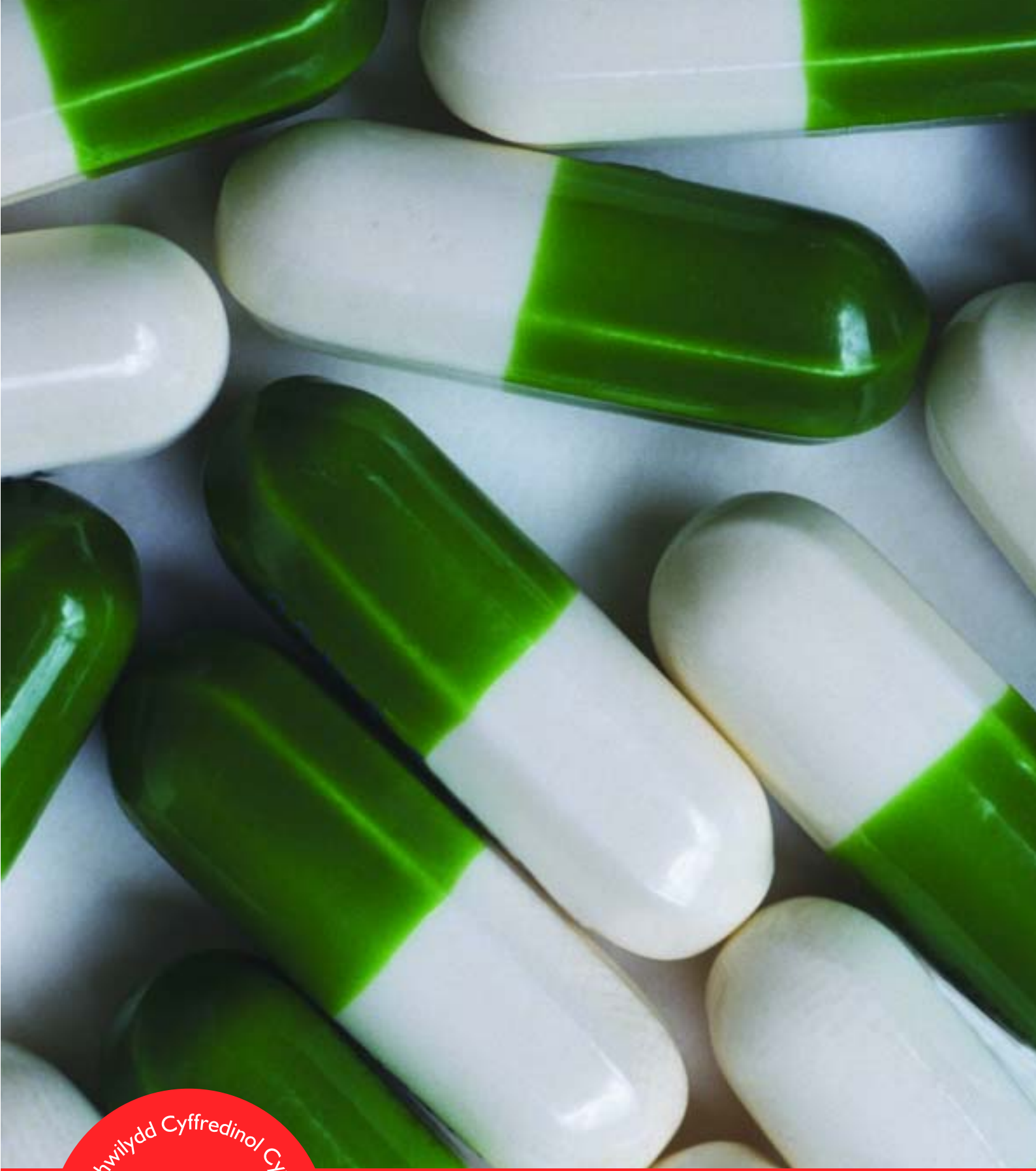

Archwilydd Cyffredinol Cymru
Auditor General for Wales

THE PROCUREMENT OF PRIMARY CARE MEDICINES

Report by the National Audit Office Wales on behalf of the Auditor General for Wales

THE PROCUREMENT OF PRIMARY CARE MEDICINES

Report by Auditor General for Wales,

presented to the National Assembly on

20 March 2003

This report has been prepared for presentation to the National Assembly under the Government of Wales Act 1998.

John Bourn
Auditor General for Wales

National Assembly for Wales
Cardiff Bay
Cardiff
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20 March 2003

The Auditor General for Wales is totally independent of the National Assembly. He certifies the accounts of the Assembly and its associated sponsored public bodies; and he has statutory authority to report to the Assembly on the economy, efficiency and effectiveness with which the Assembly and its sponsored public bodies have used their resources in discharging their functions.

This report was prepared for the Auditor General for Wales by the National Audit Office Wales.

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CONTENTS

EXECUTIVE SUMMARY

1 Primary care[1] medicine procurement in Wales accounts for some £410 million, or 15 per cent of total NHS Wales expenditure. The arrangements are shaped by a complex mixture of market forces, scientific developments, government regulation and agreements between government and industry. All of these are affected by events in other parts of the UK and beyond. The Assembly has powers under the NHS Act 1977, through the Government of Wales Act 1998, that give it some scope to make different medicines procurement arrangements. However, the Assembly's room for manoeuvre is limited by economic, contractual and practical considerations.

2 We found some indications that NHS Wales' arrangements for the procurement of primary care medicines may present opportunities to improve value for money. For example NHS Wales, like the NHS in the rest of the UK, pays substantially more for the same medicines in primary care than it does in secondary care. This may be due to primary care buying power being fractured among over a thousand independent contractors. But it may in part also reflect market conditions and incentives for pharmaceutical companies across the two sectors.

3 Our modelling also suggested that if the prices obtained under secondary care contracts were applied to the same medicines used in primary care, in 2001, the cost to NHS Wales of these medicines could have been some £50 million lower than that recorded. However, securing potential savings on this scale in practice is not straightforward and is not guaranteed. It would involve establishing centralised contracts and this in turn would bring risks and practical challenges for the Assembly's NHS Directorate:

- centralisation could weaken the security of supply. It could remove some of the ability of the present system to deal with supply problems. Manufacturers and wholesalers may give priority to customers in other markets paying higher prices. Also, if changes to procurement arrangements lead to significant price differences, parallel trade[2] between Wales and other countries could lead to shortages of medicines in Wales;

- while centralised contracts for secondary care indicate that substantial savings are possible, as the lower prices are discretionary on the part of the pharmaceutical industry there is no guarantee that similarly low prices can be negotiated for primary care;

- a reduction in primary care medicine prices may lead to a compensating rise in secondary care prices, so cancelling out some, if not all, savings overall;

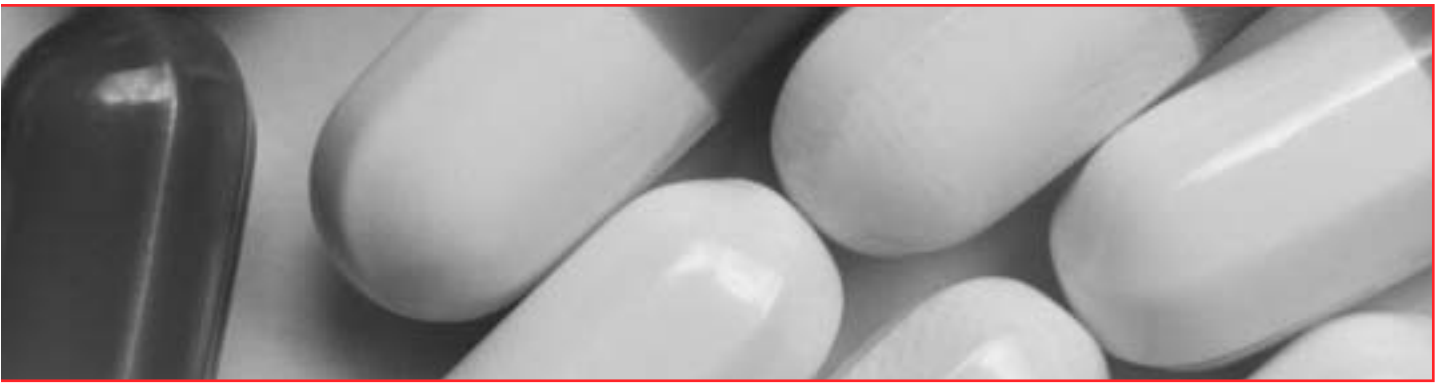
- the achievement of lower primary care medicine prices will require significant effort and expertise on the part of NHS Wales in negotiations;

- as centralisation would affect the roles and payment of pharmacists and other contractors, such changes would need to be reflected in their contracts with the NHS, and the Assembly will need to assess how the changes may affect wider pharmacy and medical services. The encouragement of the prescribing of medicines covered by centralised contracts also needs to be considered, and this may need to be backed by primary legislation;

1 Primary care is healthcare provided by general practitioners and other contractors, as distinct from secondary care, which is provided by hospitals.

2 Parallel trade is the purchase of goods in a relatively cheaper market in order to supply another relatively more expensive market.

- changes to procurement arrangements that lead to lower prices may have implications for pharmaceutical industry investment in research and development for new treatments. It would therefore be appropriate for the Assembly's NHS Directorate to involve the industry's representatives in Wales in considering such changes.



4 In addition to reviewing primary care medicine procurement arrangements, there is further scope for improving value for money by addressing prescribing behaviour: the choice of which medicine to prescribe. Although NHS Wales has a number of initiatives in this area, it is slightly behind England and Scotland in the proportion of medicines being prescribed generically[3], and there is considerable variation in this proportion within Wales. We estimate that for 2001 some £2 million could have been saved through generic substitution[4] within the existing procurement arrangements. And up to a further £1.4 million could have been saved by reducing the prescription of drugs that the *British National Formulary*[5] indicates are of limited clinical value. We note, however, that some patients may benefit from such medicines and that evidence of clinical value can change as new research is done. Work by the Audit Commission indicates that better product selection by General Practitioners could have led to savings of up to £27 million in 1998-99, though the greater degree of clinical judgement required would make achieving such savings less straightforward. We consider that the development of supplementary prescribing presents a new opportunity to improve the overall cost-effectiveness of medicines expenditure. This involves pharmacists using their extensive knowledge of medicines to select the medicines they consider most appropriate in implementing a 'Clinical Management Plan' agreed with a General Practitioner.

5 The Assembly's NHS Directorate is also aware of the potential scope for significant value for money improvements in primary care medicine management. It has estimated that some £15.6 million is wasted each year, such as through patients not taking the medicines that they are prescribed. The Assembly's NHS Directorate plans a range of initiatives, aimed at reducing waste, including extending the involvement of pharmacists in medication review and seeking rationalisation of medicine pack sizes.

3 Generic prescribing is the writing of prescriptions using the generic name of a medicine, such as fluoxetine, rather than a brand name, such as Prozac.

