noted, there has been significant activity recently in 'divestments': the sale of the IP or marketing rights in low volume medicines to businesses that are not covered by the PPRS. The medicine is commonly marketed under its generic name (thus bypassing the statutory scheme) and the price for the medicine is greatly inflated, with a price rise of 2,400% being recorded recently. The current arrangements for setting reimbursement prices are ineffective to deal with this practice. Given the current prevalence of this practice, and the very large numbers of low volume medicines, we believe the statutory scheme should address the practice. In view of the market size of some of these medicines, we believe the potential for misuse of the £5m firms' exemption for these products should be explored.

16) Is it likely that the proposed changes will create any risks around continuity of supply of branded medicines?

Timing of changes

The proposed timing of the changes to the statutory scheme and to the PPRS, 1 January 2014, is extremely difficult for pharmacy suppliers and pharmacies, and PSNC requests that the adoption of the new scheme prices be deferred to 1st February 2014.

The levels of price cuts proposed will mean both pharmacies and wholesalers will significantly reduce their stock holding in the period running up the price cut, to minimise loss of stock value. Around the Christmas period pharmacies face many pressures, with prescribers changing their prescribing practices and many patients using pharmacies other than their normal pharmacies,

when they are away from home. This always places significant pressures on the distribution network, and the need to de-stock to avoid financial loss will add significantly to the problems and to the risk that patients will be unable to obtain their medicines over the period.

Our request is made against the background of the increase in shortages of branded medicines which, although they were beginning to become a feature of the market when the PPRS was last negotiated, were a far smaller problem at the time.

In addition, we believe that manufacturers should be required to give a minimum notice period of changes to prices. This will support wholesale suppliers in managing their stocks and help pharmacies to offer a reliable and speedy service to their patients,

Ensuring access to medicines

PSNC, together with the BAPW wrote to Katy Peters on 24th June 2013, proposing provisions to include in the PPRS. This is the most recent of many attempts to ensure that manufacturers of medicines covered by the scheme have responsibility for ensuring that they can be quickly and simply obtained by the dispenser chosen by the patient, normally a local community pharmacy. The same obligation should apply to medicines covered by the statutory scheme.

In our letter we proposed inclusion of a provision that obliges a manufacturer covered by the scheme to ensure that it has effective arrangements to ensure the supply of medicines required by a dispenser to meet an NHS prescription, within 24 hours of the request being made. The obligation should specify the exceptions, which would include some provision for requests made over weekends, and when manufacturing problems make compliance impossible. We would like to see the provisions include an obligation to submit to adjudication of complaints of a breach of this requirement. In practice we would expect to have few, if any, adjudications because such a requirement would change the behaviours of those manufacturers that at present rely on the total absence of any standards regulating their supply arrangements.

This provision is necessary to support the legal duty of the pharmacy to supply any medicine prescribed for a patient 'with reasonable promptness'.

Branded generics

PSNC proposes new provisions to ensure the inclusion in the statutory scheme of medicines for which the patent has expired to which a brand name is applied, marketed by a body other than the brand originator where there are several manufacturers of the generic medicine.

This requires changes to the PPRS as well as to the statutory scheme. The PPRS is an umbrella scheme to control the prices of branded medicines sold to the NHS, and its aim is to provide a framework for pricing of patent medicines. Branded generic manufacturers, where the manufacturer is not and does not claim to be the brand originator, use the scheme to list a price, which allows them to market and encourage prescribing of their products to the NHS. In doing this they bypass the Category M pricing mechanism systems, and this results in increased costs to the NHS. The increased cost is not evident, and indeed the direct cost to the prescriber's budget will be lower. Given the financial constraints faced by the NHS, this is not an acceptable use of taxpayer funds.

PSNC believes that the PPRS should apply only to manufacturers who certify that they qualify as the brand originator, either as holder of the patent or because they have procured the certified brand from the brand originator. The statutory scheme should be extended to apply to all medicines not covered by the PPRS for which there is only one manufacturer.

Statistics

NMS

NHS Prescription Services' figures of NMS conducted to date are detailed below:

