
The Community Pharmacy Contractual Framework and the retained medicine margin

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Findings, conclusions and recommendations

Scope of this report

1. This report examines the financial impact of the **Community Pharmacy Contractual Framework** (the Framework) since its inception in April 2005. We carried out this work because the Department of Health asked us to review the arrangements for ensuring that the amount of margin community pharmacies make from the purchase of medicines—the so-called '**retained margin**', which forms part of pharmacy remuneration—is in line with the levels agreed in the Framework. The Shadow Secretary of State for Health has asked questions in Parliament about the levels of retained margin being delivered under the Framework, and also asked us to investigate the matter.

2. In order to assess the financial impact of the retained margin element of the Framework, we had to examine the Framework as a whole. We therefore:

- established the **total expenditure** on the Framework over the four years 2005-06 to 2008-09, including the outturn on the retained margin;
- established a **counterfactual total expenditure**, by calculating what total expenditure would have been, had the pre-Framework arrangements for remunerating pharmacies remained in place;
- compared actual and counterfactual expenditure to estimate the **overall savings** in NHS expenditure on medicines arising from introducing the Framework, and used actual data on outturn and dispensing volume increases over time to calculate the **productivity gain** over the four years 2005-06 to 2008-09; and
- assessed the **extent of the retained margin** element of the Framework within this context.

3. We also examined the operation of the systems for monitoring and controlling the retained margin since its introduction. We found a number of areas in which there was scope for improvement, and our recommendations for addressing these follow our overall conclusions below.

The community pharmacy contractual framework

4. There were 10,475 community pharmacies in England at 31 March 2009. They are operated by independent contractors, owned by sole traders, small multiples,

supermarkets and large chains, and are located on the high street, in communities, shopping centres and rural areas. NHS pharmaceutical services account for about 90 per cent of a typical community pharmacy's turnover. Community pharmacies provide NHS services under a Contractual Framework which has been in operation since 1 April 2005, agreed between the Department of Health, the Pharmaceutical Services Negotiating Committee (the representative body for community pharmacy contractors), and the NHS Confederation (now NHS Employers - the employers' organisation for the NHS).

5. The Framework provides for pharmacy contractors to be remunerated for the services they provide in three ways:

- (i) About half of budgeted remuneration for pharmacies is in the form of fees and allowances that are paid from a '**global sum**' budget, which over the period covered by this report was administered centrally by the Department of Health. The 2008-09 budget for the global sum was £1,049 million.
- (ii) Pharmacies also receive further fees and allowances from their Primary Care Trusts. The main one is the '**practice payment**', which takes the form of a monthly payment for smaller pharmacies, or a fee per item dispensed for pharmacies dispensing more than a threshold level of items per month. Payments for medicines use reviews and the electronic prescription service are also met by Primary Care Trusts. The 2008-09 budget for PCT payments was £664 million.
- (iii) The third source of community pharmacies' remuneration is the '**retained margin**': the margin arising from the difference between the price at which a pharmacy purchases a medicine and the price at which the pharmacy is reimbursed by the NHS when the medicine is dispensed.

6. The Department and the Pharmaceutical Services Negotiating Committee agreed at the outset of the Framework that the target level of retained margin would be set at **£500 million annually**. The Department adjusts the level at which pharmacies are reimbursed for commonly dispensed items based on the level of margin achieved in the previous year.

7. In order to assess the actual total retained margin achieved each year, the Department carries out a survey of invoices, which show actual prices paid for a sample of medicines, from a sample of pharmacies. The Department uses the survey results to determine how to set the prices at which the NHS reimburses pharmacies for the

medicines they dispense. These reimbursement prices, which are published monthly in the NHS Drug Tariff, are deliberately set higher than the actual cost of medicines to pharmacies, at least for commonly dispensed generic medicines, so that globally pharmacies can earn the agreed target £500 million margin.

8. In managing the delivery of the margin by periodically adjusting reimbursement prices, therefore, the Department has to balance the risk of exceeding the target level of margin against the risk of falling short of the agreed level, and failing to meet its commitment to community pharmacies—potentially, in the longer term, affecting the availability of local community pharmacy services across the country and the supply of medicines to patients.

9. Since April 2008, when the White Paper *Pharmacy in England: Building on Strengths – Delivering the Future* was published, the Department has also had the related objective to provide, through the Contractual Framework, an incentive structure that will further increase the chances of achieving the Government’s aims of delivering more NHS services through community pharmacies, over and above the dispensing of medicines, and of fully utilising the skills of pharmacists and their staff in contributing to primary care and public health improvement, especially in the management of long-term conditions.

Findings and conclusions

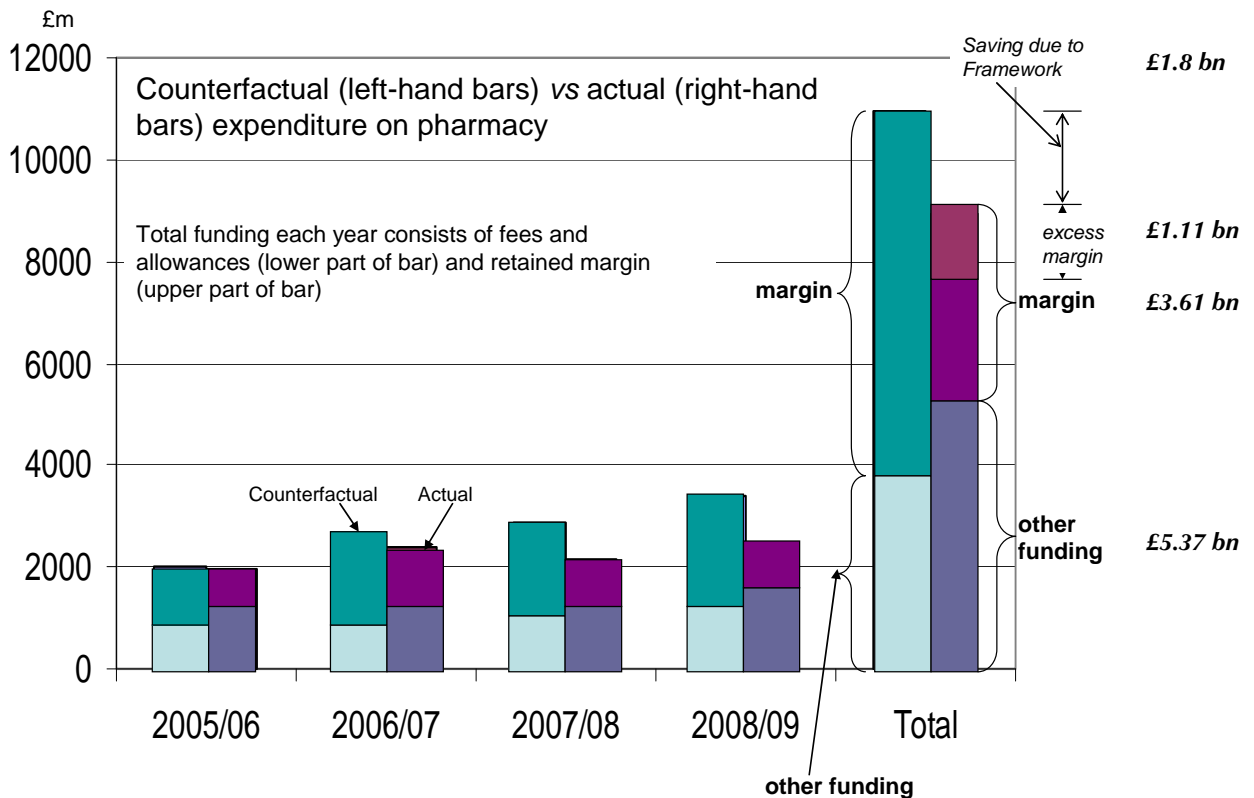
10. **The introduction of the new Contractual Framework in April 2005 has achieved two notable outcomes:**

- **There has been a cost saving to the NHS of around £1.8 billion over the period 2005-06 to 2008-09 by comparison with a counterfactual scenario of retaining the pre-Framework remuneration and medicines pricing arrangements.** The saving has arisen principally because, under the new Framework, the reimbursement prices paid to pharmacies for a number of commonly dispensed medicines have been reduced.
- **The productivity of pharmacies, with respect to core dispensing work, has also increased by 8 per cent over the four years 2005-06 to 2008-09.** In 2005-06, the total volume of medicines dispensed by pharmacy contractors was 679 million items, and total payments to contractors were £1.975 billion. By 2008-09, the number of items dispensed had increased by 17 per cent, to 795 million, for an increase in total payments of 8 per cent in real terms, to

£2.418 billion. In addition, pharmacies are now delivering new services, such as repeat dispensing, health promotion services and support for self care that were not available prior to the Framework.