4 Generic substitution is the selection of a chemically equivalent medicine, in terms of active ingredients, for dispensing in place of the original brand. Generic medicines are usually cheaper than branded medicines. However, generic substitution is not safe for medicines, such as anticonvulsants, where the rate and extent of absorption of the dose into the body's systems is especially important. Our estimate only includes medicines where substitution is straightforward.

5 The *British National Formulary* provides key information on medicines. See glossary and bibliography for further details.

6 We **recommend** that the Assembly's NHS Directorate should:

- determine and phase in any extensive changes to primary care medicine procurement arrangements to take advantage of any changes that the Department of Health may introduce as a result of its current review of generic medicine procurement arrangements. But the Assembly's NHS Directorate should not accept undue delay while the Department determines its preferred option;
- consider piloting centralised contracts covering a small number of medicines if the Department of Health does not make changes to procurement arrangements across the UK that would render centralisation inappropriate;
- in planning any centralised contracts for primary care medicine supply, refer to the work done by the All Wales Drugs Contracting Committee and the Department of Health to address security of supply and other practical arrangements for establishing such contracts;
- take account of the effect of procurement developments in undertaking its review of community pharmacy;
- set a national target for generic prescribing based on the current best levels achieved in Wales;
- review the continued justification for GPs prescribing medicines that the *British National Formulary* indicates are of limited clinical value;
- ensure that it recognises the potential links between initiatives designed to improve prescribing behaviour, such as prescribing and decision-support systems, and developments in procurement arrangements, and that it identifies the effectiveness of such initiatives taking account of those links;
- ensure that it recognises the potential links between measures to reduce medicines wastage through better medicines management, such as pack size standardisation, and developments in procurement arrangements, and identifies the cost-effectiveness of such measures taking account of those links;
- assess how it could best support the development of supplementary prescribing while seeking to achieve the benefits of generic and therapeutic substitution[6] through it.

6 Therapeutic substitution is the selection of a chemically different medicine or other treatment in place of the originally prescribed medicine in order to achieve the same or better outcomes.

PART 1 Introduction

Primary care medicine procurement is a significant element of healthcare expenditure

1.1 In Wales in 2001-02, expenditure on primary care[7] medicines amounted to some £410 million[8]. In cash terms, it has grown at an average rate of 9.2 per cent a year over the past decade. As shown in **Figure 1**, it now makes up some 15 per cent of total healthcare expenditure, up from 11 per cent a decade ago.

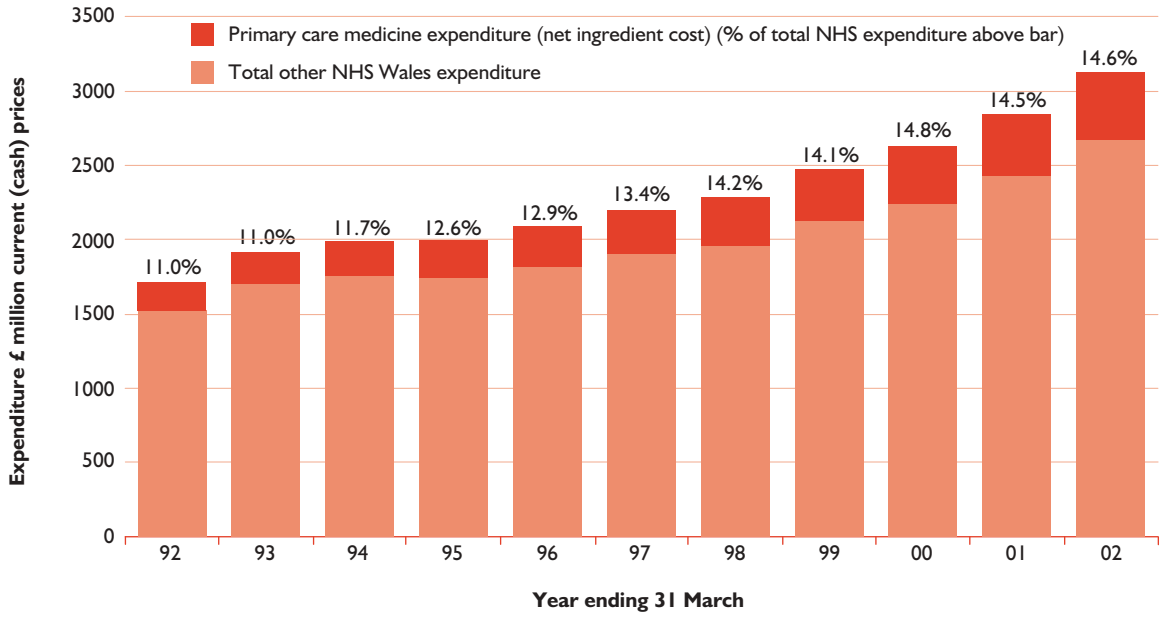
1.2 The Assembly is aware of the significance of primary care medicine expenditure and the need to press for better value for money. In 1999, it established the Task and Finish Group on Prescribing to advise on a wide range of medicine related matters, including procurement. The group reported to the Assembly's Health and Social Services Committee in March 2001, and the Assembly is taking forward the results of that work with its All Wales Medicines Strategy Group.

1.3 Building on the work of the Task and Finish Group, we have undertaken a review of primary care medicines procurement. We have concentrated our examination on the procurement of primary care medicines for two reasons. Firstly, primary care medicines account for some 85 per cent of total medicines expenditure. Secondly, as concluded by the Assembly's Task and Finish Group, secondary care[9] arrangements have been the subject of extensive review and have proved to be cost-effective.

1.4 The methods that we have employed in our study are summarised in Appendix 1. We have also consulted with a variety of relevant organisations, and these are listed in Appendix 2.

Figure 1

Expenditure on primary care medicines as a percentage of overall healthcare expenditure in Wales



Sources: National Assembly Statistical Directorate Bulletin 93/2002 and Welsh Office and National Assembly annual reports

7 Primary care is healthcare provided by general practitioners and other contractors, as distinct from secondary care, which is provided by hospitals.

8 This is the net ingredient cost less the discounts recovered. Net ingredient cost before discount recovery was £456 million. Net ingredient cost is the cost of medicines at basic price without any adjustment for discount or allowances or fees.

9 Secondary care is healthcare provided by hospitals.

1.5 Although this examination concentrates on primary care procurement arrangements, it recognises the links with other factors that affect the extent of expenditure on medicines. These include prescribing behaviour[10], developments in medicine, the overall provision of pharmaceutical services, the effects of the activities of other parts of the healthcare system and the health of the population.

1.6 The remainder of this report is in three parts:

- Part 2 provides an overall audit review of primary care medicine procurement arrangements in Wales, including comparisons with arrangements in other UK countries and secondary care procurement arrangements. It also identifies the powers of the Assembly in relation to procurement arrangements in order to make clear the Assembly's scope for changing those arrangements;

- Part 3 examines possible means of improving value for money by changing procurement arrangements;

- Part 4 points out the importance of other factors that affect medicines expenditure and their links with procurement.

10 Prescribing behaviour reflects the decisions that doctors and other prescribers make in writing prescriptions.

PART 2 Overall audit review of primary care medicine procurement arrangements

2.1 Identifying scope for improvements in primary care medicine procurement requires an understanding of the existing arrangements and the Assembly's powers to change them. This part of the report provides an overview of primary care medicine procurement arrangements, including comparisons with arrangements in other parts of the UK and with secondary care arrangements in Wales. It also sets out the Assembly's powers in relation to procurement arrangements.

Primary care medicine procurement is a complex mixture of market forces, government regulation and government-industry agreement

2.2 NHS primary care medicine procurement arrangements are shaped by a combination of market forces, scientific development, government regulation and agreement between government and industry. In respect of all of these, Wales is affected by events in the UK and beyond.

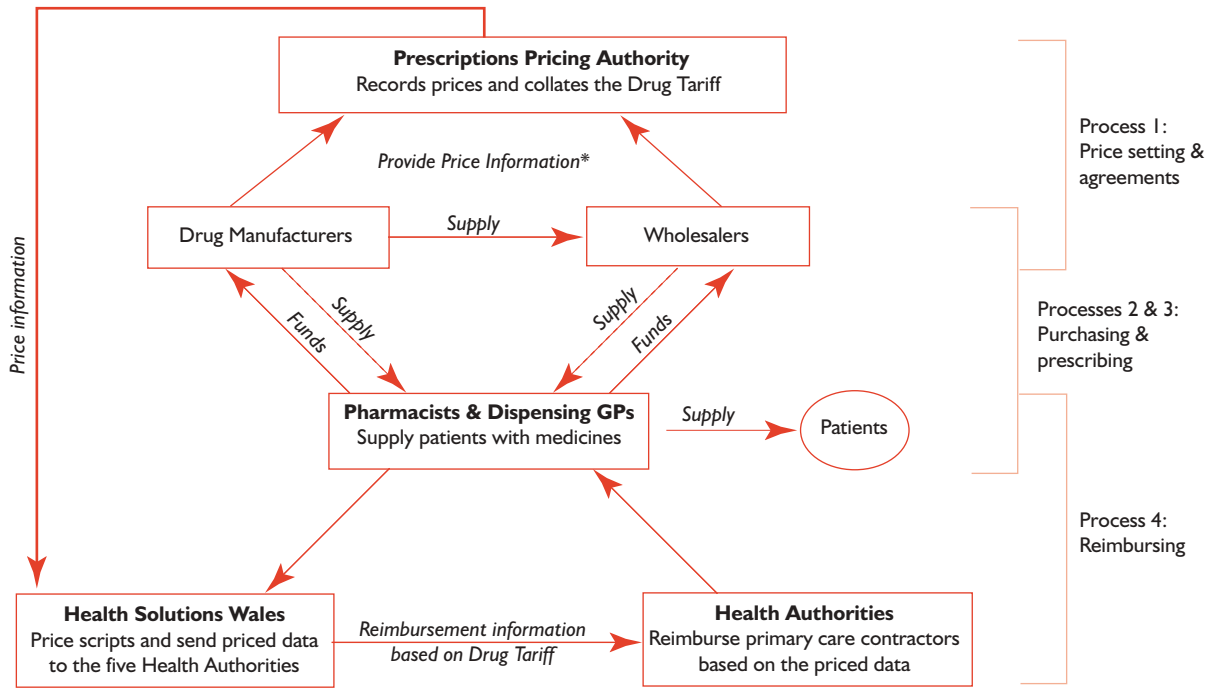
2.3 The primary care medicine procurement arrangements can be viewed as including four main processes:

- price setting by manufacturers and wholesalers;
- purchasing by contractors;
- ordering supply through prescriptions for patients;
- reimbursing contractors for the medicines that they have dispensed.

Figure 2 provides a summary of these processes, and the following paragraphs point out the main features. Appendix 3 gives further description of certain aspects highlighted in bold.