Month	Number Claimed	Number Paid	Value (£)	No. of pharmacies claiming payment	Cumulative no. of different pharmacies claiming payment since Oct 11	Number of Implementation Payment Claims	Value of Implementation Payment Claims	Payment Per conducted MUR	Percentage paid MUR
Oct-11	10,121	4,378	£109,450	2,557	2,557	1,702	£1,276,500	£10.81	43%
Nov-11	43,759	27,945	£698,625	5,840	6,257	1,847	£1,385,250	£15.97	64%
Dec-11	43,480	28,502	£712,550	5,741	7,417	1,176	£882,000	£16.39	66%
Jan-12	40,570	27,724	£693,100	5,671	8,005	1,741	£1,305,750	£17.08	68%
Feb-12	45,923	32,354	£808,850	6,905	8,957	1,573	£1,179,750	£17.61	70%
Mar-12	49,903	33,213	£830,325	6,398	9,206	161	£120,750	£16.64	67%
Apr-12	41,771	27,795	£694,875	5,564	9,291	0	£0	£16.64	67%
May-12	49,129	49,129	£1,195,348	6,129	9,392	0	£0	£24.33	100%
Jun-12	45,147	45,147	£1,096,961	5,922	9,467	0	£0	£24.30	100%
Jul-12	48,941	48,941	£1,191,090	6,140	9,542	0	£0	£24.34	100%
Aug-12	48,375	48,375	£1,173,628	6,061	9,611	0	£0	£24.26	100%
Sep-12	44,196	44,196	£1,070,242	6,081	9,676	0	£0	£24.22	100%
Oct-12	56,346	56,346	£1,337,901	6,567	9,756	0	£0	£23.74	100%
Nov-12	61,676	61,676	£1,517,600	6,774	9,823	0	£0	£24.61	100%
Dec-12	57,575	57,575	£1,398,599	6,433	9,897	0	£0	£24.29	100%
Jan-13	57,181	57,181	£1,398,284	6,631	9,970	0	£0	£24.45	100%
Feb-13	66,358	66,358	£1,646,580	7,034	10,040	0	£0	£24.81	100%
Mar-13	70,302	70,302	£1,742,501	6,999	10,101	0	£0	£24.79	100%
Apr-13	68,950	68,950	£1,707,422	6,971	10,150			£24.76	100%
May-13	73,991	73,991	£1,820,634	7,099	10,213			£24.61	100%
Jun-13	66,776	66,776	£1,650,332	7,090	10,264			£24.71	100%
Total	**1,090,470**	**996,854**	**£24,494,897**			**8,200**	**£6,150,000**		

	2011/12	2012/13	2013/14
total funding paid	£10,002,900	£15,463,609	£5,178,388
Avg payment / NMS	£16.48	£23.90	£24.69

A detailed breakdown of NMS and MUR data by PCT and LPC is available in the LPC Resources Centre (LPC Members' area of the PSNC website).

MUR

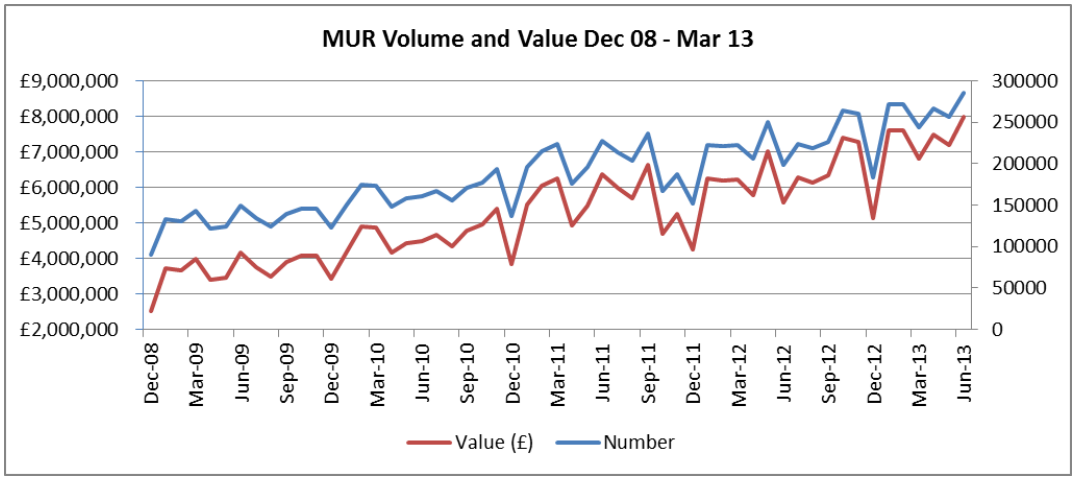
Recent NHS Prescription Services' figures of MURs conducted to date are detailed below:

