REPORT OF THE

AUDIT OFFICE

DEPARTMENT OF HEALTH: ADMINISTRATION OF THE PHARMACEUTICAL BENEFITS SCHEME

THE AUDIT OFFICE

OFFICE OF THE CONTROLLER AND AUDITOR-GENERAL,
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DEPARTMENT OF HEALTH: ADMINISTRATION OF THE PHARMACEUTICAL BENEFITS SCHEME

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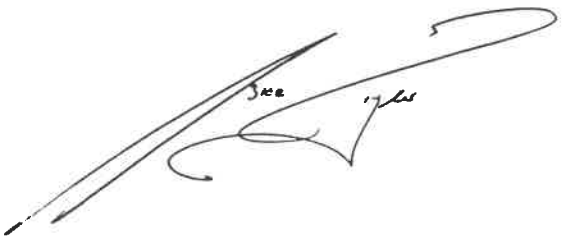
For the last four years, the Government has been spending over $500 million yearly in subsidising the cost of prescription medicines. This is clearly a major area of expenditure, and it is therefore appropriate to review how well the expenditure has been managed and the extent to which efforts are being made to keep it to a minimum.

I would like to acknowledge the work of my officers from the Major Projects Group, Pat Hoy and Darrin Goulding, who undertook the review and prepared the material for this report.

Readers of the report are invited to refer also to our separate report *Department of Health: Safety and Effectiveness of Medicines*, which is the result of an associated review.



B H C Tyler
Controller and Auditor-General

28 February 1992

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EXECUTIVE SUMMARY

The Department of Health has operated the Pharmaceutical Benefits Scheme (PBS) since its inception in 1941. The PBS is a scheme by which the Government subsidises the cost of medicines prescribed by doctors. In 1990–91, the PBS cost $545.3 million.

This report reviews the effectiveness and efficiency of actions taken by the Department to control the price of medicines and to manage the use of subsidised medicines.

Actions to Manage the Price of Medicines

The Department negotiates with pharmaceutical suppliers to determine the extent to which it will subsidise medicines.

Since 1988, the Department has adopted a much more rigorous approach to subsidy negotiations and has generally refused to consider raising subsidy levels. This has resulted in a fall in the price of prescription medicines and is in contrast to the trend in non-prescription medicine prices. The Department has no involvement in the pricing of non-prescription medicines, which have continued to rise in price.

However, significant opportunities have been missed to lower medicine subsidy levels. These opportunities have been lost through:

- Inappropriate application of negotiating policies; and
- Partial or incorrect implementation of recommendations of the Pharmacology and Therapeutics Advisory Committee. This is a committee that advises the Minister of Health and the Department on the suitability of new medicines for inclusion in the Drug Tariff. The Committee has a pivotal advisory role in the process by which the final level of subsidy is decided.

Shortcomings in the negotiation process have resulted in the Department losing opportunities to minimise PBS expenditure. The Department needs to review its procedures to remedy this situation.

The Audit Office reviewed the basis of the Department's proposal for parallel importing of lower-priced medicines from Australia. Many Australian medicines cost less than the same medicine in New Zealand, and this proposal was seen as a way of achieving large savings to the PBS. The basis of the proposal was deficient, as a result of which problems were encountered and no imports have been made after 2½ years.

The Department is also proposing to embark on an initiative to allow pharmacists to substitute, where appropriate, a generic medicine for the equivalent brand-name medicine when dispensing prescriptions. The Department expects that the initiative will

result in savings of PBS expenditure. To ensure that any benefits are secured by the PBS, the Department will need to adopt measures additional to those currently planned.

Controls on the Use of Subsidised Medicines

The increasing scale and scope of medicine usage has contributed to the rises in PBS expenditure. The Department has initiated a number of actions towards ensuring that there is appropriate use of medicines. These have included:

- Spending $23 million on a computerised prescription pricing system, one of the justifications for which was the management information that it would provide to assist in negotiating subsidies and monitoring prescribing patterns. However, except for the data supplied to the separate system mentioned below, the Department is not realising the benefits of the management information available to it.
- Funding, at a cost of $443,000, for a separate voluntary system that provides information to general practitioners on their pattern of prescribing subsidised medicines. A 1989 pilot study showed that providing such information improves the efficiency of prescribing with consequent reduction in PBS expenditure.

  The majority of general practitioners are not participating in the voluntary system. To ensure that there is appropriate prescribing by these general practitioners, the Department needs to utilise its prescription pricing system to monitor prescribing practices.
- Preparing treatment protocols. A treatment protocol is a guide to general practitioners, containing advice on how best to diagnose and treat a particular medical condition.

  Because there was concern with over-prescribing medicines for the treatment of hypertension (raised blood pressure), the Department set up a working party of health professionals to develop a treatment protocol on that subject. The protocol was completed and it was anticipated that the advice it contained would lead to both more appropriate use of hypertension medicines and savings in PBS expenditure.