Figure 2

Summary of medicine procurement arrangements



Note

The Department of Health and the pharmaceutical industry negotiate the Pharmaceutical Price Regulation Scheme (PPRS), an agreement that controls the profits on sales of branded medicines to the NHS, so limiting their prices. The Department of Health also sets the maximum price on certain generic medicines through the Maximum Price Scheme (MPS), which prohibits the sale of these medicines to primary care contractors at more than the maximum price.

Source: National Audit Office Wales

Price setting and agreements

2.4 Pharmaceutical companies set prices influenced to varying degrees by agreement and statutory intervention by the Department of Health on behalf of all the UK health departments. In the case of branded medicines[11], the Department exercises overall control of prices through the **Pharmaceutical Price Regulation Scheme** (see Appendix 3). The Scheme is an agreement between government and the pharmaceutical industry that indirectly controls the prices of branded medicines by setting limits on the overall profit[12] on pharmaceutical companies' NHS sales. It allows companies to set the prices of new medicines on entry to the market but thereafter requires them to seek the Department's agreement for any subsequent price increases. The value of such increases has been minimal in recent years. In the case of many generic medicines[13], pricing is left to market forces. However, since 1999, the **Maximum Price Scheme** (see Appendix 3) has brought statutory price control to the prices of some 150 widely used medicines[14], which account for some 70 per cent of generics by value.

2.5 The basic prices of medicines, which form the basis of **reimbursement** (see Appendix 3 and 2.7), are collated each month in the **Drug Tariff** (see Appendix 3) by the Prescription Pricing Authority, a special health authority reporting to the Department of Health. The Drug Tariff covers both England and Wales.

Purchasing

2.6 NHS Wales, like the NHS in other parts of the UK, has its primary care medicines purchased on its behalf by over a thousand contractors: principally 720 community pharmacies and 320 dispensing GPs. Many of the community pharmacies are, however, parts of chains[15]. The contractors purchase the medicines they dispense from wholesalers, manufacturers and, in the case of integrated chains, in-house distribution arrangements, according to their own assessments of demand. They therefore handle day-to-day stock control on behalf of the NHS and bear its costs, especially administration, accommodation and security. They also bear much of the attendant risks, such as excess costs caused by over-ordering.

Reimbursing

2.7 NHS Wales reimburses contractors using the basic prices provided by the Drug Tariff, or, where the dispensed item is not included in the Tariff, at the list price of the contractor's supplier. The prices are adjusted by an estimate of the discount that contractors receive from their suppliers. This discount estimate is derived from the Department of Health's periodic discount inquiry survey of a sample of contactors. The process has evolved so as to provide an incentive for contractors to seek discounts, which the NHS seeks to benefit from through discount recovery. **Figure 3** summarises this mechanism. According to the Department of Health's evidence to the House of Commons Health Committee (HC105, 1999), the fixed-price reimbursement system has encouraged pharmacists to buy at below the reimbursement price. Contractors tend to negotiate lower costs with the wholesalers and manufacturers as the reimbursement calculations are made using the tariff and not the actual amount contractors have spent on drugs. Negotiating costs with the suppliers allows contractors to make a profit[16].

11 Branded medicines are those medicines for which a company holds a patent giving it the exclusive right to bring it to market, or, where the patent has expired, the continued marketing of the original preparation. Such patents last initially for 20 years, but, because of licensing requirements, market entry occurs after the granting of patent, and the amount of patent life available after market entry varies by product. Patents may be extended. The Pharmaceutical Price Regulation Scheme also covers 'branded generics', medicines previously covered by patent but now manufactured and marketed under another trade mark, for example, *Hedex* paracetemol.

12 This is in terms of Return on Capital Employed (ROCE)

13 Generic medicines are chemically equivalent copies, in terms of their active ingredients, of original brands for which patents have expired.

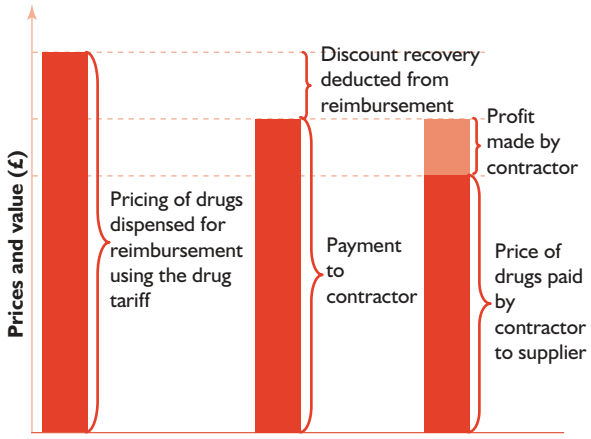
14 As medicines come in several forms, such as tablet and capsule, and in various strengths, the controls apply to some 500 different preparations.

15 The individual outlets of chains are covered by separate contracts.

16 "Wholesalers may also have an incentive to offer reduced discounts to integrated pharmacies", because of the way the discount inquiry works. "A wholesaler can reduce the overall claw back rate determined in the discount inquiry while keeping its profits upstream. " OXERA, *Fundamental Review of the Generic Drugs Market*, July 2001

Figure 3

Reimbursement and its incentive to contractors to seek discounts



Note

Not to scale

Source: National Audit Office Wales

2.8 Pharmacists and dispensing GPs also receive fees beyond **reimbursement**. For pharmacists, these are chiefly **professional fees** (see Appendix 3) and additional fees, which are paid in respect of the dispensing and other pharmacy-related services they provide. Dispensing GPs receive dispensing fees and an on-cost payment calculated at 10.5 per cent of net ingredient costs. Both also receive other payments, such as container allowance.

Exceptions

2.9 There are exceptions to the general model described. Childhood vaccines and oxygen for therapy are supplied through centralised contracts arranged by the Department of Health. These items are paid for directly by the Department, rather than through the reimbursement of contractors. Another exception is the *Cost Effective Provision of Disease Modifying Therapies for People with Multiple Sclerosis* (Health Service Circular, HSC 2002/004). This is a recently developed risk sharing scheme agreed between the UK health departments, including the Assembly's NHS Directorate, and pharmaceutical companies. It allows beta-interferon and glatiramer acetate to be acquired for use in the NHS on a cohort of patients and to be monitored for cost-effectiveness. NHS Wales will pay for these medicines in the usual way, but, if the treatment outcomes of the individual products fall short of target outcomes, payments are to be reduced on a sliding scale.

Primary care medicine procurement arrangements in Wales are similar to those in other parts of the UK

2.10 Primary care medicine procurement arrangements in Wales are essentially the same as those in England, and they are also similar to those in Scotland and Northern Ireland. However, both Scotland and Northern Ireland have their own primary legislation for the regulation of pharmacy services. This has led to both setting their own drug tariffs, which contain basic prices that are calculated using a different method to that used for England and Wales. There are also differences in the structure of their discount recovery scales.

2.11 An important difference between Wales and the other three UK countries is its greater use of dispensing GPs in terms of numbers per head of population **(Figure 4)**. In the case of comparison with England, as the regulations that allow GPs to dispense are identical, the higher ratio reflects a greater degree of access problems in rural areas. The difference with Scotland, however, reflects different regulations. In Wales, GPs are eligible to apply to dispense to patients that live more than a mile from their nearest pharmacy by virtue of being in a rural 'controlled area'. In Scotland, Health Boards decide whether a GP should dispense to patients who have difficulty in obtaining medicines.

Figure 4

Numbers of dispensing GPs per 100,000 people, 2001-02

	Number of dispensing GPs	Dispensing GPs per 100,000 people
Wales	320	11.02
England	4,455	9.06
Scotland	272	5.37
Northern Ireland	27	1.60

Sources: UK health departments and Office of National Statistics

Secondary care medicine procurement arrangements unify NHS buying power

2.12 Unlike the primary care sector, where over 1,000 contractors purchase drugs from suppliers, secondary care arrangements consist of all-Wales contracts that guarantee supply and the maximum prices that NHS trusts pay for medicines. The All Wales Drugs Contracting Committee, a group comprising pharmacists and doctors in the secondary care sector, negotiate a framework contract on behalf of all Trusts across Wales. By working together through the committee, the hospitals are able to maximise their buying power.

2.13 The secondary care sector management system brings together budgets, contracting and the design of formularies[17]. This allows a cost analysis that can influence prescribing decisions within hospitals. Such coherent information is not available in the primary care sector because of its fragmented nature.

The National Assembly for Wales has some powers to change primary care procurement arrangements

2.14 The Government of Wales Act 1998 gives the National Assembly for Wales powers under the National Health Service Act 1977 to make secondary legislation that regulates pharmaceutical services[18]. The Assembly has already used its powers to amend these regulations in order to accommodate Wales' own prescription charging regime, which it established in 2001.

2.15 The Government of Wales Act thus enables the Assembly to change the regulations that govern the way that pharmacies and dispensing GPs are reimbursed for procuring medicines on behalf of the NHS. The Act would, for example, allow the Assembly to set a separate drug tariff. If, however, the Assembly were to seek to change the arrangements beyond matters of reimbursement, such as requiring contractors to use a particular source of supply, it may need to seek primary legislation. Changes to regulations may also need to be accompanied by changes to contracts with dispensing GPs. This is because the regulations, as well providing the terms of service for pharmacists, feed in to the terms of the contracts between health authorities and dispensing GPs.

2.16 In addition, the Department of Health has powers in relation to medicines procurement that can affect arrangements in Wales. As noted in paragraph 2.4, the Department of Health negotiates the Pharmaceutical Price Regulation Scheme on behalf of all the UK health departments. Although participation on the part of pharmaceutical firms is voluntary, the Department of Health's operation of the Scheme has the statutory backing of the Health Act 1999. The Assembly does not have powers to make changes to the Pharmaceutical Price Regulation Scheme, such as making changes to company profit limits, with respect to sales in Wales. It may, however, be able to achieve change in the Pharmaceutical Price Regulation Scheme by influencing the actions of the Department of Health.

2.17 Similarly, the Department sets the regulations of the Maximum Price Scheme under the Health Act 1999 on behalf of all UK health departments. The Assembly does not have powers under this Act to set different maximum prices in respect of Wales.

17 Formularies are lists of medicines that have been agreed as suitable for use by groups of doctors and other health professionals in their unit or area.

18 Most of the existing regulations that relate to procurement arrangements are contained in the National Health Service (Pharmaceutical Services) Regulations 1992, including the provisions for the maintenance of the Drug Tariff.