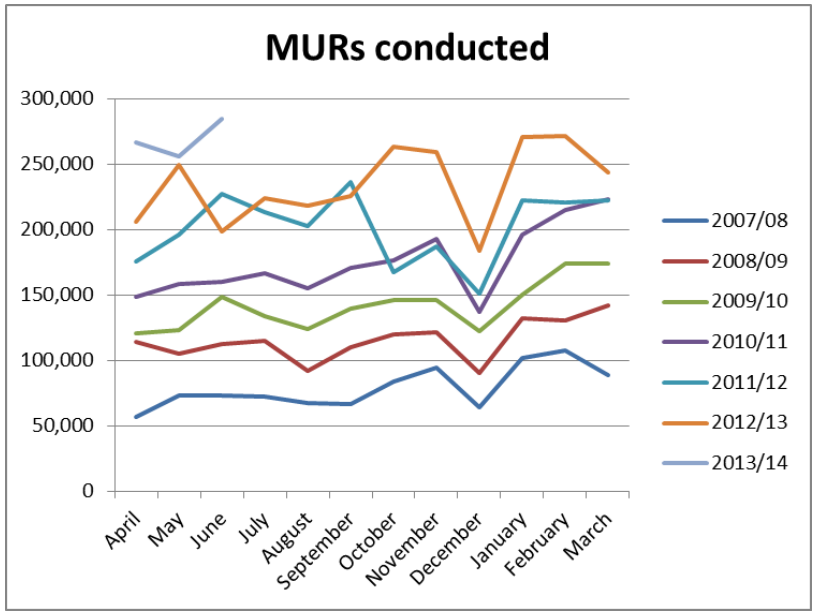
Month – No. MURS – Value (£) – Growth % YoY – No. CPs

Jul-11	213776	£ 5,985,718.66	28%	8500
Aug-11	203182	£ 5,689,086.66	31%	8393
Sep-11	236753	£ 6,629,074.66	39%	8567
Oct-11	167573	£ 4,692,044.00	-5%	8385
Nov-11	187395	£ 5,247,060.00	-3%	8502
Dec-11	151460	£ 4,240,880.00	11%	8119
Jan-12	222693	£ 6,235,404.00	13%	8505
Feb-12	220882	£ 6,184,696.00	3%	8433
Mar-12	222281	£ 6,223,866.00	-1%	8152
Apr-12	205906	£ 5,765,368.00	17%	8900
May-12	249986	£ 6,999,620.00	27%	9029
Jun-12	198820	£ 5,566,960.00	-13%	8943
Jul-12	224054	£ 6,273,524.00	5%	9021
Aug-12	218733	£ 6,124,536.00	8%	8980
Sep-12	226167	£ 6,332,689.00	-4%	9140
Oct-12	263740	£ 7,384,720.00	57%	9309
Nov-12	259591	£ 7,268,548.00	39%	9314
Dec-12	183729	£ 5,144,422.00	21%	8852
Jan-13	271147	£ 7,592,116.00	22%	9175
Feb-13	271899	£ 7,613,172.00	23%	9049
Mar-13	243610	£ 6,821,080.95	10%	7879
Apr-13	266738	£ 7,468,663.00	30%	9527
May-13	256636	£ 7,185,808.00	3%	8888
Jun-13	285191	£ 7,985,348.00	43%	10287

Note - these figures are based on actual paid MURs.

A breakdown of MURs conducted by LPC is available at www.psnc.org.uk/statistics.