  Although the protocol was completed two years ago, a series of implementation delays within the Department has meant that it has still not been distributed to general practitioners. However, a revised and updated protocol is still intended to be distributed.
- Maintaining rigorous control over the use of very expensive medicines. Without such controls, there is the potential for a significant increase in PBS expenditure. The Department nevertheless needs to re-examine the measures used to control the use of expensive medicines, as in one case the wrong measure has been used.

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BACKGROUND TO THE SCHEME

The Nature and Purpose of the Pharmaceutical Benefits Scheme

101 The Pharmaceutical Benefits Scheme (PBS) has been in existence since 1941. It is administered by the Department of Health (the Department) under section 99 of the Social Security Act 1964, and for the year ended 30 June 1991 the value of benefits paid was $545.3 million. The Department's administration costs are extra but they were not addressed in this audit.

102 The Minister of Health has the power under section 99 to determine:

- What pharmaceutical requirements by way of "medicines, drugs, appliances, and things" the Department will make payments for;
- The terms and conditions on which payments will be made; and
- The amounts paid.

103 Thus, at the discretion of the Minister, the whole or a part of the cost of prescribed pharmaceutical requirements is met by the State. When the whole cost is not met by the State, the difference may result in the patient having to pay a "part-charge".

104 In this report, the term "benefit" is used to refer to the payments made by the Department under the PBS, because that is the term used in the relevant legislation and the Government's Estimates of Expenditure. The Department commonly uses the alternative term "subsidy".

How the Scheme Works

105 Medicines and drugs approved by the Minister by way of general direction under section 99 constitute what is called the Drug Tariff (the Tariff). Currently, over 3,000 prescribable medicines are listed in the Tariff.

106 When a pharmaceutical supplier wishes to market a new medicine and believes the cost of supplying the medicine should be paid by the Department, an application is made to the Pharmacology and Therapeutics Advisory Committee (PTC). The PTC is a committee of medical practitioners that acts in an advisory capacity to the Minister. The PTC considers factors such as how useful will the medicine be and the extent to which its price should be subsidised. If the Minister accepts a PTC recommendation that a particular medicine will be useful and its supply should be paid for, the Department will

negotiate with the supplier over the extent to which the medicine will be subsidised (see Chapter 3).

Negotiations with Medicine Suppliers

107 If the PTC believes that the supplier's stated price for a medicine is too high in relation to its merits, the Department will negotiate with the supplier to have the price reduced to the level of benefit payment recommended by the PTC. If the supplier is not willing to lower the price, the medicine is not generally included in the Tariff. However, if the medicine is considered to be of real merit but over-priced, and the supplier is not willing to lower the price, the medicine may still be included in the Tariff, but with a part-charge to the patient.

108 For medicines already in the Tariff, suppliers will from time to time seek to increase the prices. This will also require negotiation, as the Department may not wish to consider raising the benefit payment to match the new price.

109 Prior to November 1986, when medicines were subject to price control, prices were set by the former Department of Trade and Industry (DTI). If a supplier wanted a price increase, it applied to the DTI, leaving the Department to decide only the amount of benefit payment.

110 In November 1986, medicines were removed from price control, so that the Department became responsible both for negotiations with suppliers over medicine prices and the determination of benefit amounts. The Department decided that it needed advice on how best to manage the PBS in this environment and it engaged the consulting firm of Coopers & Lybrand to make recommendations.

The 1987 Coopers & Lybrand Report

111 The Coopers & Lybrand report provided a detailed examination of all the issues associated with managing the PBS. On the question of negotiations with suppliers, Coopers & Lybrand observed that the Government is in a strong position as:

- New Zealand is a small market for medicines by world standards, but suppliers still wish to supply the market;
- The Government has the ability to set the rules in relation to the sale of medicines; and
- The Government is the major funder of medicines.

As is made clear in Chapter 3 on medicine price and benefit negotiations, the Department has made effective use of these strengths.

Subsequent Changes to Management of the Scheme

112 Following the Coopers & Lybrand report, in 1988 the Department informed suppliers of the management changes it had decided on. In summary, these were:

- The appointment of a chief negotiator and two pharmacists to negotiate the level of benefit to be paid in respect of each medicine;
- There would be an on-going review of all items in the Tariff to ensure that the prices/benefits remained reasonable and appropriate; and
- That, when considering whether a medicine would be included in the Tariff, or remain in the Tariff, the following criteria would apply:

  a The price of the medicine is considered justified and reasonable;

  b The supplier can maintain continuity of supply at the negotiated price for a reasonable period;

  c Prices will not be varied without sufficient time for negotiations to be held with the Department; and

  d If the outcome of such negotiations results in a price which is not acceptable for a 100% benefit, or in a part-charge that may inhibit patient use of the medicine, delisting from the Tariff may result.