11. However the new Contractual Framework also involved the introduction of an agreed annual target of £500 million in respect of the level of medicines margin allowed to be retained by pharmacies. That target was exceeded by £1.11 billion overall in the four years 2005-06 to 2008-09 (Figure 1). If reimbursement prices had been adjusted contemporaneously to meet the target, then potentially the Department could have increased savings by £1.11 billion - the difference between the £7.87 billion target and the £8.98 billion outturn set out in Figure 2. The total target retained medicines margin was £2.03 billion and the actual retained medicines margin was £3.61 billion: a difference of £1.57 billion. £0.46 billion of this difference was offset by reduced practice payments, leaving a total difference of £1.11 billion.

Figure 1: Expenditure on the Community Pharmacy Contractual Framework, 2005-06 to 2008-09



Source: NAO analysis of Department of Health data

Figure 2: Payments to pharmacy contractors under the Community Pharmacy Contractual Framework, 2005-06 to 2008-09

Element of remuneration	2005-06		2006-07		2007-08		2008-09		4-year total		
	Target (£m)	Outturn (£m)	Target (£m)	Outturn (£m)	Target (£m)	Outturn (£m)	Target (£m)	Outturn (£m)	Target (£m)	Outturn (£m)	Difference (£m)
Global sum	966	947	991	1,000	1,017	1,020	1,049	1,053	4,023	4,020	-3
PCT payments	300	228	420	247	430	281	664	595	1,814	1,351	-463
Retained margin	500	800	500	1,161	532 ¹	874	500	770 ²	2,032	3,605	+1,573
Variance on retained margin (£m)		300		661		342		270		1,573	
Total remuneration	1,766	1,975	1,911	2,408	1,979	2,175	2,213	2,418	7,869	8,976	+1,107
Variance on total contract sum (£m)		209		497		196		205		1,107	

Source: NAO analysis of Department of Health data

¹ An extra £32 million retained margin was agreed by Ministers this year, to offset some NHS Business Services Authority underpayments to pharmacies, and stock loss.

² Subject to final confirmation

12. The Department argues that the principal reason why the margin target has been exceeded is that the Framework incentivises individual pharmacy contractors to drive harder bargains with medicines suppliers, thereby driving down market prices for medicines. It argues that without this additional downward pressure on purchase prices, the adjustments made to reimbursement prices would have been sufficient to deliver a total margin closer to the £500 million target each year. The excess margin is due, therefore, to lower than expected prices in the medicines market, and is factored into reimbursement pricing decisions the following year, which in their turn incentivise pharmacies to drive down prices still further, as evidenced by the reduction in ex-factory prices. This cycle of 'catching up' with the previous year's excess is known as 'regulatory lag'. The Department tells us that it was an implicit part of the agreement with the Pharmaceutical Services Negotiating Committee from the outset that regulatory lag would be allowed for. The Pharmaceutical Services Negotiating Committee confirmed that pharmacies considered this to be an important element in the funding structure.

13. The £500 million target was set on the basis of limited information about community pharmacies' actual level of medicines margin. The figure of £500 million retained margin was agreed at the outset through negotiation, based on information available at the time. The Department advise that they suspected that there would be more than £500 million margin, but that they did not have firm evidence (such as from a margin survey). The Department say that they therefore agreed to the £500 million pending firm evidence becoming available, in order to bring the Contractual Framework, and the associated margins survey, into play, which was required to affect the savings.

14. Furthermore it is questionable whether it would have been realistic to achieve the potential additional savings required to have achieved the £500 million target. It would have entailed 25% lower expenditure on community pharmacy, over four years, as compared with a counterfactual of retaining the pre-Framework arrangements, in the context of year-on-year increases in outputs. A reduction on this scale could have threatened the viability of community pharmacies and hence access to pharmaceutical services and the supply of medicines to patients, bearing in mind that not all pharmacies would have achieved the average retained medicine margin identified in the survey.

15. Uncertainty surrounding the actual level of the margin and the achievability of the target in the early period of the new Framework's operation should, in our view, have made getting a robust assessment of actual levels of margin more of a priority for

the Department. We have identified a number of areas of weakness in the operation of the margin survey in the wider context of the Contractual Framework, as set out below.

16. The methods for assessing and monitoring the margin took several months to put in place after the Framework came into operation, and required further modification over the first two years. The approach and complex methodology had to be developed from scratch. The principles underpinning the proposed survey of pharmacy invoices, to assess the margin actually achieved, were agreed as part of the new Framework, but there was no detailed methodology in place to assess the total margin at the time the Framework commenced. The Department and the Pharmaceutical Services Negotiating Committee entered discussions in June 2005 on the detailed methodology. The first invoice surveys to assess the level of margin in 2005-06 covered 84 pharmacies in two months, October 2005 and February 2006, with the analysis finalised and agreed with the Pharmaceutical Services Negotiating Committee to take effect from October 2006, six months after the financial year end. The second survey, covering 2006-07, sampled medicines purchases for four months out of twelve and was conducted in January 2007, some nine months into the financial year.

17. After the results of the first survey exercise had shown an excess of £300 million over the agreed target margin for 2005-06, the Department commissioned independent experts to review the methodological rigour of the survey in 2006; and it commissioned a second review in 2008 after concerns were raised by the Pharmaceutical Services Negotiating Committee about the technical details of the calculations underpinning the margin estimate. It has acted to strengthen its procedures for estimating the margin following the reviewers' recommendations.

18. There is a risk of conflict of interest in a situation in which the representative body for the contractors is involved in administering a monitoring process that partially determines their members' remuneration under the contract. Collating information from sampled invoices to establish purchase prices requires a good knowledge of the pharmacy business, in order to understand both the various ways in which the medicines purchased in particular presentations and pack sizes may be described, and the ways in which suppliers may give discounts (for example these may be retrospective and not appear in the month in question). The Department agreed to work with the Pharmaceutical Services Negotiating Committee to undertake the survey, on the grounds that they had the requisite specialist knowledge, and that compliance with requests for invoices would be higher among pharmacy contractors if the survey was jointly

undertaken with the Pharmaceutical Services Negotiating Committee. The Department has full access to the invoices collected, and oversees and checks a sample of the Committee's work.

19. Over the first three years of operation of the Framework, sampled contractors were asked and encouraged through follow-up by the Pharmaceutical Services Negotiating Committee to supply the necessary information (invoices and statements). However, there was no compulsion for contractors to submit invoices. The Department realised it might have to use statutory powers to require pharmacists to take part in the survey for 2007-08, but discovered that the regulations necessary to support a statutory inquiry had inadvertently been lost as part of the implementation of the NHS Act 2006. The regulations have now been re-laid, and for the 2008-09 surveys, pharmacies were reminded that the Secretary of State has powers, under the NHS (Pharmaceutical Services) Regulations, to require them to provide the information.

Recommendations

20. The Department is carrying out a new inquiry to determine what would be a reasonable cost for the NHS to pay for the level of pharmacy services likely to be required in future. In the context of this inquiry, and the subsequent negotiations to implement its findings within the Contractual Framework, there is an opportunity to improve further the margin survey and funding arrangements. We recommend that the Department should:

- Be more timely in making adjustments to reimbursement prices for generic medicines to manage the level of retained margin. We understand that the Department's intention is to move to a process of rolling invoice surveys, which should facilitate this. However, the Department should also use evidence from other sources, such as average ex-factory prices, to make adjustments if necessary.
- Continue to work with recognised experts in survey design and analysis to maintain and improve the invoice survey. In particular, whilst the response rate has improved considerably since the inception of the Framework, the Department should take steps to ensure high response rates continue in future.
- Present the arrangements for funding the Framework more explicitly. If the Department believes that the target level of margin is likely to be exceeded every year

due to the operation of 'regulatory lag', this should be made clear, and the implications for expenditure on pharmacy services and medicines should be set out.

21. Furthermore, notwithstanding the expertise that the Pharmaceutical Services Negotiating Committee has in interpreting invoices for the margins survey, we recommend that the administration and processing of the survey should be carried out by an independent organisation. This would remove any potential or perceived conflict of interest.

Part 1: How pharmacy services are funded, and how pharmacies are reimbursed for the drugs they dispense

The provision of pharmacy services

1.1 There were 10,475 community pharmacies in England at 31 March 2009. They are operated by independent contractors, owned by sole traders, small multiples, supermarkets and large chains, and are located on the high street, in communities, shopping centres and rural areas. NHS pharmaceutical services account for about 90 per cent of a typical community pharmacy's turnover.