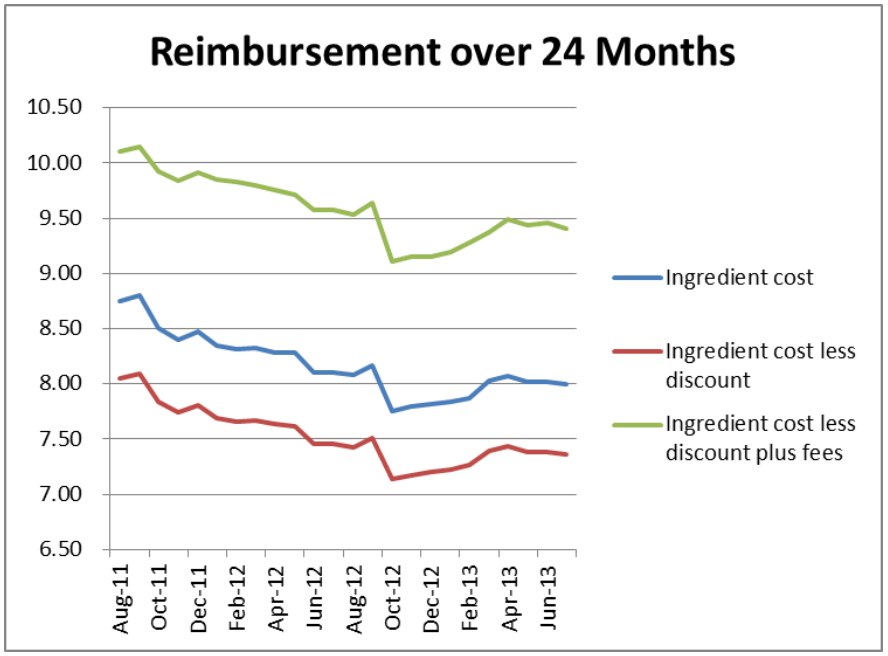


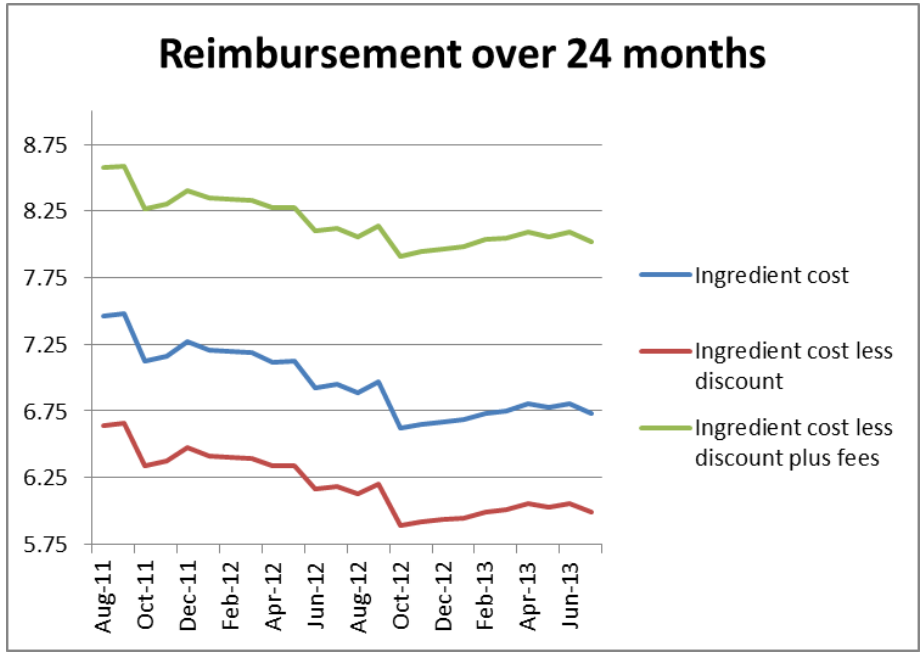
NIC, discount, cost of fees and average item value (England)

PhS Pharmacy Contractors						
	NIC	Discount	Cost of fees	AIV £pi	yoy growth	Cumulative ytd growth
Aug-12	£8.08	-£0.65	£2.11	£9.57	-5.58%	-2.80%
Sep-12	£8.16	-£0.65	£2.13	£9.68	-4.98%	-2.87%
Oct-12	£7.75	-£0.62	£1.97	£9.14	-8.21%	-3.04%
Nov-12	£7.80	-£0.62	£1.97	£9.18	-6.96%	-3.15%
Dec-12	£7.81	-£0.61	£1.95	£9.19	-7.66%	-3.28%
Jan-13	£7.84	-£0.61	£1.98	£9.23	-6.60%	-3.38%
Feb-13	£7.87	-£0.61	£2.02	£9.31	-5.53%	-3.44%
Mar-13	£8.02	-£0.63	£1.98	£9.41	-4.34%	-3.46%
Apr-13	£8.07	-£0.64	£2.06	£9.53	-2.64%	-3.44%
May-13	£8.02	-£0.64	£2.05	£9.47	-2.89%	-3.43%
Jun-13	£8.02	-£0.63	£2.08	£9.49	-1.18%	-3.37%
Jul-13	£7.99	-£0.63	£2.04	£9.44	-1.74%	-3.33%

Dispensing Doctors						
	NIC	Discount	Cost of fees	AIV £pi	yoy growth	Cumulative ytd growth
Aug-12	£6.88	-£0.76	£1.93	£8.06	-6.05%	-5.59%
Sep-12	£6.97	-£0.77	£1.94	£8.14	-5.21%	-5.52%
Oct-12	£6.62	-£0.73	£2.03	£7.91	-4.26%	-5.35%
Nov-12	£6.65	-£0.73	£2.03	£7.95	-4.27%	-5.22%
Dec-12	£6.67	-£0.73	£2.03	£7.97	-5.19%	-5.21%
Jan-13	£6.69	-£0.74	£2.04	£7.98	-4.37%	-5.13%
Feb-13	£6.73	-£0.74	£2.04	£8.04	-3.66%	-5.00%
Mar-13	£6.75	-£0.74	£2.04	£8.05	-3.33%	-4.86%
Apr-13	£6.81	-£0.75	£2.03	£8.09	-2.21%	-4.66%
May-13	£6.77	-£0.75	£2.03	£8.06	-2.60%	-4.52%
Jun-13	£6.80	-£0.75	£2.04	£8.09	-0.09%	-4.24%
Jul-13	£6.73	-£0.74	£2.03	£8.02	-1.14%	-4.05%