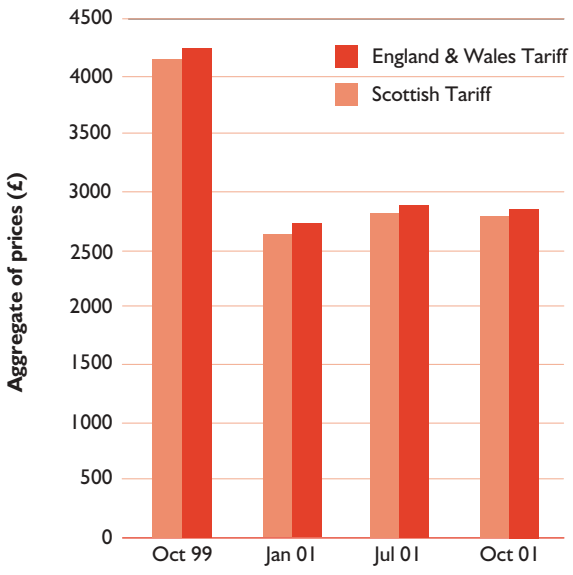
PART 3 Primary care medicine procurement arrangements may offer scope for reducing costs

3.1 Taking account of the Assembly's powers to change primary care procurement arrangements, and given our overall review of those arrangements and the work of the Task and Finish Group on Prescribing, we have examined changes that could potentially reduce costs. In particular, we have examined the potential benefits and risks of adopting:

- a different tariff along the lines of the Scottish Drug Tariff;
- various degrees of centralised procurement.

Figure 5

Differences in basic prices between the Scottish and England & Wales tariffs for sample months



Sources: Drug Tariff, NHS England & Wales, and Scottish Drug Tariff for dates shown

NHS Wales obtains medicines at much the same price as NHS Scotland and the NHS in Northern Ireland

3.2 During our work to compare Wales' procurement arrangements with those in other UK countries, we found that, in aggregate, the basic prices of medicines in the Scottish Drug Tariff were lower than those in the Drug Tariff for England & Wales (paragraph 2.5). We found that this was consistent over time, even allowing for large fluctuations in basic prices **(Figure 5)**. The prices and discounts of the Northern Ireland Drug Tariff are set at parity with those of the Scottish Drug Tariff.

3.3 We therefore explored the possibility of NHS Wales being able to achieve savings by using a different tariff, along the lines of the Scottish Drug Tariff. We modelled the effect of using the Scottish Drug Tariff by taking the differences between that tariff and the England & Wales Drug Tariff for a sample month (July 2001[19]) and multiplying them by the actual number of corresponding items used in Wales in 2001. Further details of our methods are given in Appendix 1. This modelling indicated that the use of the lower Scottish Drug Tariff prices would have led to a reduction in net ingredient cost[20] of £3.9 million.

3.4 However, the comparison of basic prices does not take into account differences in discount recovery. While the Drug Tariff for England & Wales provides a single scale that varies with monthly medicine volume by value, in Scotland a flat rate of 13.25 per cent applies to generics, while a lower variable scale applies to brands[21]. To allow for these differences, we estimated the average discounts that would be obtained by pharmacists and dispensing GPs in Wales under the Scottish Drug Tariff and the England & Wales Drug Tariff: 10.7 and 9.5 per cent respectively. The difference in discount structure would have led to some £5.5 million less discount recovery, meaning that applying both aspects of the Scottish Drug Tariff would have led to additional expenditure of £1.6 million.

19 We used July 2001 because it provided mid-year prices to match the Prescription Cost Analysis for 2001, which was the most recent full year data for all primary care dispensing in Wales. We also analysed the differences between the England & Wales and Scottish Drug Tariffs for January and October 2001, in order to ensure that July was not an unusual month.

20 Net ingredient cost is the cost of medicines at basic price without any adjustment for discount or allowances or fees.

21 These differences reflect negotiations between the Scottish Executive and Scottish Community Pharmacists, and are driven by evidence of the nature of the Scottish pharmaceutical market.

3.5 The Scottish discount structure is directly sensitive to the proportion of expenditure accounted for by the dispensing of generic medicines[22]. At Wales' current, relatively low level of generic dispensing by value (some 22 per cent), the adoption of a Welsh tariff along Scottish lines is not a worthwhile option. But at higher levels of generic prescription, and consequently dispensing, the discount recovery would be greater. The Assembly's NHS Directorate should therefore be prepared to reconsider such an option if further analysis indicates that it would be worthwhile.

NHS Wales, like the NHS in other parts of the UK, pays more for the same medicines it procures for primary care than those it procures for secondary care

3.6 The Task and Finish Group on Prescribing identified centralised purchasing as an option for dispensing GPs, and OXERA Consulting Ltd, the Department of Health's advisers, identified it as an option for all primary care generic medicines. Certain items, such as childhood vaccines, are already centrally purchased on a UK basis. We therefore examined the prices in the secondary care sector and modelled the effect on expenditure of obtaining such prices for the same drugs in primary care.

3.7 To do this, we compared the prices for 2001 obtained by the All Wales Drugs Contracting Committee, which negotiates contracts on behalf of all trusts in Wales (paragraph 2.12), with the prices paid in primary care for 2001. We found that, where prices could be matched for the same items (315 items), the All Wales Drugs Contracting Committee prices were, on average, 50 per cent less than those obtained in primary care. It should be noted, however, that only a minority of primary care medicines are covered by All Wales Drugs Contracting Committee prices: some 500 out of 14,000 items.

3.8 We applied the differences between All Wales Drugs Contracting Committee and primary care prices to the Prescription Cost Analysis compiled by Health Solutions Wales, adjusting for primary care contractor discounts. This indicated that if those medicines covered by All Wales Drugs Contracting Committee contracts had been subject to similar contracts for primary care and available at those prices, some £50 million could possibly have been saved in 2001. We also found that a small number of items account for a large proportion of the savings **(Figure 6 overleaf)**.

3.9 The exact extent of the savings figure would depend on centralisation being coupled with generic substitution—using appropriate brand or generic products for the same medicine—as is done in hospitals. We consider generic substitution as a separate means of improving value for money in paragraphs 4.21 to 4.22. We note that generic substitution is not appropriate for some medicines because of the importance of precise bio-availability[23] for some conditions. If NHS Wales were to pursue centralised contracts, it would need to take full account of the issue of bio-availability.

3.10 As the Task and Finish Group on Prescribing had specifically recommended exploring the possibility of Local Health Groups negotiating contracts for items used by GPs, we separately modelled the effect of secondary care prices on dispensing GPs. This indicated that up to £2.8 million could possibly have been saved in 2001 if those medicines had been supplied under All Wales Drugs Contracting Committee contracts and substitution had been practised.

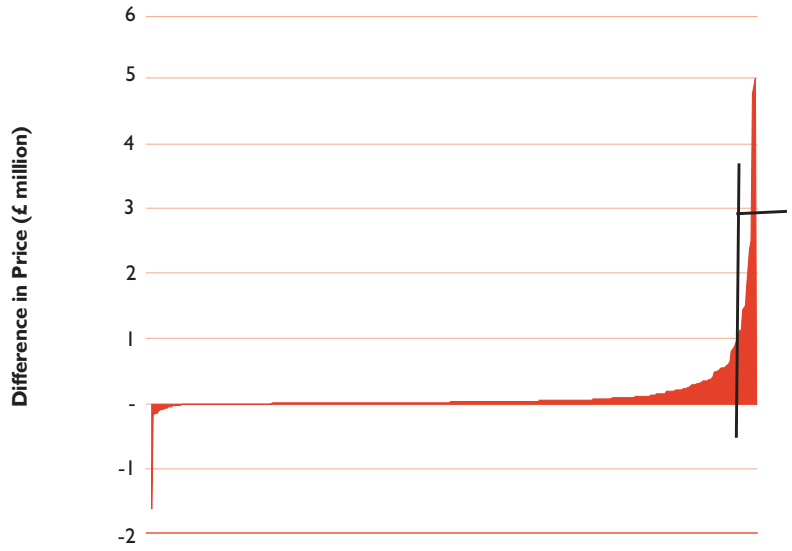
3.11 NHS Wales would not necessarily have to confine attempts to achieve savings to those medicines that are covered by All Wales Drugs Contracting Committee contracts. Theoretically, any item could be covered by a centralised contract. Items covered by All Wales Drugs Contracting Committee contracts do, however, provide a useful precedent in negotiations, as the negotiation of a similarly priced contract for primary care provides suppliers the opportunity to demonstrate that they are not subsidising one sector at the expense of the other.

22 Indirectly, through the discount inquiry, the discount for England and Wales is also periodically affected by changes in the proportion of medicines expenditure accounted for by generics. Changes in Wales alone would only lead to a small effect.

23 Bio-availability is the rate and extent of absorption of the dose into the body's systems. Among other things, it is affected by the formulation of the medicine, such as capsule form or tablet coating. This is of great importance for certain medicines such as anticonvulsants.

Figure 6

Differences in total costs of individual primary care medicines arising from applying All Wales Drugs Contracting Committee prices



Items with largest differences

Simvastatin Tablets 20mg	£5,012,765
Lansoprazole Caps 30mg	£4,760,450
Simvastatin Tablets 10mg	£2,489,628
Paroxetine HCL Tablets 20mg	£2,374,568
Lisinopril Tablets 20mg	£1,838,767
Isosorbide Mnit Tablets 60mg	£1,501,840
Lisinopril Tablets 5mg	£1,444,814
Gliclazide Tablets 80mg	£1,125,269
Ranitidine HCL Tablets 150mg	£1,120,588
Lansoprazole Caps 15mg	£991,822
Total	**£22,660,510**

Sources: Health Solutions Wales Prescription Cost Analysis 2001 and All Wales Drugs Contracting Committee prices 2001

3.12 Seeking centralised contracts for certain items could also be useful for stimulating the entry of generic equivalents into the market and for addressing supply problems for particular medicines. This is because such contracts could provide a greater degree of certainty about demand, so assisting manufacturers in their planning. However, there is also the possibility that such invitations to tender will not attract any response. This could occur if pharmaceutical companies regarded the period of the contract as insufficiently long, and the risk of losing tenders too high, to justify the investment. A further risk is that centralised contracts could cause the number of manufacturers of established generics to reduce, though centralised contracts for Wales alone would be a marginal influence.

3.13 Several medicines that account for significant proportions of expenditure have recently come off patent, but no generic equivalent is yet available. Examples include Acarbose[24] (£185,000 net ingredient cost in 2001) and Goserelin[25] (£5.2 million). Goserelin is an implant and is therefore not straightforward to manufacture, which may make it unattractive to many potential generic manufacturers. Similarly, some items are shortly to come off patent. These include Simvastatin[26] in May 2003 (£13.6 million). If similar levels of reduced price to those in secondary care procurement contracts could have been achieved, the individual savings for such items in 2001 would have been worthwhile: £92,500 for Acarbose, £6.8 million for Simvastatin and £2.6 million for Goserelin alone.

3.14 The equivalent savings for individual medicines used by dispensing GPs are, however, quite small: £10,000 for Acarbose, £182,000 for Simvastatin and £78,000 for Goserelin. The administrative cost of establishing contracts for individual items for dispensing GPs only may therefore mean that such contracts would have limited cost-effectiveness. However, such contracts might be useful as pilots for more widespread centralisation.