The 1988 Audit Review

113 In 1988, the Audit Office carried out a preliminary review of the management of the PBS. The Audit Office action was prompted by the growing cost of benefit payments which had increased as follows:

- 1985-86 $346.3 million
- 1986-87 $439.6 million
- 1987-88 $506.7 million.

114 In view of the improvements which the Department was proposing to make to the management of the scheme, the Audit Office review was temporarily discontinued. The need to complete the review would be reconsidered once the Department had implemented the improvements.

Factors Behind the Growth of Benefit Payments

115 A 1988 study by the Department identified two main factors contributing to the annual growth in benefit payments. These were:

- Increases in the prices of medicines; and
- Increased use of medicines, particularly more-expensive medicines.

116 In resuming the audit of the management of the PBS, the Audit Office has paid particular attention to actions taken by the Department to constrain both the price of medicines and the use of medicines.

Structure of the Report

117 The remainder of this report is divided into four parts, as follows:

- *Chapter 2* examines how medicines are considered by the PTC for listing in the Tariff.
- *Chapters 3 to 5* examine the methods adopted or proposed by the Department to minimise the benefit paid on medicines. These include:
  - ★ Negotiations on benefit amounts (Chapter 3);
  - ★ Proposals for parallel importing of less expensive medicines (Chapter 4); and
  - ★ Generic substitution (Chapter 5).
- *Chapters 6 to 8* examine methods adopted or proposed by the Department to minimise the quantity of medicines used. These include:
  - ★ Providing information on individual prescribing practices to general practitioners (Chapter 6);
  - ★ Treatment protocols (Chapter 7); and
  - ★ Restrictions on expensive medicines (Chapter 8).
- *Chapter 9* examines the methods to restrain the costs associated with distributing medicines through pharmacies.

2

PHARMACOLOGY AND THERAPEUTICS ADVISORY COMMITTEE

Introduction

201 The case to have a medicine considered for inclusion in the Tariff is considered by the PTC. The PTC is chaired by a Department official and all members are medical practitioners. The main functions of the PTC are:

- Advice to the Minister on which medicines should be included in the Tariff;
- Regular reviews of the Tariff to ensure that it only contains those medicines that continue to be of use; and
- Advice on the kinds of information that should be provided to medical practitioners on the use of medicines listed in the Tariff.

202 The PTC usually meets three times a year, although provision exists for this to be adjusted where warranted by the workload. Administrative services for the PTC are provided by the Department.

203 Following each meeting, the PTC's recommendations are communicated to the Minister of Health for approval.

Requirements of Tariff Medicine Applications

Findings and Discussion

204 When applying for listing in the Tariff, applicants must provide information on:

- Comparative clinical studies of the medicine in relation to existing medicines and treatments; and
- Other comparative information, such as the advantages and disadvantages of the medicine in comparison to other similar medicines on the market.

205 Although approval of an application will have financial consequences for the PBS, applicants are not required to state whether use of their medicine will produce savings in other areas of health expenditure. For example, a medicine might be expensive, but could result in patients not requiring surgery.

206 Medicine suppliers sometimes provide cost/benefit studies. However, the studies use a variety of methodologies, ranging from an estimation of the cost

savings of a new medicine directly substituting for hospital care, to providing a valuation of benefits such as improvements in a patient's quality of life.

Conclusions

207 Applicants are required to give details of the medical need for a medicine. But there is no requirement to indicate whether use of a medicine is capable of generating other savings that might outweigh the cost of paying a benefit for the medicine. Consideration should be given by the PTC to imposing such a requirement.

Criteria for Assessing Tariff Medicine Applications

Background

208 Our analysis of the minutes of 15 PTC meetings over the period December 1986 to August 1991 showed that, of 209 applications for listing in the Tariff, 127 medicines were recommended for listing and 82 were recommended as not suitable for listing.

209 Listing new medicines in the Tariff can have a significant financial impact. At each meeting of the PTC between December 1986 and December 1989, recommendations were made which resulted in additional direct PBS expenditure of approximately $5 million per annum. That figure, however, does not allow for new Tariff medicines reducing the use of, and benefit payments on, other Tariff medicines.

210 In assessing applications, we expected that the PTC would have:

(i) considered whether the medicine is:
- needed; and
- reasonably priced; and

(ii) estimated its financial impact on the PBS.

Findings and Discussion

211 The need for a new medicine is determined partially on the basis of PTC members' personal judgements as medical practitioners and partially on the basis of reports provided by other medical practitioners who have been selected to contribute their experience with the medicine. PTC members we interviewed stated that the question of need for the medicine was relatively easy to determine.

212 We found that the main concern of the PTC was the cost at which a new medicine is to be reimbursed by the Department. Cost is determined by the appropriate "average daily cost" of a medicine.