*AIV includes container allowance





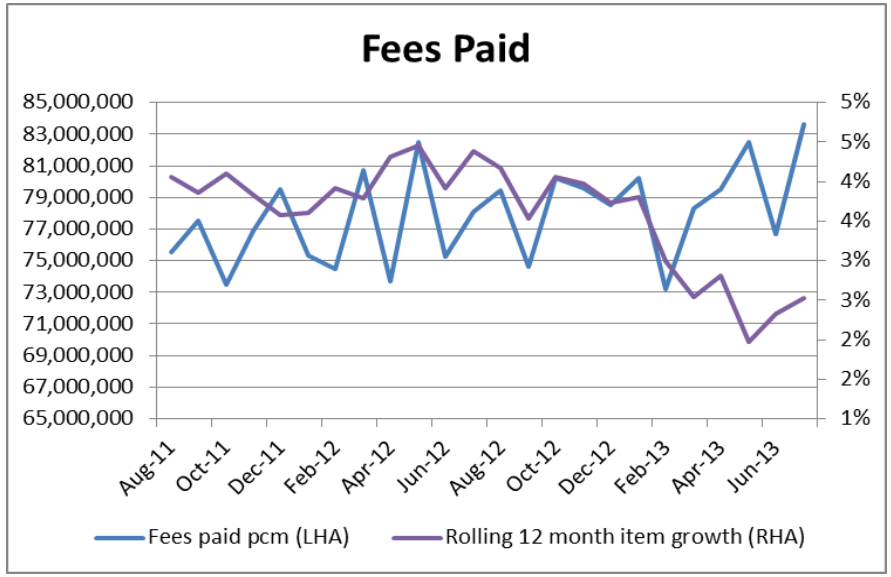
Prescription volume (England)

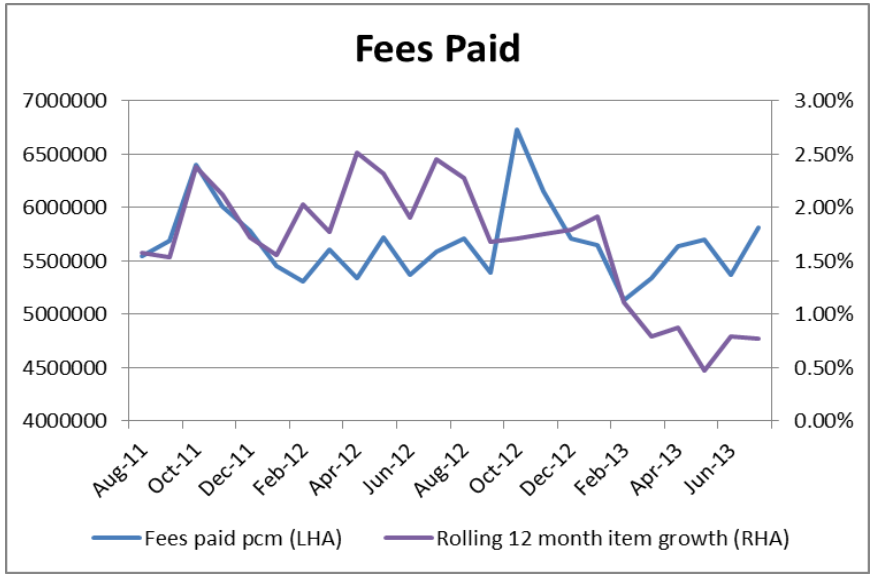
PhS Pharmacy Contractors

	Fees paid pcm (LHA)	yoy growth	Cumulative ytd growth	Rolling 12 month item growth (RHA)
Aug-12	79,419,906	5.18%	4.40%	4.17%
Sep-12	74,602,257	-3.78%	2.99%	3.53%
Oct-12	80,194,115	9.16%	3.86%	4.05%
Nov-12	79,585,840	3.53%	3.82%	3.98%
Dec-12	78,497,580	-1.29%	3.22%	3.74%
Jan-13	80,238,908	6.53%	3.55%	3.81%
Feb-13	73,161,789	-1.73%	3.08%	3.00%
Mar-13	78,282,406	-2.99%	2.54%	2.54%
Apr-13	79,485,591	7.82%	7.82%	2.81%
May-13	82,500,614	0.00%	3.69%	1.98%
Jun-13	76,640,588	1.85%	3.10%	2.33%
Jul-13	83,636,084	7.07%	4.10%	2.52%

Dispensing Doctors

	Fees paid pcm (LHA)	yoy growth	Cumulative ytd growth	Rolling 12 month item growth (RHA)
Aug-12	5,706,997	3.02%	2.49%	2.27%
Sep-12	5,388,059	-5.20%	1.15%	1.68%
Oct-12	6,731,945	5.24%	1.82%	1.71%
Nov-12	6,155,954	2.46%	1.91%	1.75%
Dec-12	5,703,666	-1.26%	1.55%	1.79%
Jan-13	5,642,543	3.48%	1.73%	1.92%
Feb-13	5,135,928	-3.25%	1.30%	1.11%
Mar-13	5,332,697	-4.90%	0.79%	0.79%
Apr-13	5,636,573	5.67%	1.15%	0.87%
May-13	5,696,581	-0.47%	1.03%	0.47%
Jun-13	5,365,833	-0.12%	0.95%	0.79%
Jul-13	5,813,607	4.12%	1.15%	0.77%