24 Acarbose is used in the treatment of diabetes.

25 Goserelin is used in the treatment of breast and prostate cancer, and some other conditions.

26 Simvastatin is a lipid regulating drug that has widespread use in the treatment of cardiovascular conditions.

Achieving savings from centralised procurement would not be straightforward for Wales acting alone

3.15 Although the potential for savings from centralising primary care procurement appears to be extensive, there are considerable economic and practical limitations to introducing such arrangements and achieving that scale of savings. These limitations lie in the effects of market forces, the effort and expertise needed to negotiate contracts and the need to ensure security of supply. These would probably be exacerbated if Wales were to seek to introduce centralised procurement without being accompanied by similar developments in the rest of the UK.

Centralisation increases risk to security of supply

3.16 Security of supply is important for ensuring that patients receive the medicines they need, when they need them, and this is a strength of the current system. The use of centralised supply contracts could potentially raise risks for this security of supply.

3.17 In the present system, there is useful duplication in wholesalers' distribution networks: a pharmacy may be served by more than one wholesaler. This enables frequent deliveries, which is useful for emergency cases. Also the 1,040 pharmacists and dispensing GPs each hold their own buffer stocks, which, in aggregate, enable supply shocks to be absorbed. Changes to the system caused by centralisation could remove some of this ability to deal with emergency cases and supply problems. This risk would need to be addressed, for example, by seeking to contract to make maximum use of the existing supply networks.

3.18 Threats to security of supply may also arise from lower prices themselves, as manufacturers and wholesalers may prefer to ensure that customers paying higher prices are given priority in supply. Such risk to supply might be addressed by dividing supply needs between several contracts. The Department of Health's advisers, OXERA, have produced a considerable volume of work on the best ways to address this issue.

3.19 Lower prices could also lead to supply problems through the stimulation of parallel trade, and European law does not allow this to be prevented by regulation. This means that pharmacists and dispensing GPs outside Wales would be tempted to buy their medicines in Wales in order to make savings. If such parallel trade were to develop to any significant extent, it could lead to supply shortages in Wales, which would jeopardise patient care.

3.20 The All Wales Drugs Contracting Committee and the Department of Health have undertaken considerable work to address security of supply in their work on centralised procurement. We therefore **recommend** that NHS Wales should seek to use this work in preparing any centralised contracts.

Low prices may be harder to negotiate for primary care than secondary care

3.21 The Department of Health's consultants, OXERA, have reported that:

> "*… the mere volume demanded by the NHS would lead to significantly lower prices than those obtained by the pharmacies because of production efficiencies. This is certainly the experience of the secondary care sector, although the lower prices for drugs to hospitals may have other explanations…*
>
> "*Anecdotal evidence suggests that patients who begin a course of treatment in hospital are unwilling to switch (for example, from a branded product to a generic equivalent) on leaving hospital. It has been said that each prescription in a hospital generates around 15 repeat prescriptions in the primary care sector. Thus, manufacturers may be eager to sell their products to hospitals at a substantial discount (perhaps even below cost) in order to capture a portion of the primary care market, where prices are higher.*
>
> "*Furthermore, under the PPRS [Pharmaceutical Price Regulation Scheme], revenues, rather than prices, are controlled. Thus, companies are to a certain extent free to cross-subsidise between the hospital and primary-care sectors.*" *(Fundamental Review of the Generic Drugs Market, July 2001)*

3.22 Further evidence of this incentive to supply hospitals at low prices is provided by the All Wales Drugs Contracting Committee's refusal to accept manifestly loss-leading bids because of the subsequent effect on primary care medicines expenditure. Discounting to secondary care is purely discretionary on the part of the pharmaceutical industry and reflects the fact that secondary care accounts for a relatively small part of overall medicines expenditure. The successful negotiation of low-price contracts may therefore be more difficult for primary care.

Achieving low prices for primary care medicines may lead to higher prices for secondary care medicines

3.23 The erosion of any cross-subsidy may drive up the prices that the All Wales Drugs Contracting Committee can negotiate for secondary care medicines. As the proportion of secondary care medicine price differences that is attributable to cross-subsidisation is not known, the extent of such an effect cannot be predicted with any certainty. However, making prices in each sector more transparent is desirable in itself, as this will enable more rational decision making.

The achievement of low prices will be limited by the expertise and effort NHS Wales can devote to negotiating contracts

3.24 NHS Wales' ability to negotiate centralised contracts will be limited by the effort and expertise that it can put into negotiations. The Assembly's NHS Department would need to identify who could most effectively undertake negotiations, develop the commercial skills of those negotiating contracts and give them adequate support. Their negotiating strength could also be increased by undertaking price comparisons with other European countries. This might enable negotiators to seek, for example, 'most favoured nation' terms from suppliers, guaranteeing that prices charged to NHS Wales are no higher than those charged to other countries.

3.25 If the Assembly's NHS Directorate were to pursue centralised contracts, it would also need to be realistic about the number of items that NHS Wales can cover with such contracts. The All Wales Drugs Contracting Committee has demonstrated that it is possible to negotiate contracts for 500 items, covering most hospital medicine needs. Attempting to negotiate contracts for the thousands of items used in primary care is unlikely to be a practical proposition. The limiting of the number of items covered is, however, in many ways desirable, as it provides an impetus to the consideration and selection of the most suitable medicines for most patients.

Centralisation would require changes to the contracts of primary care contractors and may require primary legislation

3.26 Centralisation would affect the roles of pharmacists and other contractors, and this would need to be reflected in their contracts with the NHS. At the most basic level, contracts would need to take account of the removal of reimbursement from items that are covered by centralised contracts. The Assembly would have to negotiate and agree the new terms and conditions with the relevant professional bodies.

3.27 It would also be necessary to list the medicines covered by centralised contracts in order to make GPs and other prescribers aware of them and encourage their prescribing. The Assembly will need to consider the extent to which the prescription of medicines covered by centralised contracts is encouraged by incentives or other means, which may need to be backed by primary legislation. The effectiveness of simple listing could be tested by piloting.

Overall, there is scope for savings from NHS Wales undertaking centralised procurement, but this is accompanied by risks and practical challenges

3.28 Centralising primary care procurement presents some scope for savings, even if confined to a limited number of significant items. However, such arrangements would be accompanied by substantial risks and practical problems. We therefore **recommend** that, following the Department of Health review, (see paragraphs 4.2 to 4.4), if the Department does not make changes to procurement arrangements across the UK that would render centralisation inappropriate, the Assembly's NHS Directorate should consider piloting centralised contracts with a small number of medicines.

PART 4 Wider considerations for primary care medicine procurement

4.1 In addition to the complexities that are specific to centralised procurement of primary care medicines, we have identified wider factors that need to be taken into account in making any decision about changes to procurement arrangements. These are:

- the possible development of primary care medicine procurement on a UK-wide basis, stemming from a review of generic medicine procurement arrangements that the Department of Health is currently undertaking;
- the effects that changes in procurement may have on wider pharmaceutical industry investment in research and development of new treatments;
- the effects that changes in procurement may have on wider pharmaceutical industry investment in research and development of new treatments;
- the importance of prescribing behaviour and medicines management.

The Department of Health has a review of procurement arrangements underway that could have implications for Wales

4.2 Since 1999, the Department of Health has been reviewing the supply and reimbursement of generic medicines for the NHS. This is intended to provide a basis for long-term reform of generic medicine procurement arrangements, following on from the Maximum Price Scheme. The Department's objectives are to secure the supply of generic medicines at reasonable prices for the NHS and a reasonable return for manufacturers and other parts of the supply chain. The Department is consulting with the Assembly's NHS Directorate and the other devolved administrations about the review.

4.3 The Department has developed various options for reform, including reference based pricing and central purchasing through tendering. Reference based pricing would entail calculating an 'NHS price' for medicines from the prices charged by manufacturers to wholesalers, adding a government determined margin for wholesaling. The Department would use powers under the Health Act 1999 to obtain details of actual prices charged by manufacturers, rather than relying on price lists. The Department would also undertake a periodic margin review to ensure that the wholesale margin encouraged efficient wholesaling and cost-effective purchasing by pharmacies, while still providing reasonable returns to wholesalers. Under the centralised purchasing option, the Department would let contracts, by competitive tender, for the exclusive right and obligation to supply a specified volume of specified medicines at a specified price to community pharmacies and dispensing GPs for NHS dispensing.

4.4 The Department has not published any estimates of the financial benefits of any of its options. However, given the Department's objectives, it is clear that pursuing new arrangements would have the potential to achieve savings. In view of this we **recommend** that the Assembly's NHS Directorate should determine and phase in any extensive changes to primary care medicine procurement arrangements to take advantage of any changes that the Department of Health may introduce as a result of its current review of generic medicine procurement arrangements. But the Assembly's NHS Directorate should not accept undue delay while the Department determines its preferred option.

The Assembly will need to assess how changes in procurement arrangements may affect wider pharmacy and medical services

4.5 Any significant changes to procurement arrangements may affect pharmacy and medical services, and the situation could be further complicated by other developments, in particular by the response to the recommendations of the Office of Fair Trading's January 2003 report, *The Control of Entry Regulations and Pharmacy Services in the UK*. The report recommends deregulating community pharmacy in terms of entry requirements, and it is possible that this will affect patient access in some areas.

The Assembly's Pharmacy Strategy needs to take account of possible changes to procurement arrangements

4.6 The Assembly's NHS Directorate has drafted a strategy for the development of pharmaceutical services in Wales, and consulted on this in 2002. It proposes, as part of the strategy, a review of community pharmacy, covering among other things a mapping of the distribution of community pharmacy outlets in relation to population need. However, the strategy, as set out in *Remedies for Success,* does not explicitly take account of possible developments in primary care medicine procurement, though it does acknowledge the Task and Finish Group's recommendation that medicines used by GPs should be purchased using contracts negotiated by Local Health Groups. We therefore **recommend** that in undertaking its review of community pharmacy, the Assembly's NHS Directorate takes full account of the effect of procurement developments as well as the implications of the Office of Fair Trading's January 2003 report.

Changes to procurement arrangements could affect access to community pharmacies

4.7 In the course of preparing this report, we consulted the body that represents the commercial interests of community pharmacists, Community Pharmacy Wales. It commented that the removal of a reimbursement based system, or reductions in the levels of reimbursement, could threaten the viability of community pharmacies that are at the margins of profitability. It considers that this would hinder the maintenance of a pharmacy network that matches the needs of the population and in particular its more vulnerable members such as the elderly. This would be most problematic in rural areas with sparse populations, and in areas of high levels of deprivation.

4.8 The Assembly's NHS Directorate will therefore need to assess the risk to patient access that any reduction in reimbursement that changes to procurement arrangements could cause, and whether this risk can be addressed satisfactorily. This would include assessing whether the Essential Small Pharmacy Scheme prevents gaps in coverage of the population by pharmacies, and whether the Assembly should use its powers under the Government of Wales Act 1998 to reform the Scheme.