> "Average daily cost" is the cost of the number of units of a medicine that is required to achieve the stated therapeutic effect (average daily dose) multiplied by the price per unit of the medicine. For example, the number

of tablets used per day by the average patient multiplied by the cost per tablet. The Department provides the PTC with the comparative average daily costs of medicines considered to be comparable with the medicine under consideration.

213 Our analysis of the PTC's recommendations for approval shows that 47% are on the condition that prices are reduced. A further 23% placed various restrictions on the use of the medicine in an attempt to limit the quantity of the medicine prescribed.

214 Of the recommendations against listing a medicine in the Tariff, 36% were on the basis that the medicines were too expensive. A further 26% were on the basis that they were not needed.

215 When a medicine is being considered by the PTC, the quantity of the medicine that will be used in practice is not precisely known. Hence, its impact on PBS expenditure is also unknown. Suppliers have not been required to define the expected usage of the medicine. If expected usage was defined, the Department could then monitor usage trends and submit to the PTC, for its reconsideration, any medicines where significant deviations from expectations were observed.

216 The PTC did not generally specify its usage expectations of new approved Tariff medicines. Only 1.5% of its listing recommendations were given on the basis that the usage would be monitored. One example when the PTC identified its usage expectations was where a new medicine was approved for listing in the Tariff in 1990 on the basis that it would compete with a number of similar existing medicines. This was expected to reduce total expenditure upon these medicines. The PTC also stated that it wished to be kept informed of expenditure changes arising from its recommendation. Our analysis of expenditure trends for a subsequent 12-month period shows that expenditure actually increased by $1.1 million (or 12.75%). Despite this significant deviation from expectations, the Department did not bring this to the PTC's attention for its reconsideration.

Conclusions

217 In deciding whether or not to recommend a medicine for listing in the Tariff, the PTC pays close attention to the level of benefit for a new medicine. However, as the PTC does not specify usage expectations of a newly approved Tariff medicine, there is no formal indicator to prompt review.

Review of the Tariff

Background

218 We expected that, given advances in medical knowledge and the increasing budgetary restraint upon the PBS expenditure, the PTC would periodically review the composition of the Tariff. This would ensure that the medicines

listed in the Tariff provided maximum benefit to patients and therefore the taxpayer.

Findings and Discussion

219 There have been two recent reviews of the Tariff. The first review, in October 1987, resulted in the removal of laxatives and antihistamines from the Tariff, following the Department's budgetary requirement to save $10 million. The PTC's advice was not sought and the measure was reversed in late-1988. The second review, in August 1990, resulted in the PTC approving the deletion from the Tariff of medicines which were considered to be "outdated" or "unavailable".

220 Neither of these reviews fundamentally challenged the appropriateness of the current composition of the Tariff. The medicines currently in the Tariff therefore hold their place on the basis of historical precedent. In contrast, the consideration of new medicines to be included in the Tariff is made in the context of a restricted budget, and, where such medicines are expensive (which is increasingly the case), their listing in the Tariff is either rejected or severely restricted (refer to Chapter 8).

Conclusions

221 There has been no effective review of the Tariff. This means that there is no assurance that the medicines for which benefits are being paid continue to represent the best use of taxpayers' funds.

The PTC's Education Function

Background

222 One of the terms of reference of the PTC is to promulgate therapeutic information relating to the appropriate utilisation of medicines. The PTC carries out this task by making recommendations on topics which should be discussed in the Department's newsletters to medical practitioners.

Findings and Discussion

223 The PTC made 16 recommendations in the period December 1986 to December 1990, of which 14 were made in the first two years of that four-year period. Of the 16 recommendations, 7 were not acted upon by the Department and the PTC was not provided with any explanation as to why. Furthermore, the item "Promulgation of Therapeutic Information", which was included as a

regular agenda item to remind members of this role, was deleted from the agendas for PTC meetings after December 1988.

Conclusion

224 Only partial use is being made of a valuable source of advice on the use of medicines.

Chapter Conclusions and Recommendations

225 The PTC has the function of recommending which medicines should be included in the Tariff. Recommendations from the PTC can therefore commit the Government to significant expenditure. The Department should periodically review the usage of medicines approved for listing to determine if usage exceeds the PTC's expectations in respect of particular medicines. Where significant deviations occur, the PTC should be asked to review the matter.

226 The PTC also needs progressively to review the medicines in the Tariff to ensure that they still represent effective use of public funds.

227 The Department needs to implement PTC recommendations on the best use of medicines, or at least to explain and justify to the PTC the reasons for not proceeding with recommendations.

3

MEDICINE PRICE AND BENEFIT NEGOTIATIONS

The Department's Negotiating Policies

Background

301 The Department is responsible for recommending to the Minister of Health the level of benefits for medicines listed in the Tariff. The Department's objective is to minimise the cost of benefits to the Government. To that end, the Department applies two important policies when negotiating with medicine suppliers.