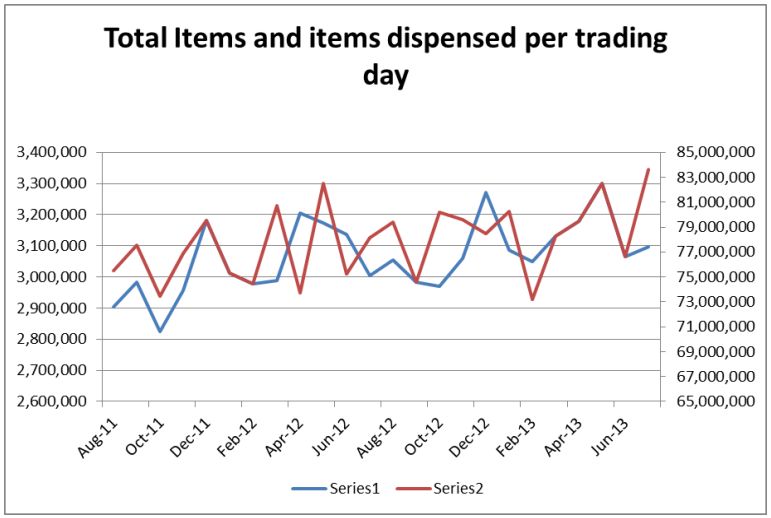


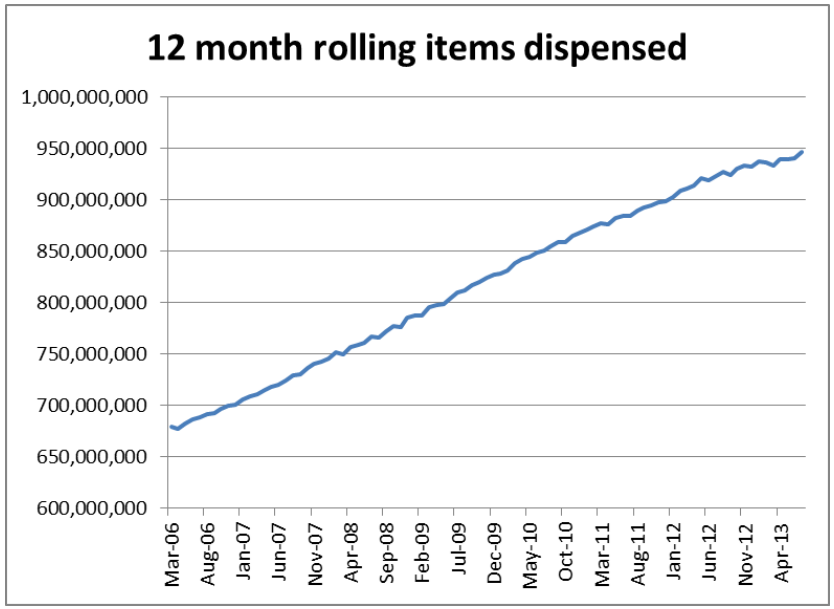


Growth in Prescription Items

Month – Itens – Trading Days – Items / Day

Aug-11	75,509,826	26	2,904,224
Sep-11	77,536,263	26	2,982,164
Oct-11	73,462,091	26	2,825,465
Nov-11	76,868,689	26	2,956,488
Dec-11	79,526,647	25	3,181,066
Jan-12	75,322,071	25	3,012,883
Feb-12	74,453,381	25	2,978,135
Mar-12	80,694,007	27	2,988,667
Apr-12	73,718,226	23	3,205,140
May-12	82,497,714	26	3,172,989
Jun-12	75,244,930	24	3,135,205
Jul-12	78,111,633	26	3,004,294
Aug-12	79,419,906	26	3,054,612
Sep-12	74,602,257	25	2,984,090
Oct-12	80,194,115	27	2,970,152
Nov-12	79,585,840	26	3,060,994
Dec-12	78,497,580	24	3,270,733
Jan-13	80,238,908	26	3,086,112
Feb-13	73,161,789	24	3,048,408
Mar-13	78,282,406	25	3,131,296
Apr-13	79,485,591	25	3,179,424
May-13	82,500,614	25	3,300,025
Jun-13	76,640,588	25	3,065,624
Jul-13	83,636,084	27	3,097,633