1.2 Community pharmacies provide NHS services under the Framework which has been in operation since 1 April 2005, and is agreed between the Department of Health, the Pharmaceutical Services Negotiating Committee (the representative body for community pharmacy contractors), and the NHS Confederation (now NHS Employers - the employers' organisation for the NHS).

1.3 The Framework is designed to give pharmacists a greater role in providing primary care, beyond simply dispensing medicines, with particular emphasis on the role that pharmacists can play in promoting health and wellbeing, advising on self care, safe and effective use of medicines and also services that can identify potential health problems such as screening. The Framework specifies three different levels of service:

- **Essential services** – These must be provided by all community pharmacies and include dispensing, repeat dispensing, health promotion, support for self-care and disposal of unwanted medicines.
- **Advanced services** – These require both the pharmacist and the pharmacy premises to be accredited. The first of these services is the medicines use review (MUR) where pharmacists review a patient's current medication to ensure patients get best use and resolve any problems.
- **Enhanced services** – These are services commissioned locally by PCTs to reflect the needs of the local population. These can include minor ailment treatment schemes, stop smoking services, emergency hormonal contraception and support for substance misusers.

How pharmacy services are funded

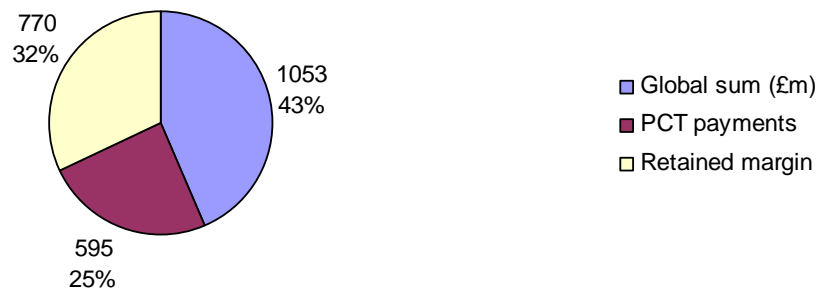
1.4 In 2003, prior to the introduction of the current Framework, the Department carried out a 'cost-of-service' enquiry, in conjunction with the Pharmaceutical Services Negotiating Committee, to establish a fair estimate of the cost of providing pharmacy services. The Department agreed with the Committee that over time, the fees and allowances that had previously formed the basis of Government funding of pharmacy services had ceased to be sufficient to cover pharmacy costs. At the same time, growth in the market for generic medicines had led to pharmacies making an increasing proportion of their income from margin earned from medicines purchases, since reimbursement prices were often considerably higher than actual average manufacturers' or wholesalers' prices.

1.5 The Framework recognises three principal sources of remuneration for community pharmacies:

- About half of budgeted remuneration for community pharmacies comes from the '**global sum**', which over the period covered by this report was administered centrally by the Department of Health. Following the Health and Social Care Act in 2008, the global sum is being devolved to Primary Care Trusts from April 2010.
- Community pharmacies receive '**practice payments**' from their Primary Care Trusts, in the form of a monthly payment for smaller pharmacies, or a fee per item dispensed for pharmacies dispensing more than a threshold level of items per month. Primary Care Trusts also fund payments for the electronic prescription service and medicines use reviews.
- The third source of community pharmacies' remuneration is the '**retained margin**': the margin arising from the difference between the price for which a pharmacy can purchase a medicine and the price at which the pharmacy is reimbursed when the medicine is dispensed. The Department and the Pharmaceutical Services Negotiating Committee agreed at the outset of the Framework that the total target level of retained margin would be set at £500 million annually.

1.6 In 2008-09 community pharmacies received a total of £2.418 billion under the Framework. **Figure 3** shows the breakdown of this figure.

Figure 3: Structure of community pharmacies' remuneration through the Framework in 2008-09



Source: NAO analysis of Department of Health data

1.7 The Department of Health and the Pharmaceutical Services Negotiating Committee agreed that they would re-negotiate the target sum for the total remuneration each year, to take into account:

- inflation, as measured by the GDP deflator;
- increases in the volume of dispensing at marginal cost;
- increases in staff salaries in excess of GDP deflator levels; and
- an efficiency assumption, which assumes some ability to make annual efficiencies and is consistent with efficiency targets in the NHS as a whole.

1.8 In addition, the target sum may be updated to reflect costs necessitated by significant additional regulatory burdens on contractors. Regulatory burdens and the uplift are assessed on a retrospective basis.

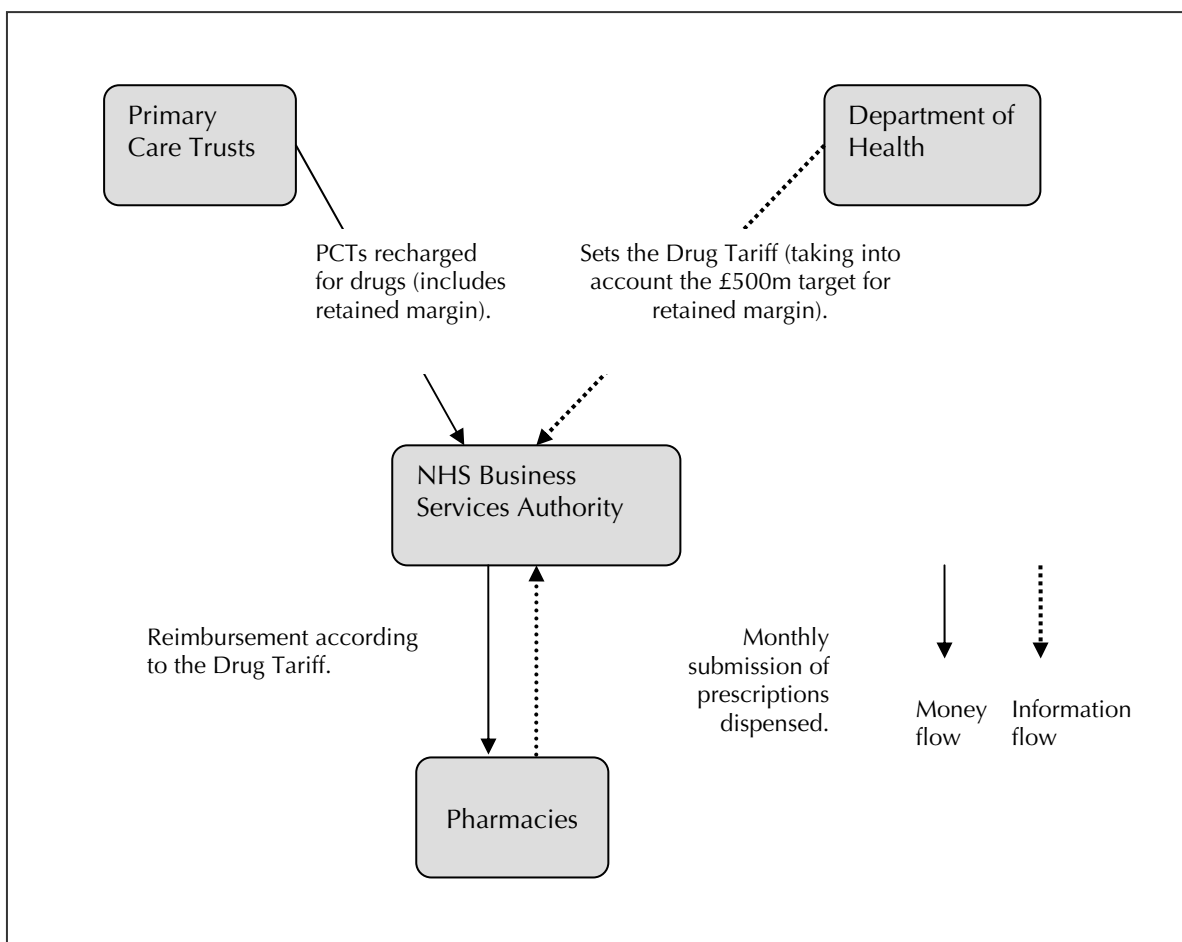
1.9 While the total target sum is adjusted each year in accordance with these factors, the target level of retained margin remains at £500 million each year, and hence represents a decreasing proportion of total remuneration over time. Any excess retained margin, above the agreed £500 million, is considered in the negotiations between the Department and the Pharmaceutical Services Negotiating Committee, and may lead, for example, to reductions in other elements of remuneration such as practice payments.

How pharmacies are reimbursed for the medicines they dispense

1.10 Pharmacies dispensing drugs prescribed on the NHS are reimbursed in arrears for the costs of these items by Primary Care Trusts. The Prescription Services Division of the NHS Business Services Authority calculates reimbursements and pays pharmacies, and Primary Care Trusts' prescribing budgets are then debited accordingly (it is Primary Care Trusts that bear the costs of drugs dispensed). The total cost to the NHS of medicines dispensed in primary care in 2008-09 was about £8.1 billion.