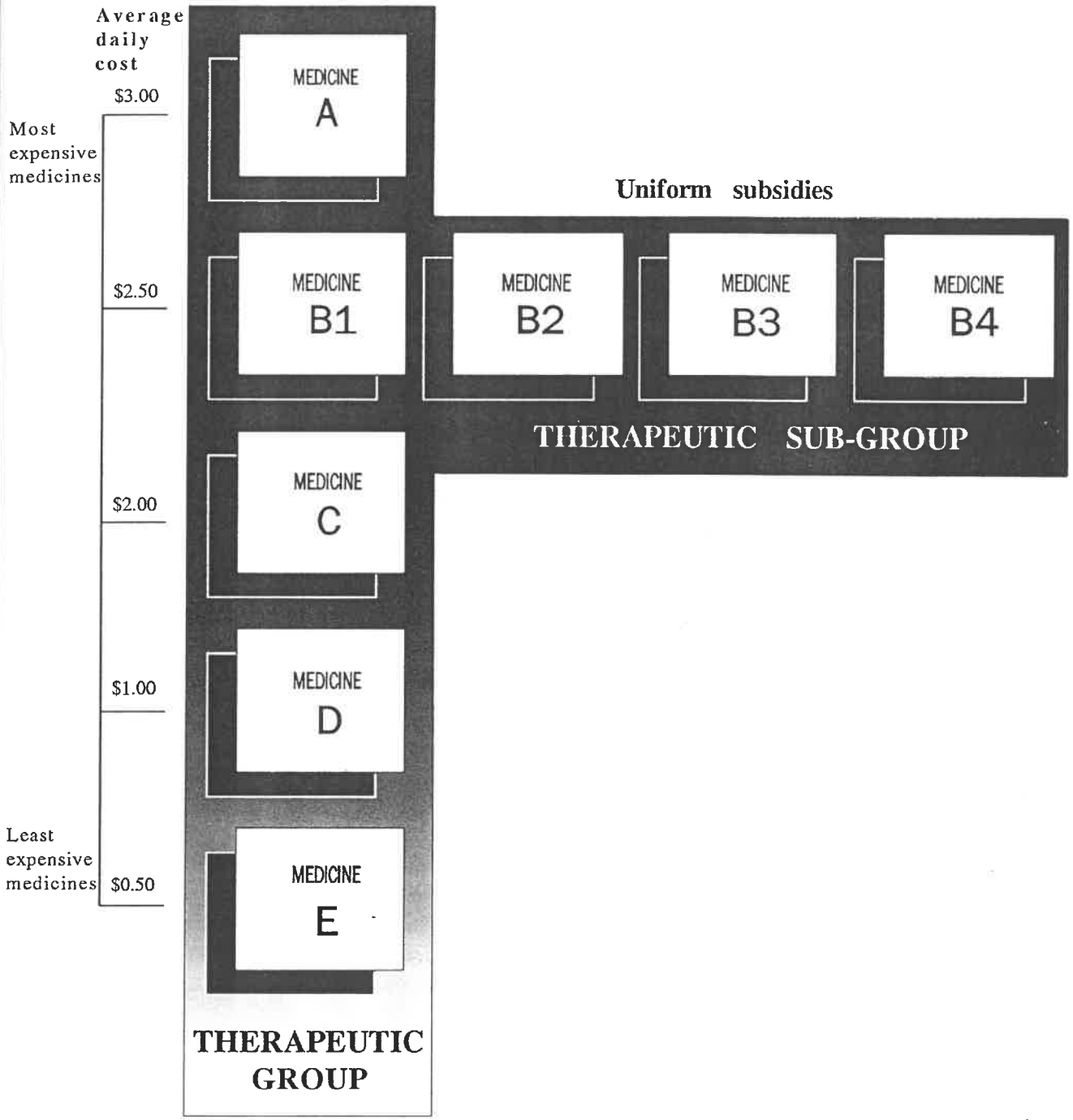
302 The policies are known as the "Therapeutic Group Pricing Policy" and the "Uniform Subsidy Policy". The Uniform Subsidy Policy is a sub-set of the Therapeutic Group Pricing Policy (see Figure 1). The policies are intended to maximise the competitive advantages of the Department when negotiating medicine benefits.

303 The Therapeutic Group Pricing Policy operates as follows:

- Medicines which are intended to treat the same disease or condition are grouped into "therapeutic groups". Within a therapeutic group, benefits are related to each other on the basis of perceived merit.
- The PTC may determine that one medicine is superior because it is more effective and has less side effects than other medicines in the therapeutic group. This is illustrated by Medicine A in Figure 1. In the case of the medicine judged to be more effective, the PTC may recommend that the benefit be the full price of the medicine, even if it is more expensive than other medicines in the group.
- Within each therapeutic group, there is thus a hierarchy of medicines, priced and subsidised according to their merit. This is shown in Figure 1, where the hierarchy ranges from Medicine A at $3.00 per day to Medicine E at $0.50 per day.