Changing procurement arrangements could also affect GP services in rural areas

4.9 In preparing our report, we also consulted the British Medical Association's General Practitioner Committee (Wales). The Association was concerned that changes to the reimbursement of dispensing GPs could act as a disincentive to GPs considering taking up practice in rural areas of Wales.

4.10 We note that the Assembly's NHS Directorate, along with the Department of Health, is addressing the transparency of support to dispensing GPs in negotiations with the British Medical Association concerning a new GP contract for England and Wales. In particular, we note that both sides have made progress in considering the replacement of the 10.5 per cent on-cost—a payment to dispensing GPs calculated on 10.5 per cent of the net ingredient cost of medicines that they procure—with payments that reflect services to patients. Such a change would reduce the extent to which dispensing GPs are reliant upon reimbursement to maintain the financial viability of their practices.

Changes to procurement arrangements could adversely affect distribution networks

4.11 Community Pharmacy Wales also expressed concern about the possible effects of changes in procurement arrangements on the wholesalers' distribution networks and the consequent effects this might have on patient care. They argued that reductions in the margins of wholesalers would lead to retrenchment of those networks, leading in turn to fewer deliveries, especially in rural areas. This would increase the risk of pharmacists not being able to dispense the medicines prescribed at the time patients present their prescriptions. This could lead to a serious deterioration in pharmaceutical service to those who are least able to visit a pharmacy. The Assembly will therefore need to consider how it can address such a risk before undertaking any change in procurement arrangements that would affect wholesalers' margins.

The Assembly should consider the possible impact of changes to procurement on wider pharmaceutical industry investment in research and development of new treatments

4.12 Our discussions with the representatives of the pharmaceutical industry raised the concern that developments that might undermine the Pharmaceutical Price Regulation Scheme by eroding price levels could, ultimately, undermine investment in research and development for new treatments to deal with critical illnesses, such as cancer. At present, the industry invests some £3.2 billion a year in research and development in the UK. A separate figure for Wales is not available, though clearly Wales benefits from the results of such investment world-wide.

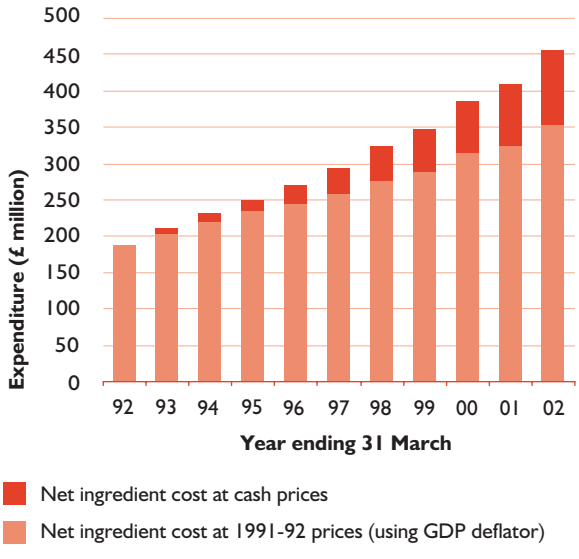
4.13 It would therefore be appropriate for the Assembly's NHS Directorate to address the risk of changes to procurement arrangements leading to reductions in investment in research and development of new treatments by involving the Wales Industry Group[27] in its considerations. The Directorate already involves the Wales Industry Group in medicine developments through representation on the All Wales Medicines Strategy Group.

The Assembly should continue to keep in view the importance of prescribing behaviour and medicines management

4.14 GP prescribing behaviour and effective medicines management are also important factors in determining overall expenditure on medicines in Wales. The Audit Commission has done extensive work on prescribing behaviour in England and Wales, starting with its report, *A Prescription for Improvement* (1994). Similarly, Audit Scotland has examined cost-effective prescribing behaviour in its report, *Supporting Prescribing in General Practice* (1999), and is shortly to publish an update. Consequently, it is important that the Assembly's NHS Directorate continues to address these as it attempts to control expenditure on medicines. It is also important that, where possible, changes to procurement arrangements support improvements in prescribing behaviour and medicines management.

Figure 7

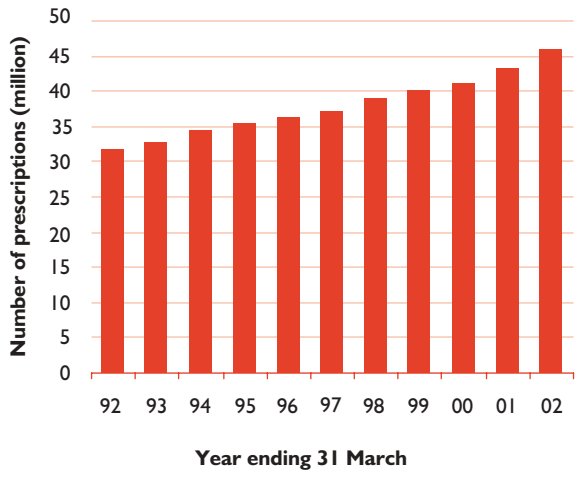
The growth in expenditure on primary care medicine in Wales, as indicated by net ingredient cost



Source: National Assembly Statistical Directorate Bulletin 93/2002

Figure 8

The growth in the number of prescriptions dispensed



Sources: National Assembly Statistical Directorate Bulletin 93/2002

27 The Wales Industry Group is part of the Association of British Pharmaceutical Industry.

Changes in prescribing behaviour have led to increased expenditure on medicines

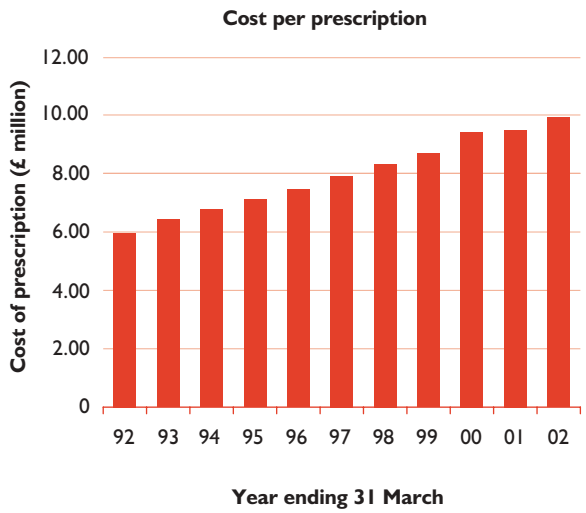
4.15 Over the past decade expenditure on primary care medicines has increased at an average of 6.5 per cent a year in real terms **(Figure 7)**.

4.16 The largest component of this growth is the increase in the number of prescriptions dispensed, which has risen at an average annual rate of 3.8 per cent. **Figure 8** shows the growth in the number of prescriptions. The report of the Assembly's Task and Finish Group on Prescribing set out some explanations for this scale of growth. It cited the ageing of the population as one cause: in 2001-02, people over 60 (23 per cent of the population) accounted for 56.6 per cent of prescriptions. The Group identified the main driver as being developments that enable more conditions to be effectively treated with medicines. Such developments lead to new, relatively more expensive[28] medicines being introduced, replacing older, cheaper medicines and other treatments and the absence of treatment.

4.17 The net ingredient cost per prescription has also grown, as shown in **Figure 9**, though at 2.6 per cent a year in real terms not quite so rapidly as the number of prescriptions. However, this does not mean that the prices of individual lines of medicines are rising year on year, as data for England indicates that the average pure price effect has been a decline in prices of 1.8 per cent[29]. With the exception of certain generic medicines in 1999 and 2000, which accounted for a small minority of medicines expenditure, the prices of most medicines have remained static or fallen. Instead, the increase in the average cost of medicines is largely due to a combination of new, relatively more expensive medicines being introduced into clinical practice. This is offset to a limited extent by generic substitution, as medicines come off patent.

Figure 9

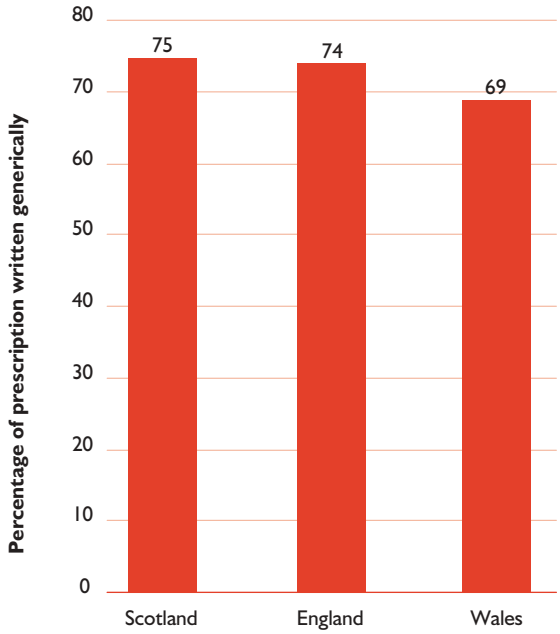
The growth in the average net ingredient costs of prescriptions since 1991-92



Sources: National Assembly Statistical Directorate Bulletin 93/2002

Figure 10

Generic prescribing rates in the UK, 2001-02



Note: Northern Ireland does not produce a comparable statistic.

Sources: National Assembly Statistical Directorate Statistical Bulletin 93/2002

28 New drugs tend to be initially relatively expensive because of research and development costs.

29 *PPRS [Pharmaceutical Price Regulation Scheme]: the Study into the Extent of Competition in the Supply of Branded Medicines in the NHS*, Department of Health and Association of the British Pharmaceutical Industry

4.18 In recent years, other factors in expenditure on medicines have been the work of the National Institute for Clinical Excellence and the National Service Frameworks, which set out good practice in the care of particular conditions, including the use of medicines. The National Institute for Clinical Excellence acknowledges that its recommendations incur expenditure. But as it looks at the global cost effectiveness of medicines, not just their prescribing costs, this expenditure may be justifiable through savings in secondary care.

Despite good reasons for increasing expenditure on medicines, there is scope for savings

4.19 There are several indicators that NHS Wales could achieve savings from improving prescribing behaviour. One is that Wales is slightly behind England and Scotland in its generic prescribing rate, as shown in **Figure 10**. Another is that there is considerable variation in the rate within Wales: from 77 per cent in Rhondda, Cynon Taff Local Health Group through to 63 per cent in Swansea Local Health Group[30] in 2001-02.

4.20 Local Health Groups and Health Authorities have set targets for various aspects of prescribing behaviour. To give focus for further improvement, we **recommend** that the Assembly's NHS Directorate sets a high profile national target for generic prescribing based on the level of the best rates in Wales.

4.21 Given this indication of scope for improvement, we also examined the extent to which increased generic prescription or generic substitution would lead to financial savings. To do this, we took data for 23 brands that accounted for significant amounts of medicines expenditure and for which generic equivalents were available in 2001, and we substituted the average cost per item for the generic equivalents. We did not substitute where the *British National Formulary*[31] indicates that this would not be safe, such as where bio-availability is critical (paragraph 3.9). We also only substituted generics that came in equivalent strength, form and pack size.