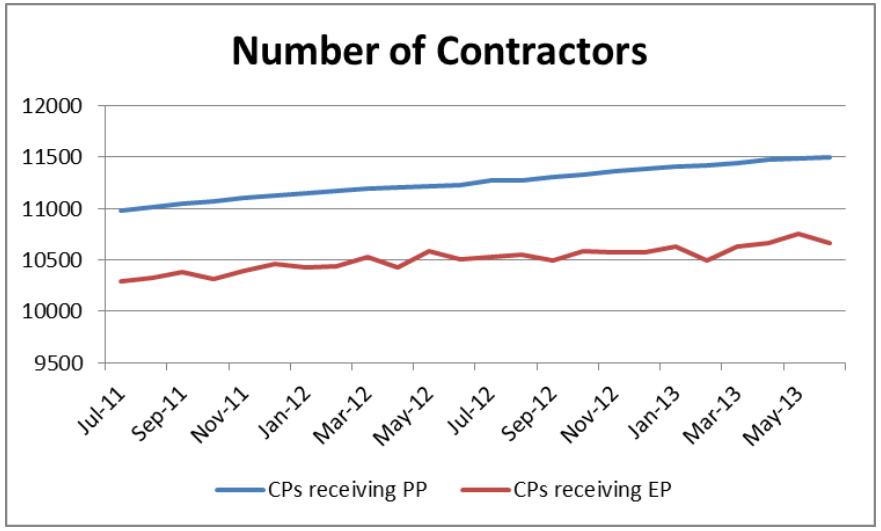


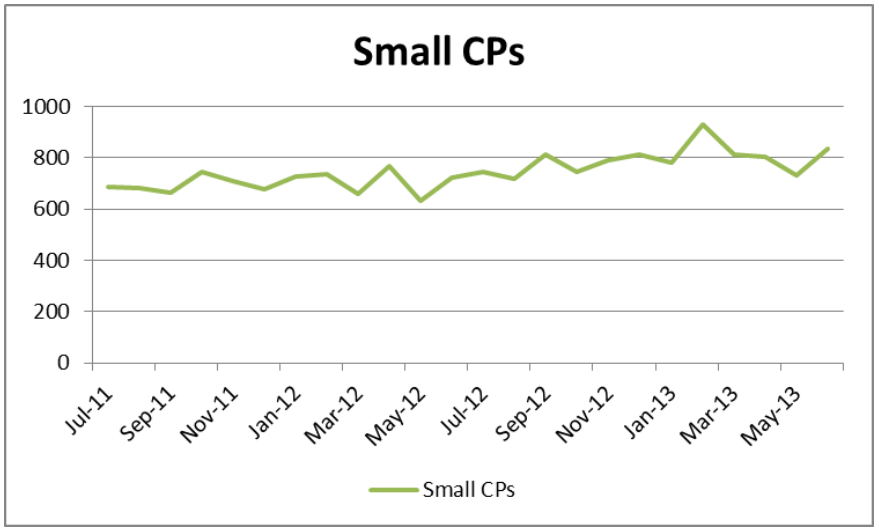


Number of English contractors receiving Practice & Establishment Payments, number of small pharmacies.

Month – CPs receiving PP – CPs receiving EP – Small CPs

Jul-11	10981	10292	689
Aug-11	11014	10330	684
Sep-11	11047	10381	666
Oct-11	11068	10320	748
Nov-11	11102	10392	710
Dec-11	11133	10457	676
Jan-12	11155	10425	730
Feb-12	11173	10435	738
Mar-12	11191	10533	658
Apr-12	11203	10434	769
May-12	11215	10581	634
Jun-12	11233	10508	725
Jul-12	11270	10525	745
Aug-12	11275	10557	718
Sep-12	11307	10493	814
Oct-12	11333	10587	746
Nov-12	11366	10576	790
Dec-12	11390	10575	815
Jan-13	11406	10626	780
Feb-13	11420	10491	929
Mar-13	11449	10634	815
Apr-13	11474	10668	806
May-13	11491	10757	734
Jun-13	11502	10666	836