1.11 **Figure 4** describes the mechanism for reimbursing pharmacies. Every prescription processed by a pharmacy is retained and sent as part of a batch each month to the Prescription Services Division of the NHS Business Services Authority, where it is scanned and information entered into a database, so that the drug type and volume dispensed by each pharmacy can be accurately reimbursed in accordance with that month's Drug Tariff.

Figure 4: Processes for reimbursing pharmacies for the medicines they dispense



Source: National Audit Office

Other sources of remuneration for pharmacies

1.12 In addition to reimbursement for drugs, the NHS Business Services Authority also administers the fees and other payments that are made to community pharmacies under the terms of the Framework. These cover a range of essential and advanced services, set at fixed rates in some instances, and on sliding scales in others. For example:

- A professional fee of 90p per item is payable on all items dispensed.
- Practice payments (34.5p per item for April 2008 to September 2008) are paid for each item dispensed, over a threshold (2,120 items per month for April 2008 to September 2008). Payment is conditional on demonstration that the pharmacy has sufficient dispensing staff levels to support the number of items dispensed each month and other essential services (for example, a pharmacy dispensing 5,000 to 6,499 items per month should have a minimum of 75 hours of dispensing staff time per week). Below the threshold, pharmacies are paid a monthly payment according to the band of prescription items per month into which they fall. For April 2008 to September 2008, pharmacies dispensing fewer than 1,100 items per month received one-sixth of £300 per month; one-sixth of £1,750 per month if they dispensed between 1,100 and 1,599 items per month; and one-sixth of £2,450 per month if they dispensed 1,600 to 2,119 items. Further details of fees and payments are given in Annex 2.

1.13 A further cash flow to pharmacies arises from prescription charges which are paid directly to pharmacies by members of the public who are not entitled to free prescriptions. Pharmacies retain the income from these charges and it is offset against the overall reimbursement calculated by the NHS Business Services Authority. However, cash flow benefit from prescription charges is small by comparison with the total reimbursements to pharmacies, since by far the majority of prescriptions are dispensed free of the prescription charge.

Reimbursement prices and the NHS Drugs Tariff

1.14 There are two main types of drugs – branded and generic. Branded drugs are initially patent protected and produced by a single manufacturer, while generic drugs are produced by multiple manufacturers.

1.15 Branded drugs represent about three-quarters of total NHS expenditure on prescription drugs in primary care. The prices manufacturers charge for branded drugs are regulated by the Pharmaceutical Price Regulation Scheme, an agreement between the Department of Health, acting on behalf of the Health Departments for England, Scotland, Wales and Northern Ireland, and the Association of the British Pharmaceutical Industry, that is re-negotiated at regular intervals. The reimbursement price for branded medicines is calculated with reference to the manufacturers' list price.

1.16 Although branded drugs account for 74 per cent of NHS expenditure on drugs by value, they only account for about 35 per cent of the total volume of items dispensed. Most of the items that pharmacies dispense are generic drugs, and there is greater scope for pharmacies to earn a margin on generics, as there is price competition between manufacturers, wholesalers and other suppliers. Reimbursement prices for generic medicines are determined centrally by the Department of Health, and published monthly in the NHS Drug Tariff. Pharmacies are reimbursed for the generic items they dispense each month at the prevailing Tariff prices.

1.17 Generic drugs are divided into five 'categories' for the purposes of the Drug Tariff, as shown in **Figure 5**.

Figure 5: Categories of medicines in NHS Drugs Tariff

Category A—Drugs which are readily available. The Tariff price is set each month as a weighted average of the prices listed by the following manufacturers and suppliers: AAH, Alliance Healthcare (Distribution) Ltd, Teva UK and Actavis.

Category B—Drugs whose usage has declined over time. The Tariff price is set by considering price lists from the following manufacturers or suppliers: Alliance Healthcare (Distribution) Ltd, AAH, UCB Pharma and Thornton & Ross. Price lists are considered in the order listed and the Tariff price is set as the list price in the first price list that contains a price for the product.

Category C—Drugs which are not readily available as a generic, where the Tariff price is based on the price of a particular proprietary product, or as listed by the manufacturer or, as the case may be, supplier.

Category E—Extemporaneously prepared items, made up of two or more products listed elsewhere in the Tariff. The Tariff price is the sum of the Tariff prices of the components.

Category M—Drugs which are readily available. The Tariff price is set by the Department of Health based on information submitted by manufacturers under Scheme M (see paragraph 1.18).

1.18 Category M is the largest of these categories, accounting for about 55 per cent of all items reimbursed, and for about 86 per cent of all generic items reimbursed. It contains over 500 commonly dispensed items. The Tariff prices for items in Category M are updated every quarter, while Tariff prices for items in the other categories are updated monthly. The Department believes that updating Category M prices quarterly ensures greater stability in reimbursement prices and adds lag into the system which discourages manipulation of the market.

1.19 Category M prices are deliberately set somewhat higher, on average, than average manufacturers' prices, in order to incentivise pharmacies to purchase more efficiently by allowing them to make some margin. Making quarterly adjustments to Category M prices, therefore, is the main mechanism that the Department has to calibrate the system in aiming to deliver the target total retained margin of £500 million per annum.

1.20 In calculating the payment due to pharmacies, a deduction factor is applied to the total reimbursement due for medicines dispensed. Discount deduction (also known as clawback) has been a part of the pharmacy reimbursement system for over 20 years and was not changed with the introduction of the new Contractual Framework in 2005. The discount factor varies according to the volume of items dispensed monthly by the pharmacy in question, reflecting the fact that pharmacies can generally negotiate some discount on list prices, and historically any such discount is likely to be higher for pharmacies that buy larger quantities of medicines each month than for smaller pharmacies. The discount deduction rate is the same for both brands and generics and over the period covered by this report was about 9 per cent on average. The Pharmaceutical Services Negotiating Committee told us that in practice this means that pharmacies tend to make losses on some branded medicines that offset some of the margin from generic medicines, and that these losses are increasing.

Part 2: How the Department estimates and controls the retained margin

2.1 The Department of Health calculates the annual total retained margin on the basis of a survey of invoices, which show actual prices paid for medicines, from a sample of pharmacies. These prices act as the benchmark for the Department to gauge by how much to adjust reimbursement payments to pharmacies periodically, so that globally the target income of £500 million from medicines margin is achieved.

2.2 The average margin achieved on a given prescription item in a given month is the difference between the average purchase price and the average reimbursement price for that item in that month. The total retained margin achieved in a year, therefore, can be calculated by multiplying the monthly average margin for each item by the monthly volume of that item dispensed, and summing the result across all items and months.

2.3 The difficulty with performing this calculation in practice is that while there is good information available on the volumes of items dispensed (since each item is recorded by the NHS Business Services Authority), and good information on reimbursement prices (since these are set by the Department of Health), there is no single source of data on the prices pharmacies actually pay suppliers for medicines. These vary from pharmacy to pharmacy, and depend on factors such as which suppliers are used and the levels of discount pharmacies can negotiate.

2.4 There are two possible sources of information that can be used to estimate purchase prices:

- suppliers' trade price lists and data on volumes sold and sales income generated, as well as lists of ex-factory prices; and
- invoices from pharmacies showing which items have been purchased and how much pharmacies paid for them.

2.5 An advantage of estimating average purchase prices on the basis of price lists is that this information is logistically easy to obtain, provided appropriate safeguards are put in place to maintain commercial confidentiality. However, suppliers' list prices do not necessarily reflect the prices paid by pharmacies, and stock may not be available in practice to contractors at the prices shown in price lists. Average ex-factory prices are collected by the Department for Category M and generic medicines (although these do

not include wholesaler distribution costs). A disadvantage of using price lists is that it does not have the 'face validity' of using evidence gathered from physical checking of invoices. The Pharmaceutical Services Negotiating Committee and the pharmacy owners it represents would find it difficult to accept an estimate of the retained margin that was not based on a review of evidence from invoices.

2.6 A disadvantage of estimating the margin on the basis of evidence from invoices, however, is that obtaining the data requires considerably more time and resources than obtaining sales information from suppliers, and the resulting estimate is necessarily retrospective, based on a sample of prescription items and of pharmacies, and subject to sampling and non-sampling error.

The invoice surveys

2.7 At the time the Framework commenced in April 2005, it had been agreed that medicine margins would be monitored by periodic surveys of pharmacy invoices. The Department and the Pharmaceutical Services Negotiating Committee entered discussions in June 2005 on the detailed methodology for assessing the level of medicine margin achieved.