304 The Uniform Subsidy Policy operates as follows. Within each therapeutic group there may be sub-groups of medicines which are considered to be similar in their effectiveness and side effects. As a consequence, these medicines are considered to be interchangeable in the majority of patients. The Department pays benefits for such similar medicines at a "uniform level of subsidy", so that medicines B1 and B2 in Figure 1 are both subsidised at $2.50 per day. This level of benefit, within a newly recognised therapeutic sub-group, is determined by the lowest average daily cost medicine within the sub-group. This is also known as the "benchmark".

Figure 1. Therapeutic group policy and uniform subsidy policy.



Discussion and Findings

305 We expected the Department to have documented clear descriptions of its negotiating policies and the manner in which they were to be implemented. The Department had no such documentation and we had to piece together particulars of the policies from statements of the Department's officers contained in letters and Ministerial briefing notes, in order to arrive at the descriptions given.

Conclusions

306 The Department has not clearly documented its negotiating policies. Documentation is necessary to give assurance that the policies are:

- Sufficiently detailed to give the Department's officers comprehensive guidance as to the factors that should be considered when the policies are implemented. This would reduce the probability of error and/or unauthorised departure from the policies.
- Applied in a consistent and impartial manner to all medicine suppliers.
- Sufficiently transparent in their meaning and implementation so as to avoid misunderstandings developing between the Department and medicine suppliers.

Implementation of the Negotiating Policies

307 The policies are applied to the following four functions:

1 Considering medicine supplier requests for benefit increases;

2 Adjusting benefits within a therapeutic group in response to the entry into the group of a lower-cost generic medicine;

3 Identifying new therapeutic sub-groups and adjusting medicine benefits to that of the lowest-subsidised medicine in the new sub-group; and

4 Adjusting medicine benefit in response to PTC recommendations.

308 The Department's performance of these functions is discussed in the following sections of this chapter:

- *Function 1*—Considering whether to raise medicine benefits—paragraphs 309 to 319.
- *Functions 2 and 3*—Adjusting benefits within a therapeutic group or identifying new sub-groups—paragraphs 320 to 328.

- *Function 4*—Adjusting benefits in response to PTC recommendations—paragraphs 329 to 338.

Considering Whether to Raise Medicine Benefits

Background

309 When the supplier of a medicine in the Tariff wishes to raise the price of the medicine, it is obliged first to notify the Department. This is to allow the Department to decide if it will consider raising the benefit to the level of the proposed new price.

310 Refusal by the Department to consider meeting the full new cost of the medicine may mean that patients will bear a part-charge on the medicine. If there are alternative medicines available, the Department may refuse to consider a benefit increase on the basis that patients can be prescribed the cheaper alternatives. Where there are no alternative medicines available, the Department may agree to recommend that the Minister approve an increase in the benefit.

311 We expected the Department to assess all benefit increase requests against established criteria, and that the assessment would be documented and be subject to managerial review.