Latest Cat M list analysis

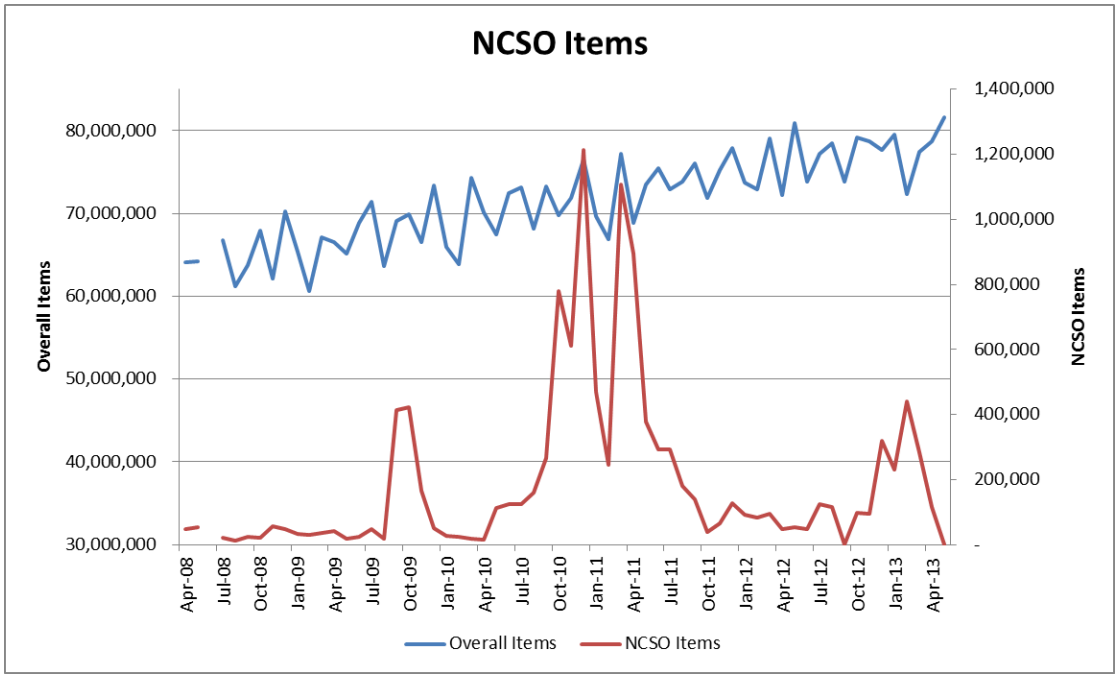
Category M value		
Jul 13 Cat M value*	**£395,459,158**	*per quarter*
Oct 13 Cat M value*	**£374,627,304**	*per quarter*
Movement*	**-£20,831,854**	*per quarter*

Total no. of increases	**49**
Total no. of decreases	**475**
Total no. of no change	**3**
Total no. of products	**527**

*indicative figures based on fixed 2012 product vols.

Biggest Movers					
Drug Name	Pack Size	Oct-13 DT	Jul-13 DT	change	% change
Isosorbide mononitrate 20mg tablets	56	14.53	1.97	12.56	638%
Isosorbide mononitrate 40mg tablets	56	16.21	4.32	11.89	275%
Indapamide 2.5mg tablets	28	13.98	4.1	9.88	241%
Fosinopril 20mg tablets	28	5.93	2.48	3.45	139%
Nifedipine 5mg capsules	84	13.62	7.23	6.39	88%
Trazodone 50mg capsules	84	21.27	11.85	9.42	79%
Isosorbide mononitrate 10mg tablets	56	12.53	7.19	5.34	74%
Ranitidine 150mg tablets	60	1.85	1.38	0.47	34%
Trazodone 50mg/5ml oral solution sugar f	120	34.89	26.89	8	30%
Trazodone 150mg tablets	28	14.19	11.19	3	27%
Sildenafil 100mg tablets	4	1.55	23.5	-21.95	-93%
Sildenafil 50mg tablets	4	1.45	21.27	-19.82	-93%
Sildenafil 25mg tablets	4	1.31	16.59	-15.28	-92%
Ondansetron 4mg tablets	10	1.79	12.72	-10.93	-86%
Rivastigmine 1.5mg capsules	28	5.99	22.25	-16.26	-73%
Rivastigmine 3mg capsules	28	6.12	20.19	-14.07	-70%
Valaciclovir 500mg tablets	10	6.63	16.54	-9.91	-60%
Ibandronic acid 150mg tablets	1	3.63	6.64	-3.01	-45%
Pramipexole 180microgram tablets	30	1.57	2.6	-1.03	-40%
Clarithromycin 250mg/5ml oral suspensic	70	8.09	12.52	-4.43	-35%

Number of NCSO items:

Month – national items – NCSO items - % of items which are NCSO

Jun-11	75,468,525	293,492	0.39%
Jul-11	72,942,271	293,492	0.40%
Aug-11	73,855,590	181,481	0.25%
Sep-11	75,981,066	139,459	0.18%
Oct-11	71,906,194	38,033	0.05%
Nov-11	75,277,264	66,797	0.09%
Dec-11	77,854,614	126,320	0.16%
Jan-12	73,772,423	90,933	0.12%
Feb-12	72,895,257	82,723	0.11%
Mar-12	79,068,949	94,446	0.12%
Apr-12	72,219,650	46,577	0.06%
May-12	80,908,242	52,592	0.07%
Jun-12	73,818,270	48,626	0.07%
Jul-12	77,173,997	124,061	0.16%
Aug-12	78,486,866	115,794	0.15%
Sep-12	73,796,255	1,398	0.00%
Oct-12	79,198,964	96,691	0.12%
Nov-12	78,650,528	95,535	0.12%
Dec-12	77,647,597	320,267	0.41%
Jan-13	79,476,818	230,296	0.29%
Feb-13	72,348,808	440,810	0.61%
Mar-13	77,437,155	284,498	0.37%
Apr-13	78,719,637	114,159	0.15%
May-13	81,593,114	-	0.00%