2.8 The Department has developed and refined the methodology for its surveys each year to improve the accuracy with which it assesses the levels of medicine margin. We describe below the surveys carried out since the Framework came into force, and describe the steps the Department has taken to strengthen the survey methodology.

2.9 Performing a robust survey requires detailed planning and the application of complex statistical methods together with a thorough knowledge of the pricing and reimbursement system and how medicines costs are documented on invoices. The Department argues that the imperative to gather survey evidence in the time remaining in 2005-06, in order to identify the excess margin it suspected was in the system, meant that there would necessarily be some technical and logistic limitations in the first surveys. They told us that both they and the Pharmaceutical Services Negotiating Committee considered that developing the surveys would be a learning process.

2.10 The Department performed the first surveys in 2005-06. Independent pharmacies were surveyed for two months: in October 2005 and February 2006. The October survey was of a sample of 42 pharmacies (from a total of over 10,000, of which over 4,000 are independent pharmacies) and 126 medicines (105 generic and 21 branded), and covered

9,335 separate purchases. The February 2006 survey also covered 42 pharmacies but sampled 210 medicines (105 generic and 105 branded) and 18,860 separate purchases.

2.11 The methodology used in the 2005-06 surveys was, at the request of the Department, reviewed by the Southampton Statistical Sciences Research Institute at the University of Southampton – recognised experts in the field of survey design and analysis. The reviewers concluded that there were some limitations that needed to be addressed, in particular that:

- the sample sizes should be increased, and the coverage of pharmacies should be more representative of the target population; and
- there was a high degree of non-response to the survey, due to some sampled pharmacies not supplying invoices.

2.12 The reviewers concluded that “as a consequence, providing estimates for the total retained margin based on these two survey editions required adopting some strong and unverifiable assumptions” and that the “findings for the October 2005 Invoice Survey must be interpreted with caution”.³ Our subsequent discussions with the team from Southampton suggest that, while the methods needed improvement, there was no statistical reason to conclude that the margin was likely to be under- or over-stated.

2.13 The Southampton team’s more detailed recommendations, and the Department’s responses to them, showing how they have addressed the reviewers’ concerns in taking forward the invoice surveys, are set out in Annex 3.

2.14 The key improvements the Department has introduced are:

- increasing the sample size of pharmacies: to 80 in 2006-07; to 100 in 2007-08; and to 120 for 2008-09;
- improving the method for sampling different pharmacies in different months, and for calculating inclusion probabilities for different strata within the sample; and
- reducing non-compliance rates by reminding sampled pharmacies that the Secretary of State has powers, under the NHS (Pharmaceutical Services) Regulations, to require them to provide the information requested.

2.15 The Southampton reviewers also concluded that the way in which the point estimate of the total retained margin was derived from the data was not entirely grounded

³ Silva, P. L. d. N. and Holmes, D.J. (2007) *Point and variance estimation for the Department of Health’s Invoice Survey*. Technical report provided to Department of Health.

in the actual sample design adopted in the surveys. They derived an alternative way of calculating the estimate, although this had no material impact on its point value, and also alternative formulae for obtaining confidence intervals to quantify the level of uncertainty in the estimate arising from sampling error. These methods of analysis were adopted by the Department for future surveys.

2.16 During 2008, the Pharmaceutical Services Negotiating Committee raised concerns with the Department about the technical details of the calculations underpinning the estimate of the retained margin, and its standard error, for 2007-08. The Department asked the Southampton team to revisit the approach to these calculations that the reviewers had proposed, and the Department had accepted, following the 2005-06 surveys.

2.17 The Southampton team concluded their review in August 2008. Table 2 in Annex 3 summarises the main concerns raised by the Pharmaceutical Services Negotiating Committee, the conclusions of the Southampton review team, and the Department's actions in response. It shows that the Department has addressed the concerns raised, although more work is needed to establish the best way of eliminating any possible bias in the estimate of the component of the total retained margin arising from purchases of branded drugs.

Conclusion on the effectiveness of the invoice surveys

2.18 The fact that the level of excess margin was so high in 2006-07 may suggest that the estimate of the 2005-06 retained margin, based on a sample of 84 pharmacies in two months, and which in turn informed the adjustments made to reimbursement prices going forward, was too small, and that there was, in fact, more margin in the system than actually detected. While the Southampton review indicates there is no reason to suppose that the margin estimate was biased downwards (i.e. was more likely to be below than above the true figure), there was still a wide statistical confidence interval around the estimate, because of the relatively small sample size. The Department tells us that there were significant reductions in ex-manufacturer prices in the early years of the new arrangements, due to pharmacies having stronger incentives to seek out better deals, which account for the increase in the observed medicines margin.

2.19 The Department also argues that, even if the 2005-06 surveys had found greater levels of margin, it is unlikely that the system would have sustained adjustments to Category M prices aimed at reducing the margin by more than the £300 million that was

achieved, and that it has a responsibility to ensure that its actions do not undermine the overall viability of pharmacy services or the generic medicines market.

2.20 The Department has subjected its survey procedures to independent review, and has acted upon the recommendations made by the reviewers. As the survey design and coverage has improved, reimbursement prices have been adjusted on the basis of more strongly evidenced assessment of how much excess is occurring.

2.21 The surveys provide assessments of the total margin that has been achieved. The principal mechanism for actually calibrating the system, and hence for delivering a total margin as close as possible to the agreed target amount, is the mechanism for setting reimbursement prices for medicines.

2.22 When the Framework was introduced in April 2005, the Department also brought in arrangements, known as Scheme M and Scheme W, for collecting price and volume information from manufacturers and wholesalers of generic medicines, in order to inform the process of determining reimbursement prices. The Department did not, however, use the information supplied under Schemes M and W to inform estimates of the retained margin, as this was not part of the negotiated agreement. We discuss how reimbursement prices are set in the next part of this report.

How Category M prices were initially set in 2005

2.23 As noted in paragraph 1.19, the Department's main tool for calibrating the level of retained margin is setting reimbursement prices for Category M drugs. At the time of bringing in the new arrangements, relative reimbursement prices for the medicines allocated to Category M were, for historical reasons, not well correlated with actual market prices.

2.24 The Department of Health had its own estimates of the level of margin being earned immediately prior to the introduction of the Framework, through various sources of intelligence, but no firm evidence such as an invoice survey. In order to reach a settlement the Department and the Pharmaceutical Services Negotiating Committee agreed on a working assumption that the total margin being achieved on these items was about £800 million a year.

2.25 Prices were therefore:

- recalibrated to have a higher degree of correlation with market prices; and

-
- adjusted downwards such that the total expected reimbursement from Category M items, allowing for predictable increases in dispensing volume, would be £300 million lower than the estimated £800 million margin for those items, if their pre-Category M reimbursement prices had remained in force.

In this way the Department expected that the total margin achieved in 2005-06 would be close to the target figure of £500 million.

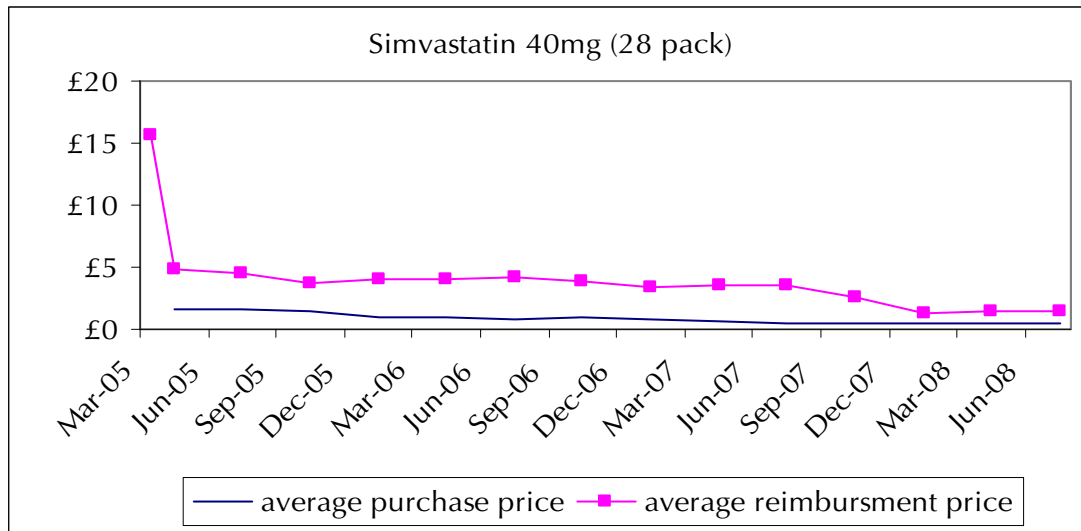
2.26 The evidence base for the estimate of £800 million as the total margin 'in the system' prior to the introduction of the new Contractual Framework, however, was weak. The Department advise that they suspected that there would be more than £500 million margin, but that they did not have firm evidence (such as from a margin survey). As it turned out, £800 million was an underestimate. The first margins surveys suggested that there was more margin in the system: in other words, that Category M prices had been set too high to deliver a total margin of £500 million. Part of this may have been down to the stronger purchasing incentives leading to lower prices in 2005-06, and thus yielding increased assessed margin in year. The Department took the view, however, that to have removed more than the £300 million in margin at the outset of the Framework would have risked turbulence in the generic medicines market, which would have had serious consequences in the short to medium term and put the Framework at risk.