Discussion and Findings

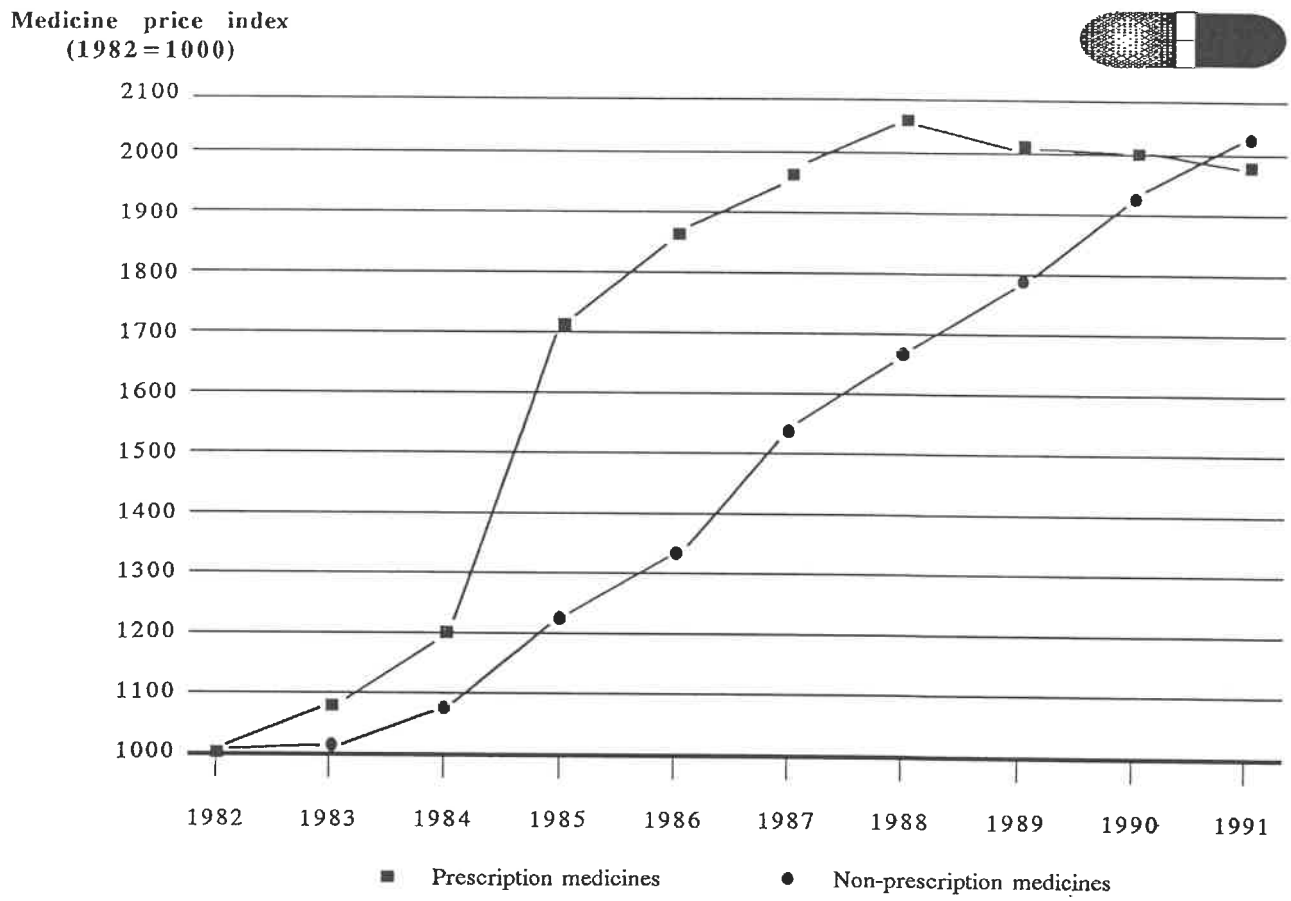
312 Over the last three years, the Department has generally refused to consider recommending requests for benefit increases. The basis for such refusals has usually been that the prices for alternative medicines within the therapeutic group concerned have not changed. As the amount of benefit is based on the relative merits of each medicine, an increase in the benefit for one medicine would distort the relativities.

313 The success of the Department in restraining the rate of price and benefit increases since 1988 is illustrated in the indexes of prices given in Figure 2. Those indexes are based on a sample of medicine prices and, accordingly, are only indicative of price movements.

314 Where medicine supplier requests for higher benefits have been approved, they have generally been for medicines that will have a small monetary effect on total benefit payments (i.e. usually less than $10,000 per annum). These are low volume medicines.

315 There have been occasions when benefit increases have resulted in a large impact on benefit expenditure (more than $10,000 per annum). There is a lack of documentation explaining the reasons for such decisions and neither is there any managerial review of these decisions against any established criteria.

Figure 2. Price changes, prescription and non-prescription medicines.



316 For example, in 1990, approval to increase the benefit for one medicine resulted in additional expenditure of $295,000 per annum. The application to raise the benefit was initially declined, but the decision was later reversed. The increase was approved despite the fact that:

- A 5% increase had been approved 10 months earlier;
- There was no exploration of whether there were alternatives available; and
- Two Ministerial advisory committees had earlier raised concerns regarding the expense, wastage and increasing incidence of abuse of the medicine.

317 In our view, it is unsatisfactory for such a decision costing the Government $295,000 per annum to be made with no rational explanation recorded.

Conclusions

318 The Department is in a dominant position when negotiating medicine benefits. It is virtually the sole agency subsidising the purchase of medicines and is in a powerful position to decline supplier requests to adjust benefits levels. The Department has made good use of this position to restrain increases in medicine subsidies.

319 There is poor documentation of decisions, and there is no managerial review of decisions that entail substantial additional benefit expenditure.

Adjusting Benefits—Therapeutic Groups and Sub-groups

Background

320 The Department has no central record of the benefit adjustments made and the reasons for them. Furthermore, the Department has no comprehensive record which identifies the historical relativities between medicines.

321 We audited those benefit adjustments which we were able to clearly identify from PTC minutes and the Department's supplier files. We were unable to establish whether these adjustments are a representative sample of the Department's negotiating activities. However, in our opinion, the findings from this sample are sufficiently significant to allow conclusions to be drawn.

322 We expected the Department to adjust medicine benefits in accordance with its negotiating policies.

Discussion and Findings

323 There were instances where the negotiating policies had been implemented inappropriately and in an untimely manner. As a consequence, the Department has forfeited opportunities to reduce PBS expenditure by the downward adjustment of benefits.