4.22 This modelling indicates that some £2 million, in terms of net ingredient cost less discount, could have been saved on these items. The results by individual brand are set out in Appendix 5. As time passes, medicines come off patent, while others are superseded. The extent of potential savings indicated by such modelling will therefore change, and it would be appropriate for the Assembly to periodically review the situation.

4.23 During our analysis we noted that some generics were more expensive than their branded equivalents. We conclude from this that generic substitution does not always lead to savings. However, except where there are clinical safety considerations, generic prescribing still allows the dispensing of a cheaper brand.

4.24 The Audit Commission has done extensive work to identify potential savings from appropriate product selection. In particular, it has compared prescribing in Wales with that of the North East of England, a broadly comparable English region in terms of morbidity and deprivation. It reported that, in 1998-99, up to £27 million might have been saved by GPs achieving more appropriate product selection, though the exact extent of savings would have been limited by matters of clinical judgement.

4.25 We have also identified that £1.4 million was spent in 2001 in Wales on drugs that the *British National Formulary* indicates are of limited clinical value. We note, however, that evidence of clinical value can change as new research is done. In view of this, we **recommend** that the Assembly's NHS Directorate should review the continued justification for GPs prescribing medicines that the *British National Formulary* indicates are of limited clinical value.

30 100 per cent generic prescribing is not clinically safe. This is because for certain conditions the rate and extent of absorption of the dose into the body's systems is of great importance. The rate and extent of absorption can vary between overall formulations, so the prescribing of a particular brand is appropriate in such circumstances.

31 The *British National Formulary* provides key information on medicines. See glossary and bibliography for further details.

The Assembly's NHS Directorate supports initiatives to improve prescribing behaviour

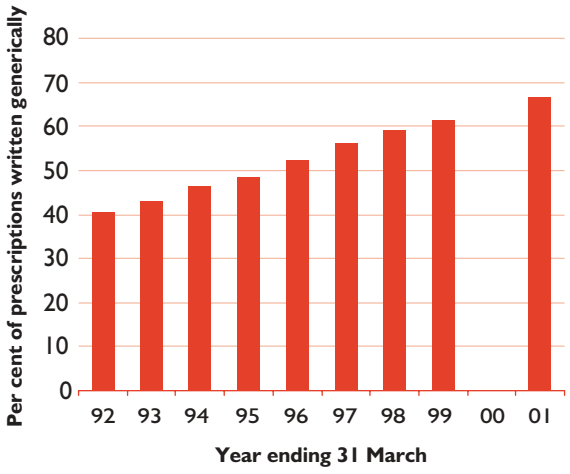
4.26 The Assembly's NHS Directorate is well aware that there is potential for savings from changing prescribing behaviour. It also recognises that there are several drivers of prescribing behaviour and that this is a complex area. It supports a variety of initiatives to improve prescribing behaviour, which include:

- the Welsh Medicines Resource Centre (WeMeRec);
- the development of local formularies;
- prescribing incentive schemes;
- prescribing advisers;
- prescribing indicators, and prescribing audit reports and catalogues;
- PRODIGY, a computerised prescribing and decision-support system for primary care.

Appendix 4 gives further details of these initiatives.

Figure 11

The increasing rate of generic prescribing in Wales since 1991-92



NOTE

Data for year ending 31 March 2000 not available

Sources: National Assembly Statistical Directorate Bulletin 93/2002

4.27 In terms of the level of generic prescribing, the indications are that these initiatives are having an effect in improving prescribing behaviour **(Figure 11)**. There is scope for assessing the possibility of further improvement, for example by exploring whether the menu structures of computerised prescribing and decision support systems are conducive to good prescribing practice, rather than simply favouring any particular preparation. This could enable the removal of a possible barrier to good prescribing behaviour, and this would be important to achieving the full benefits of centralisation. We therefore **recommend** that the Assembly's NHS Directorate obtains research to assess the effectiveness of initiatives to improve prescribing behaviour in the context of developments in procurement.

Savings could be achieved through generic substitution

4.28 Our identification of the scope for financial benefit from straightforward generic substitution within current procurement arrangements, outlined in 4.21 to 4.23, indicates that savings of some £2 million would result from enabling this practice. In 1999-2000, when Scottish prescribing levels were at much the same level as Wales in 2001-02, the Scottish Information Services Directorate estimated that 0.32 per cent of expenditure could be saved through generic substitution. This would have been equivalent to £1.3 million in Wales in 2001-02.

4.29 In countries such as the United States and Germany, generic substitution is allowed in primary care as well as secondary care. In Wales, however, along with other parts of the UK, such substitution is prevented by the Medicines Act 1968 and pharmacists' contractual obligations to dispense brands when these are prescribed. There are also questions of liability and patient compliance that would need to be addressed.

4.30 Given the modest level of savings from straightforward substitution, obtaining changes to primary legislation, renegotiating contracts and developing local primary care pharmacy committees is unlikely to be justified on cost grounds alone. However, the Audit Commission's work on prescribing behaviour indicates that much larger additional savings could be achieved through therapeutic substitution, which involves substituting chemically different medicines, as well as generic

substitution. Such substitutions require the exercise of a considerable degree of clinical judgement, and therefore could only be taken forward on the basis of agreements between GPs and pharmacists. The development of supplementary prescribing from April 2003, which involves pharmacists using their extensive knowledge of medicines to select the medicines that they consider most appropriate in implementing a 'Care Management Plan' agreed with a GP, could form the basis of such agreements.

4.31 We therefore **recommend** that the Assembly assess how it could best support the development of supplementary prescribing while seeking to achieve the financial benefits of generic and therapeutic substitution through it.

Savings may also be achieved through better primary care medicines management

4.32 The Assembly's NHS Directorate has estimated that some £15.6 million of medicines (in terms of Net Ingredient Cost) is wasted each year. Avoidable wastage arises from a variety of causes, such as patients not taking the medicines that they are prescribed. And both the Royal Pharmaceutical Society of Great Britain and the British Medical Association have told us that they believe that improved medicines management presents considerable scope for savings.

4.33 As part of its pharmacy strategy, the Assembly's NHS Directorate plans to work with pharmacy's representative bodies to develop the involvement of community pharmacy expertise so as to improve medicine management. In particular, it has identified that extending the involvement of pharmacists in medication review has, on the basis of experience elsewhere, the potential to significantly improve patient care and reduce expenditure on medicine. Such reviews are a process in which the overall treatment regime for individual patients is considered with a view to identifying whether the correct medicines have been prescribed and whether there is any adverse reaction. Reducing the risk of adverse reactions, which are a costly source of hospital admissions, and the cessation of inappropriate treatment should lead to financial savings as well as improved care.

4.34 The Assembly's NHS Directorate also plans to develop an original pack dispensing implementation plan so as to ensure that appropriate pack sizes are available, so reducing wastage. The standardisation of pack sizes is also desirable in establishing centralised contracts, as it reduces the numbers of lines of a medicine that require contracts to be negotiated. It would also help to reduce the barrier to substituting one medicine for another caused by differences in pack size.

4.35 We believe that, given its estimate of the value of wastage, the Assembly's NHS Directorate is right to pursue improvements in medicines management. In order that it ensures that worthwhile initiatives are pursued, we **recommend** that the Assembly's NHS Directorate recognises the links between measures to reduce medicines wastage and developments in procurement arrangements, and identifies the cost-effectiveness of such measures taking account of those links.

APPENDIX 1

Methods of examination

The main objectives of this study were to examine the economy of existing primary care procurement arrangements and to identify the extent to which improvements could be made to those arrangements, in order to control expenditure.

The issues examined were:

i) whether existing arrangements for procuring primary care sector drugs present risks to value for money;

ii) the extent to which the National Assembly for Wales has powers to improve procurement arrangements;

iii) whether different arrangements would yield savings;

iv) whether different arrangements would raise risks to overall value for money.

We used a variety of techniques to address these study issues:

We assessed the current arrangements, firstly by identifying them by interviewing officials, reviewing regulations and undertaking a literature review. We then compared primary care procurement arrangements in Wales with those in other UK countries, and with secondary care arrangements. We identified the Assembly's powers through a review of legislation.

From our overall review, we identified risks that the Assembly could use its powers to address. These were principally primary care buying power being fractured by reliance on over a thousand individual contractors and the risk that the tariff used in Wales was not providing an appropriate level of reimbursement. We explored these risks further by modelling the use of centralised contracts and the use of a different tariff.

To explore the use of a different tariff, we examined the operation of the Scottish and Northern Irish tariffs. We checked for consistency of differences in price between the Scottish Drug Tariff and the England & Wales Drug Tariff over a period of two years. We examined the effect of the use of the Scottish Drug Tariff, in place of the England & Wales Drug Tariff, by applying the differences between the two tariff's prices to the top 500 items used by NHS Wales in 2001, by total cost, from Health Solutions Wales' prescription cost analysis 2001.

We modelled centralisation by applying the prices obtained by the All-Wales Drugs Contracting Committee for 2001 to the primary care prescription cost analysis. We subtracted the average Prescription Cost Analysis cost per item from the All Wales Drugs Contacting Committee price and multiplied this difference by the number of prescription items dispensed in 2001. In order to model centralisation for dispensing GPs, we performed the same operations on a Prescription Cost Analysis covering only dispensing GPs.

APPENDIX 2

Organisations consulted by the National Audit Office Wales

Public sector outside Wales

Department of Health

Department of Health, Social Services & Public Safety (Northern Ireland)

Information & Statistics Division, Common Services Agency, NHS Scotland

Scottish Executive Health Department

Industrial and professional

British Medical Association General Practitioner Council (Wales)

Community Pharmacy Wales

Dispensing Doctors' Association

The Royal Pharmaceutical Society of Great Britain (Welsh Executive)

Wales Industry Group (part of the Association of the British Pharmaceutical Industry)

Other

Celtic Dimensions

APPENDIX 3

Description of existing primary care medicine procurement arrangements

Price setting and agreements

1. The **Pharmaceutical Price Regulation Scheme** operates at the level of the individual company and controls the overall profits made by the company from its sales of branded medicines to the NHS. There is a common profit target, usually expressed as a return on capital employed of 21 per cent for assessing profits and 17 per cent for assessing price increase applications. If a company exceeds its target profit by 40 per cent, or more, it must repay the excess to the Department either as a lump sum or equivalent price reductions. Where a company's profit is 50 per cent or less of the return on capital target, it may apply for a price increase to take it to 80 per of the target. Companies may set the prices of new chemical entities on market entry in the UK, but thereafter must obtain the agreement of the Department of Health for any increase. Although the scheme is voluntary, all suppliers of branded medicines with NHS sales of more than £1 million are members, as are the majority of those with NHS sales of below £1 million

2. In the case of most generic medicines, pricing is left to market forces. However, since 1999, **the Maximum Price Scheme** has brought statutory price control to the prices of some 500 preparations of 150 medicines, which, by value, account for some 70 per cent of UK generic dispensing. Although only a minority of generic medicines are subject to the Maximum Price Scheme, any could be added if the Department deemed it necessary. The prices of medicines subject to the Maximum Price Scheme are based on historic average prices. The scheme prohibits the sale of certain unbranded generic medicines to community pharmacies and dispensing GPs at more than the maximum price.