2.27 Category M prices were therefore adjusted in following quarters to reduce estimated total reimbursement on Category M items, by the amounts the previous years' margins surveys had suggested were necessary, to 'remove' excess margin. There is no unique way to determine by how much the Tariff price for each of the 500 Category M items should be changed in order to achieve this result. A new reimbursement price was set for each of the 500 Category M items, bearing in mind the amount by which total reimbursement had to be reduced, and changes in market prices. The volume of each item to be dispensed over the next quarter was estimated using historical time series data, and this estimated volume was multiplied by the difference between the old and the new reimbursement prices. The new prices were then adjusted until the sum, across all items, of the product of volume and change in price, is as close as possible to the target sum to be 'removed'.

2.28 The Department's strategy in reducing prices of Category M drugs was to concentrate on items with the highest volume of dispensing rather than to apply a consistent rate of reduction to all Category M drugs.

2.29 An example of reduction in reimbursement price is shown in **Figure 6** for Simvastatin 40mg (28 pack). This was the most commonly dispensed Category M drug during the operation of the Framework to March 2009, with 66.5 million dispensed items over the period. The reduction of the reimbursement price from £15.60 in March 2005 to £4.87 when the Framework commenced in April 2005 and then down to £1.34 in March 2009 has led to savings of over £850 million over the last four years. Figure 6 demonstrates an ‘ideal’ trajectory for the delivery of a constant total margin as prescription volumes increase, in that the reimbursement price has come into line with the purchase price and tracks it downwards with the margin reducing over time.

Figure 6: Purchase and reimbursement prices for Simvastatin 40mg (28 pack)



Source: Department of Health

2.30 We asked the Department to supply details of how the calculations to set Category M prices each quarter were performed, but were told that much of the information had now been destroyed, because of its commercially sensitive nature. We did, however, obtain a list of the adjustments that were made to set the tariff prices for October 2007. Those prices were set soon after the agreement of the invoice survey results for 2006-07, with agreement that £400 million needed to be removed from the total reimbursement to pharmacies. We checked the calculations to confirm that, on the basis of predicted increases in volumes of dispensing over the following quarters, the expected reduction in the total margin would be £400 million.

2.31 The calculations did not, however, provide any estimate of what the *absolute* value of the total margin would be likely to be, on the basis of similar assumptions about

volume growth. They only showed that the level of margin likely to be achieved—whatever it might be—would be £400 million lower than it would have been had the adjustment not been made. They did not, therefore, provide any information about the risk of exceeding the £500 million target for the total retained margin.

2.32 It would, however, have been possible to use information on manufacturers' prices, collected under Scheme M, to inform an assessment of this risk. Scheme M information could not be used as the basis for agreeing with the Pharmaceutical Services Negotiating Committee what the total margin was, because it had been agreed to use the invoice survey to do this. Nevertheless, Scheme M data could be used to provide an approximate prediction of what the likely impact of the proposed price adjustments would be on the overall level of margin, albeit with some time lag, and to give an indication of whether the prices set were likely to be broadly 'on track' to deliver a total margin close to the target figure.

2.33 For example, we ran our own analysis, combining the July 2007 and proposed October 2007 Category M prices from the list we were given with information on the volume of each item dispensed in July 2007 from the NHS Business Services Authority and the July 2007 Scheme M information on average ex-factory prices for each item. From these we derived estimates of item-level margins, and hence the total margin that would be derived from each item in the October-December quarter of 2007-08.

2.34 Our calculations led to an estimate of about £180 million for the margin that would be achieved in the October-December quarter: equivalent, without any further price reductions, to about £740 million over a 12 month period—that is to say, an excess margin of more than £200 million. In other words, this analysis, based on information available to the Department at the time it set the October 2007 Tariff prices for Category M items, would suggest that setting prices for Category M items at the levels being considered entailed a significant risk of exceeding the agreed target margin of £500 million.

2.35 There are, of course, uncertainties involved in projecting the margin in this way. Firstly, although the majority of medicines margin arises from Category M medicines, they account for only about one-seventh of total primary care medicines expenditure. Secondly, such projections rely on time-series information on ex-factory prices and have to make assumptions about the wholesaler margin (e.g., that it remains stable). Moreover the Department argues that, even allowing for the difficulties associated with projecting

the margin in this way, reducing the prices of high-volume Category M items further in October 2007 would have been unrealistic given the impact on pharmacies' cash flows for the second half of the financial year and the impact on the generic medicines market.

2.36 In summary, the Category M pricing mechanism is complex, and the combination of invoice surveys and Category M price adjustments, combined with the Department's aim of building 'regulatory lag' into the system, has resulted in the target retained margin of £500 million being exceeded each year. The Department should consider using Scheme M information to help assess prospectively the risks of not achieving the target margin each year. Following its planned new cost-of-service enquiry for community pharmacy, it should present the arrangements for funding the Framework more explicitly. If the Department believes that the target level of margin is likely to be exceeded every year due to the operation of 'regulatory lag', this should be made clear, and the implications for expenditure on pharmacy services and medicines should be set out.

Part 3: The overall financial impact of introducing the Framework

Reducing practice payments to offset the excess margin

3.1 From 2006-07 onwards the Department adjusted practice payments in order to offset variance on the retained margin. Following the results of the 2005-06 invoice surveys, the Department recognised that, unless reimbursement prices were further reduced, it was likely that there would be an excess of £300 million over the target retained margin for 2006-07. It therefore reduced Category M prices in October 2006 with the intention of decreasing the available retained margin in that year by £150 million. To offset the estimated remaining £150 million excess margin already earned in the first part of the financial year, the Department also reduced practice payment fees during the second half of 2006-07.

3.2 In that year the Department had planned to increase total remuneration for pharmacies by 8.2 per cent (from £1.77 billion to £1.91 billion), with the biggest increase coming from practice payments. With the target for the retained margin set at a constant £500 million, the Department aimed to increase the global sum by only 2.6 per cent (from £966 million to £991 million), with practice payments increasing by around 165 per cent per item in the second half of the year, to make up the difference. Reducing practice payments by £150 million in the second six months of 2006-07 had the effect of reducing that increase to 20 per cent.

3.3 As a result of the 2006-07 invoice surveys, the Department assessed that the overall margin in 2007-08 was likely to be around £1 billion (i.e. an excess of around £500 million). Taking a similar approach as in 2006-07, the Department agreed an adjustment to Category M prices in October 2007 to reduce the potential variance by £400 million per annum. For the remaining six months of 2007-08, savings of £200 million were achieved from lower Category M prices between October 2007 and March 2008, with the balance of £200 million being removed from practice payments over the 12 month period commencing October 2007. The reason for not attempting to make the full adjustment to practice payments within the financial year 2007-08 was the disruptive effect such a change would have on pharmacies' planned cash flow for the year.

3.4 The reductions made to practice payments have, as shown in Figure 1, offset some of the excess margin, but not sufficiently to avoid an excess against the budget for the Contractual Framework as a whole.

Overall savings achieved through introduction of the Framework

3.5 As a result of the new pricing arrangements that came into operation as part of the Framework in April 2005, reimbursement prices for generic drugs that are dispensed in high volumes have been reduced to levels that are more in line with market prices. These price reductions have led to significant savings for the NHS, even after taking into account the excess margin generated in each year. For example, in 2005-06, pharmacy contractors would have made an additional £320 million if the price reductions had not been made (assuming all the margin would have stayed with contractors). **Figure 7** shows that if prices had remained at their March 2005 levels, the NHS would have spent £3.26 billion more than it actually did over the last four years on Category M items.

Figure 7: Savings arising from reductions in reimbursement prices for Category M medicines, due to the introduction of the Framework

Year	Volume of items dispensed (million)	Cost to NHS (£m)	Cost to NHS, at March 2005 prices (£m)	Saving (£m)
2005-06	460	1,104	1,424	320
2006-07	530	1,476	1,974	498
2007-08	570	1,283	2,251	968
2008-09	596	1,035	2,505	1,470
Total	2,156	4,898	8,154	3,256

Source: NAO analysis of NHS Business Services Authority data

3.6 **Figure 8** compares the actual (outturn) expenditure, across the three funding streams for the Framework, with a counterfactual scenario in which prices remained at their March 2005 levels (so that pharmacy contractors would have made more purchase profit). Under the arrangements prevailing before the introduction of the new Framework, contractors would have received lower levels of remuneration via the global sum, and would not have received PCT practice payments. Moreover, medicines use reviews and the electronic prescriptions service would not have been funded from the total contract sum under the counterfactual scenario, so we have removed expenditure on these (totalling £148 million over the four years) from the 'actual' expenditure in

Figure 8. The counterfactual assumes that the global sum would have continued to increase year-on-year in accordance with the pre-2005 trend.

3.7 Figure 8 shows that, overall, the introduction of the Framework has resulted in an efficiency gain for the NHS. By comparison with the counterfactual of retaining the previous, pre-2005, remuneration and pricing arrangements, about £1.8 billion has been saved over four years.

3.8 We made a number of assumptions to derive the ‘counterfactual’ figures in Figure 8, namely that:

- prices for Category M items would have remained at their March 2005 levels (this assumption becomes increasingly unsustainable over time);
- all the savings arising from the Category M price reductions (as shown in Figure 7) would have stayed with pharmacies as retained profit margin;
- there would have been no practice payments, electronic prescription service or medicines use reviews payments in the counterfactual scenario; and
- there would have been a 4.5 per cent annual increase in global sum (based on the trend in the years prior to the inception of the Framework).

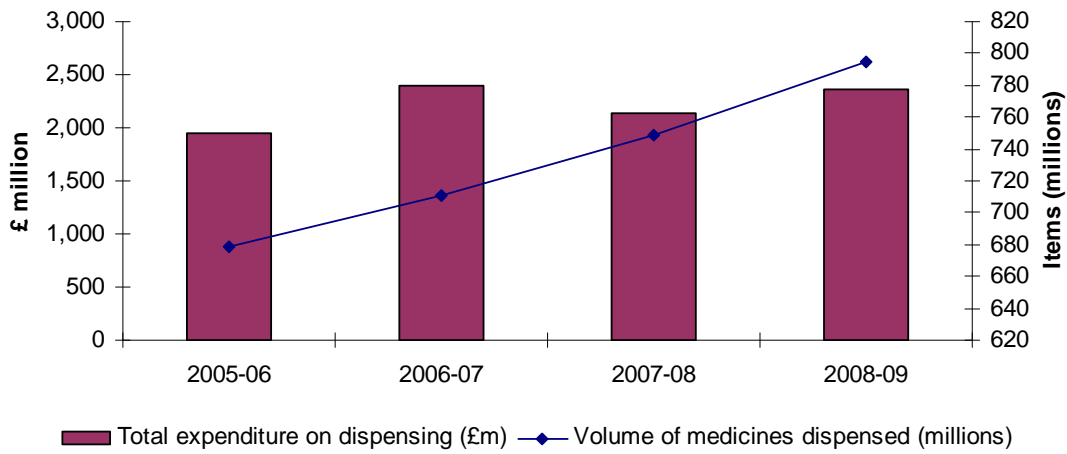
Figure 8: Financial impact of the Community Pharmacy Contractual Framework

	Counterfactual			Actual			Overall saving (£m) due to Framework (Actual-Counterfactual)
	Global sum (£m)	Margin (£m)	Total expenditure on pharmacy (£m)	Global sum + practice payments (£m)	Margin (£m)	Total expenditure on pharmacy (£m)	
2005/06	870	1,120	1,990	1,146	800	1,946	-44
2006/07	910	1,659	2,569	1,228	1,161	2,389	-180
2007/08	951	1,842	2,793	1,262	874	2,136	-657
2008/09	993	2,269	3,262	1,587	770	2,357	-905
Total	3,724	6,890	10,614	5,223	3,605	8,828	-1,786

Source: NAO analysis of Department of Health data

3.9 At the same time, pharmacy outputs have increased. For example, the growth in the volume of items dispensed has been faster than the growth in real-terms expenditure on pharmacy, so productivity has improved. **Figure 9** shows the relationship between the volumes of medicines dispensed and total expenditure on community pharmacy over the last four years.

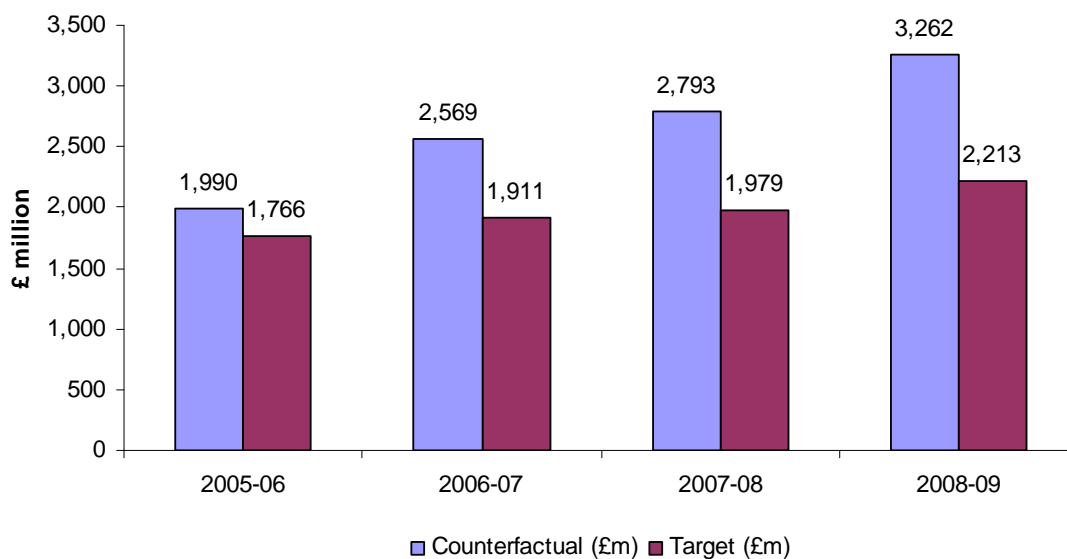
Figure 9: Total expenditure on the Community Pharmacy Contractual Framework vs. volume of medicines dispensed



Source: NAO analysis of Department of Health data

3.10 Notwithstanding the productivity gain illustrated in Figure 9, it remains the case that the Department has exceeded its target levels of remuneration for pharmacies each year. The parameters set at the outset of the contractual framework—for a target retained margin of £500 million and for the other elements of remuneration—would, in fact, have entailed a cut in spending on pharmacy services of £2.75 billion over four years, as shown by the difference in counterfactual and target total expenditure on pharmacy in **Figure 10**.

Figure 10: Counterfactual and target total expenditure on the Community Pharmacy Contractual Framework, 2005-06 to 2008-09 (£m)



Source: NAO analysis of Department of Health data

3.11 The Department adjusts the level at which pharmacies are reimbursed for commonly dispensed items based on the level of margin achieved in the previous year. It argues that the principal reason why the margin target has been exceeded is that the Framework incentivises pharmacy contractors to drive harder bargains with medicines suppliers, thereby driving down market prices for medicines. It argues that without this additional downward pressure on purchase prices, the adjustments made to reimbursement prices would have been sufficient to deliver a total margin closer to the £500 million target each year. The excess margin is due, therefore, to lower than expected prices in the medicines market, and is factored into reimbursement pricing decisions the following year, which in their turn incentivise pharmacies to drive down prices still further. This cycle of 'catching up' with the previous year's excess is known as 'regulatory lag'. The Department tells us that it was an implicit part of the agreement with the Pharmaceutical Services Negotiating Committee from the outset that regulatory lag would be allowed for. The Pharmaceutical Services Negotiating Committee confirmed that pharmacies considered this to be an important element in the funding structure.

Annex 1: How we carried out this examination

We carried out this work following a request from the Department to review its calculations of the retained margin, and subsequent Parliamentary interest on how much margin on medicines purchases was being retained by pharmacies.

We examined the systems and processes in place to monitor the margins on medicines being achieved by pharmacies by:

- reviewing relevant papers at the Department of Health, including ministerial submissions and statements;
- analysing financial information and administrative datasets, and re-performing Departmental calculations to understand how reimbursement prices had been calculated;
- consulting experts from Southampton University on the technical design and implementation of the medicine margin survey;
- visiting the NHS Business Services Authority to observe the systems for collating prescription information and reimbursing dispensers, and the Pharmaceutical Services Negotiating Committee to observe how information from invoices selected in the margin survey are collated into a database; and
- conducting interviews with officials at the Department of Health, the NHS Business Services Authority, the Pharmaceutical Services Negotiating Committee and the British Generic Manufacturers Association.