3. The Prescription Pricing Authority prices generic medicines for both England and Wales. The Prescription Pricing Authority calculates the basic prices of the **Drug Tariff** using a weighted average of prices from the price lists of two major drug wholesalers and three major manufacturers.

Purchasing

4. The size and nature of contractors and their purchasing needs vary considerably, and the means by which they obtain their stock varies accordingly. At one end of the spectrum, vertically integrated chains are engaged in distribution as well as dispensing, and may even undertake some manufacturing. At the other end of the spectrum independent pharmacists buy their stock from a variety of wholesalers and directly from manufacturers. With the exception of a small number of items—certain vaccines and oxygen—the contracts between pharmacists and dispensing GPs, on the one hand, and health authorities, on the other, do not require pharmacists to obtain their supplies of medicines in any particular way, other than to obtain them from licensed manufacturers, wholesalers and other authorised suppliers, such as other pharmacists.

Reimbursing

5. As contractors themselves purchase the medicines that they dispense to NHS patients, NHS Wales, like the NHS in other parts of the UK, aims to reimburse their net acquisition costs. Health Solutions Wales (HSW), an NHS Wales organisation based in Velindre Trust, calculates reimbursements using the scripts that it receives from the contractor and the prices and discount rates in the Drugs Tariff. It passes this information on to the five health authorities who make the actual reimbursement payments.

6. To achieve **discount recovery,** the Department of Health periodically conducts a discount inquiry survey of a sample of contractors to set discount rates that are related to contractor size in terms of turnover. The aim of these discount enquiries is to make reimbursement payments reflect the discounts on list prices that pharmacists receive from their suppliers. From this it calculates discount rates, which are included in sections of the tariff document to enable HSW to calculate deductions from reimbursements. A similar scale is included in the GP contract for dispensing GPs. The scales vary with the month total of prices for each contractor, ranging from 6.51 to 13.10 per cent for community pharmacists and 3.70 to 11.18 per cent for dispensing GPs. For community pharmacists, certain items are excluded from discount recovery and are listed in a section of the tariff. HSW estimate the average recovery for contractors in Wales to be 10 per cent.

7. Pharmacists and dispensing GPs also receive fees beyond reimbursement. **Figure 12** summarises the structure of reimbursement fees for pharmacists and dispensing GPs.

Figure 12

Summary of the structures of reimbursement and professional fees for community pharmacists and dispensing GPs

Pharmacists	**Dispensing General Practitioners**
Net Ingredient Cost (NIC)*	Net Ingredient Cost (NIC)*
Deduction Scale (6.51 - 12.5%)	Discount Scale (3.70 - 11.18%)
Container Allowance (3.24 pence per prescription)	On-Cost (10.5%)
Professional Fees	Container Allowance
Additional Fees	Dispensing Fees
Out of Pocket expenses	Out of Pocket expenses

NOTE

* Net Ingredient Cost refers to the cost of drug before discounts, it does not include any dispensing costs or fees.

Source: Prescription Pricing Authority, Drug Tariff Guidance Notes 2002

APPENDIX 4

Initiatives to support improvements in prescribing behaviour

Local formularies, such as that produced by Rhondda Cynon Taff Local Health Group, provide a guide to preferred medicines, chosen on the basis of evidence of effectiveness, cost and local consensus. Some formularies, such as that developed by the Anglesey & Gwynedd Local Health Group, are joint formularies between primary and secondary care. These have the additional aim of improving co-ordination of therapy by encouraging continuity in the choice of medicines between primary and secondary care.

Prescribing advisers are advisers with pharmacy or pharmaceutical industry experience who visit GPs to provide information on good prescribing practice. They will, for example, aim to ensure that GPs are aware of newly available generic medicines.

Prescribing audit reports and catalogues, produced by Health Solutions Wales, provide information on prescribing costs and frequencies.

Prescribing incentive schemes aim to encourage economic prescribing by allowing practices to retain a proportion of savings in prescribing expenditure.

Prescribing indicators are intended to indicate the quality of GP's prescribing behaviour. Health Solutions Wales produce 32 such indicators, which range from overall indicators, such as overall generic rate, to drug specific indicators, such as the rate of Minocycline as a percentage of all tetracyclines. Not all GPs accept that these indicators are a true reflection of prescribing quality.

PRODIGY is a computerised prescribing and decision-support system for primary care. It allows GPs to generate prescriptions based on choices of scenario that represent patients' conditions. It incorporates information that is intended to allow the ready selection of the most appropriate and effective treatment.

The Welsh Medicines Resource Centre provides information on therapeutically effective prescribing through its publication programme, which includes learning packs for GPs.

APPENDIX 5

Generic substitution and the savings that could have resulted in 2001

We selected 23 branded drugs that we considered would be likely to be significant in terms of potential savings from generic substitution, as indicated by size of net ingredient cost in 2001 and by patent expiry. From the prescription cost analysis for 2001 produced by Health Solutions Wales, we compared the branded cost against the generic equivalent and calculated total savings using the number of prescriptions dispensed.

To ensure realistic modelling, we only included generics that were available in equivalent strength and pack size. To ensure clinical safety, we omitted items, such as Ciclosporin (Sandimmum) where the *British National Formulary (BNF44)* indicates that substitution is clinically inappropriate. We also omitted modified release preparations, working on the conservative assumption that substitution of these would be inappropriate for clinical reasons.

	BNF Chemical Name	Brand Name	NIC	Saving after discount
1.	Aciclovir	Zovirax	£358,906	£169,500
2.	Atenolol	Tenormin	£193,547	£149,333
3.	Beclometasone Dipropionate	AeroBec, Beclazone, Becloforte, Beconase, Becotide, Nasobec, Propaderm, Qvar	£2,911,015	£435,727
4.	Bezafibrate	Bezalip	£16,035	£546
5.	Bisoprolol Fumarate	Monocor	£110,807	£6,519
6.	Budesonide	Pulmicort	£789,376	£9,770
7.	Captopril	Acepril, Capoten, Kaplon, Tensopril	£29,055	£18,817
8.	Cefaclor	Distaclor	£64,702	£8,254
9.	Celiprolol Hydrochloride	Celectol	£134,473	£3,829
10.	Cephalexin	Ceporex	£9,636	£3,178
11.	Cholestyramine	Questran	£43,876	£3,265
12.	Cimetidine	Tagamet	£73,076	£48,073
13.	Co-Amoxiclav	Augmentin	£602,555	£11,0159
14.	Co-Tenidone	Atenix, Tenoret, Tenoretic	£336,917	£156,799
15.	Enalapril Maleate	Innovace	£352,814	£163,827
16.	Fenbufen	Lederfen	£52,865	£14,814
17.	Fluoxetine Hydrochloride	Prozac	£827,010	£447,599
18.	Ketoconazole	Nizoral	£163,780	£1,075
19.	Piroxicam	Feldene	£165,260	£20,061
20.	Ranitidine Hydrochloride	Zantac	£559,339	£296,579
21.	Terazosin Hydrochloride	Hytrin	£92,365	£3,555
22.	Tiaprofenic acid	Surgam	£2,767	£124
23.	Zopiclone	Zimovane	£352,657	£13,469
	Totals		**£8,242,833**	**£2,084,872**

GLOSSARY OF TERMS

All Wales Drugs Contracting Committee	A committee of NHS Trust representatives that negotiates supply contracts for all Trusts in Wales
Association of British Pharmaceutical Industry (ABPI)	A trade association representing manufacturers of branded medicines
Branded Medicine	A proprietary medicine product that is, or has been, covered by a patent providing exclusive manufacturing and marketing rights
British National Formulary	A publication that provides key information on the selection, prescribing, dispensing and administration of medicines. The basic information is drawn from product literature, medical and pharmaceutical literature, and regulatory and professional authorities. It is published under the authority of the Joint Formulary Committee, which consists of representatives of the British Medical Association, the Royal Pharmaceutical Society of Great Britain and the UK health departments
Community Pharmacy Wales	A committee representing the interests of community pharmacists in contractual negotiations
Discount inquiry	A survey of pharmacists to identify the level of discounts they receive in order to set discount recovery rates
Discount recovery	The method by which reimbursements paid to primary care medicines contractors are reduced to take account of discounts they have received
Dispensing Contractors	Pharmacists, Appliance Contractors and General Medical Practitioners providing pharmaceutical services under the National Health Service
Dispensing GPs	General Practitioners that are authorised to dispense medicines to patients who have difficulty in accessing a community pharmacy
Drug Tariff	A list of reimbursement prices for generic drugs and the scale of discount recovery reductions from pharmacists. The Department of Health and the National Assembly for Wales publish a Drug Tariff for England & Wales every month. The Scottish and Northern Irish health departments publish separate tariffs
Essential Small Pharmacy Scheme	A scheme that provides a minimum fee remuneration of £40,350 to pharmacies located at least one kilometre from the nearest pharmacy and dispensing fewer than 23,040 prescription items in the year (in 2001-2002)
Generic medicine	Drugs sold under non-propriety names. They may be manufactured and sold by any licensed manufacturer
Generic substitution	The selection of a chemically equivalent medicine in place of the original brand, either at the point of prescribing, or dispensing

National Service Frameworks (NSFs)	National Service Frameworks set national standards and define service models for a specific service or care group. They set out the appropriate medicines to use, based on an overall evaluation of cost-effectiveness
Net Ingredient Cost (NIC)	The cost of a medicine, or medicines, in terms of basic price before discounts. It does not include dispensing fees or costs
Local formulary	A list of medicines that have been agreed as suitable for use by a group of doctors and other health professionals for use in their area
Patient Packs	Medicines supplied for individual patients in the manufacturers' original packs, or in similar packs created by a pharmacy, as distinct from in traditional brown bottles and other similar containers
Pharmaceutical Price Regulation Scheme	A voluntary scheme, with statutory backing, agreed between the Department of Health and the Association of British Pharmaceutical Industry, that sets overall limits on the profit margins of manufacturers of branded medicines with respect to their NHS sales
Prescription Pricing Authority	A Special Health Authority responsible for pricing and checking prescriptions dispensed in England, for remunerating dispensing contractors in England, and other related functions, including the compilation of the Drug Tariff for England and Wales
Reimbursement	Payment to a pharmacist for the cost of drugs dispensed against NHS prescriptions. This comprises the list price of the drugs minus the discount recovery
Remuneration	All reimbursement, fees and allowances paid to pharmacies for dispensing NHS prescriptions and for other professional services

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