Annex 2: Details of fees payable for essential and advanced pharmacy services

Table 1: Fees payable in relation to Essential Services for April to September 2008

Item	Description	Amount paid
Professional Fee	Payable on dispensing of all items (and appliances).	90p per item
Establishment Payment	Pharmacies which submit at least 2,120 prescription items per month receive an Establishment Payment. This payment is based on the volume of prescription items submitted by the pharmacy contractor and processed for payment by the NHS Business Services Authority for that month.	One-twelfth of £23,278 per month if between 2,120 and 2,389 items per month are dispensed. One-twelfth of £24,190 per month if between 2,390 and 2,649 items per month are dispensed. One-twelfth of £25,100 per month if 2,650 or more items per month are dispensed.
Special Fees and Allowances	Fees earned in a range of instances where additional work is required by the pharmacist e.g. where a formula must be prepared by pharmacist.	These fees are variable. The average fee payable per item is 7.1p
Repeat Dispensing set up fee	Pharmacies are required to be able to provide repeat dispensing as an 'essential service'.	£125 paid monthly amounting to £1,500 each year.
Transitional Allowance	All pharmacies will receive a Transitional Payment which is paid monthly and is calculated based on the number of prescription items submitted and reimbursed in the relevant month.	1 to 500 items per month: £7.40 per month 501 to 1000 items per month: £14.80 per month Rising in bands of 500: increased by £7.40 per month for each band
Practice Payment	At a threshold of 2,120 items per month or more, a fee is paid for each item dispensed. Payment is conditional upon demonstration that the pharmacy has sufficient dispensing staff levels to support the number of items dispensed each month. E.g. a pharmacy dispensing 5,000 to 6,499 prescriptions per month should have a minimum dispensing staff level of 75 hours per week. Below the 2,120 item threshold, the following payments apply: Up to 1,099 items per month: one-sixth of £300 per month	34.5p per item

	1,100 to 1,599 items per month: one-sixth of £1,750 per month 1,600 to 2,119 items per month: one-sixth of £2,450 per month	
Electronic Transmission of Prescriptions (ETP) Allowances	Following two set-up allowances totalling £2,600 for Phase 1, a pharmacy operating the ETP service will be entitled to a monthly payment. A further one-off allowance of £1,000 is payable for Phase 2.	£200 per month

Source: NHS Business Services Authority

Table 2: Additional fees which may be earned by Pharmacies offering Advanced Services

Item	Description	Amount paid
Medicines Use Reviews	Payments made up to a maximum of 400 medicines use reviews per pharmacy per financial year	£27 per medicines use review

Source: NHS Business Services Authority

Annex 3: Actions taken in response to reviews of the invoice surveys

Table 1: Recommendations from the University of Southampton's review of the 2005-06 invoice surveys, and the Department's responses

Recommendation	Department's response
<p>The sample selection mechanism must be such that the coverage of the target population is sufficiently large. In particular, networked pharmacies (those belonging to chains or multiples) were not included in the sample, yet they purchase some 58 per cent of the total of drugs dispensed by pharmacies.</p>	<p>There are three reasons for excluding multiples.</p> <p>a) The most important is that the invoiced cost of medicines for multiples, in particular the vertically integrated, follow accounting protocols rather than representing true cost. Many multiples have invoicing arrangements that charge their pharmacies Tariff prices (sometimes plus VAT) rather than acquisition prices. There are a number of reasons why they do this, one of which is that it incentivises good stock control.</p> <p>b) It might be possible in theory to get purchase prices for the chains, but an element for distribution and associated overheads would need to be added. This would require further information from companies which might not be verifiable (again, management accounts may not reflect actual costs).</p> <p>c) Finally, this was agreed in the negotiations. Multiples were excluded from the costings underpinning the contractual framework negotiations in 2005, because not all of their costs—in particular head office costs—could be verified. It could be argued in principle that they should be excluded from the survey for this reason, as well as the reasons listed above.</p>
<p>If only one of the sample sizes can be increased (pharmacies or drugs), it is suggested that the sample of pharmacies be increased, because for this sample the current sample size is relatively small (42 at each survey round), compared to the total number of drugs sampled (210 in the February 2006 edition).</p>	<p>In 2007-08 the sample size of pharmacies was increased to 100.</p> <p>For 2008-09 the Department surveyed 120 pharmacies (achieved sample 118 pharmacies).</p>
<p>If the survey is to be repeated every month of the year, the best rotation design option would be to have the monthly samples drawn independently, or otherwise use disjoint (non-overlapping) samples for the different months.</p>	<p>Every pharmacy in the sampling frame is now allocated to a month before drawing the sample, thereby using non-overlapping samples. This method was preferred to drawing samples independently to avoid sampling a pharmacy in more than one month of the survey.</p>

<p>If there is to be a selection of areas, this must be carried out in such a way that the probabilities of inclusion of the areas and then of the pharmacies can be obtained from the survey frames utilised.</p>	<p>The Department has now corrected its method of calculating inclusion probabilities, as recommended by Southampton. It has also corrected the sampling method for pharmacies by stratifying the complete independent sampling frame into metropolitan and other areas, before selecting ten pharmacies (simple random sampling without replacement) for each month.</p>
<p>The survey data collection procedure must be designed to minimize non-response, but at the same time, must include some structured mechanism of control for non-response or refusal. There was a high degree of non response in 2005-06. Out of 113 pharmacies selected in October 2005 only 42 provided data. Similarly, in the February survey, 84 pharmacies were selected and only 42 provided data.</p>	<p>The participation request letter sent to sampled pharmacies has been amended for the 2008-09 survey to remind pharmacies of the importance of complying with the survey and that the Secretary of State has powers, under the NHS (Pharmaceutical Services) Regulations, to require them to provide the information. Response rates were much higher in 2008-09 (73 per cent, compared with 43 per cent in 2005-06). The regulations were re-laid for this year's survey after they were inadvertently lost following the consolidation of the NHS 2006 Act. Responsibility for taking action against non-compliant pharmacies would fall to individual PCTs. Pharmacies are requested to provide all invoices from all suppliers for the relevant month, something that they already provide to their accountants, meaning there is no undue burden placed upon them. For the latest survey, for April - Sept 09, the response rate was 94 per cent - the letter that went out with the survey was changed so that pharmacies were obliged to give a reason for non-participation.</p> <p>The Department has investigated pharmacy non-response and has not found any discernible patterns.</p>

Source: University of Southampton and Department of Health

Table 2: Actions following further review of the survey methodology

Concern raised by Pharmaceutical Services Negotiating Committee	Southampton reviewers' conclusions	Department's response
The true standard error of the total margin estimate—and hence the range of uncertainty around the estimated total—was greater than that found by the Department.	The formulae for estimating standard errors were correct, but there had been an error in their implementation by the Department.	This has now been corrected.
The Department was not using specialist statistical software to run the analyses.	The Department had used Excel spreadsheets to perform the calculations, which can increase the risk of errors in the kinds of computations required for analysis of the survey data.	The statistical package SAS will be used by the Department for the analysis of future surveys, starting with the 2008-09 surveys.
There was some selection bias	There was no evidence of bias in the estimate of the margin for generic drugs, but there may be some bias in the estimate for branded drugs, possibly due to differential response rates, if pharmacies that refuse to participate in the survey have lower than average transactions for branded drugs compared with those agreeing to take part, or possibly because the sample only includes independent pharmacies. The reviewers suggest that estimated total retained margins be calculated separately for	<p>The Department has amended the participation request letter sent to sampled pharmacies to remind them of the importance of complying with the survey, and that the Secretary of State has powers, under the NHS (Pharmaceutical Services) Regulations, to require them to provide the information.</p> <p>The Department is exploring further with the Southampton team and the Pharmaceutical Services Negotiating Committee (in the context of the current cost-of-service enquiry) the possibility of</p>

	networked and independent pharmacies.	separately estimating total margins for networked and independent pharmacies in future.
Some of the observations, which significantly increased the observed margin, were unduly influential, and should be discarded.	Down-weighting or discarding influential observations on one side of the distribution without treating those on the other side would lead to unwanted bias in only one direction. Either an appropriately developed and tested robust estimator should be used to down-weight influential observations on both sides of the distribution, or else the current estimation procedure, which gives full sampling weights to all genuine observations, should be maintained.	The Department is discussing the need for any modifications to estimation procedures with the Southampton team and the Pharmaceutical Services Negotiating Committee.

Source: University of Southampton and Department of Health