324 In one case, despite the Department explicitly recognising the potential to reduce benefits within a therapeutic group following the entry of a lower-priced generic medicine, no action was taken and the opportunity for an estimated reduction in PBS expenditure of $3.3 million per annum was lost. Furthermore, the Department's failure to act on this opportunity was, one month later, indirectly identified by the PTC. The PTC noted that there were considerable differences in the benefits for similar medicines and it requested that the therapeutic group in question be included on the agenda of its next meeting. Notwithstanding this explicit request, the Department failed to ensure that the matter was included on the agenda and it was therefore not reconsidered.

325 In another case, two medicines (for the purposes of this report, referred to as Medicine A and Medicine B) were deemed by the PTC to be equivalent. Medicine A's price was reduced by 17.5% due to the entry of a generic medicine. Despite the traditional parity of benefits for Medicines A and B, for approximately 10 months no effective action was taken to re-equate the benefits by also lowering the benefit for Medicine B. The Department had estimated the savings arising from such action would amount to $1,345,016 per annum. On this basis, the Department's delayed action resulted in a failure to achieve savings of $1,120,846.

326 In a further instance, the Department requested the PTC's advice on a particular therapeutic group's medicine benefits and whether one medicine within the group should continue to be restricted to subscribing by specialists. The PTC recommended that the Department seek the advice of a specific specialist on whether the medicines in the group where interchangeable. However, the Department sought the specialist's advice only on the necessity for the particular medicine's specialist restriction.

327 Prior to seeking the PTC's advice, the medicine supplier which distributed the lowest-subsidised medicine in this therapeutic group sought a benefit increase. Following the specialist's advice, the Department dealt with the benefit increase request by setting a uniform benefit for the therapeutic group. This uniform benefit level resulted in the subsidy for the initially lower-subsidised medicine increasing by 18% and the subsidy for the two other medicines decreasing by 31% and 26% respectively. Not only did the Department's action contradict the uniform subsidy policy by not setting the uniform benefit on the existing lowest-cost medicine, but the Department also had not explicitly sought advice on whether the medicines were interchangeable. If the uniform subsidy policy had been appropriately implemented, the ultimate saving would have been approximately $217,000 per annum. See Appendix I.

Conclusions

328 In the instances described, the Department has not consistently implemented its negotiating policies. As a consequence, significant savings in PBS expenditure have been forfeited.

Adjusting Benefits—PTC Recommendations

Background

329 Advice to the Minister of Health on what medicines should be listed in the Tariff is provided by the PTC. In addition, the PTC has the function of providing ongoing advice on the relative benefits paid for Tariff medicines. This advice can result in significant savings in PBS expenditure.

330 We reviewed the actions of the Department following PTC recommendations concerning adjustments to the benefits for medicines already in the Tariff. These were PTC recommendations that:

- Had been accepted by the Minister; and
- Were aimed at achieving savings on benefit payments for those therapeutic groups of major expense.

331 We expected all PTC recommendations to be fully implemented by the Department, or any exceptions to be communicated to the PTC.

Discussion and Findings

332 The Department did not always implement the PTC recommendations. In particular, there were instances where the Department ignored a recommendation, only partially implemented a recommendation, and, in one case, took action directly opposite to that recommended. Furthermore, the Department's negotiating policy was not followed.

333 The Department generally did not provide any feedback to the PTC on what it had done with the recommendations.

334 One consequence of the Department's actions is that significant ongoing potential savings for PBS expenditure have not been fully achieved. The three following examples illustrate the consequences of the Department's failure to follow PTC recommendations:

335 *Example One*

- A medicine from one supplier (Company A) is restricted to prescribing by specialists and its price was 52% greater than the medicine from another supplier (Company B) in the same therapeutic group.
- In response to Company B's request for a benefit increase, the Department's negotiator proposed an increase in the benefit for Company B's medicine by making it the uniform benefit and thereby significantly lowering the benefit for Company A's medicine.
- Company A complained in response to this proposal and the Department sought the advice of the PTC regarding the interchangeability of the two medicines.
- The PTC advised the Department that no benefit change should be implemented as the medicines concerned were not therapeutically interchangeable.
- Approximately four months later, the Department advised Company A that there would be no change in the relative level of benefits paid. However, on the same day, the Department informed Company B that the benefit for its medicine would increase by 29%.
- This action contradicted the Department's Therapeutic Group Pricing Policy, whereby benefits are set according to the therapeutic merit of medicines. We estimate that the benefit increase will cost the Government an additional $74,000 per annum.

336 *Example Two*

- The PTC determined that there was no clinical basis for a benefit differential between medicines in a particular therapeutic sub-group (i.e. there should be a uniform benefit). Nonetheless, the Department delayed equating the benefits within the sub-group for approximately two years after the PTC recommendation.
- The cost of allowing continuation of the benefit differential was approximately $2.5 million. Furthermore, following the entry of a generic medicine, the medicine upon which this benefit differential was based had its benefit reduced by 11.7%. The medicine with the higher benefit maintained its benefit at the previous level. This resulted in the benefit differential actually being allowed to increase from the historical level of 5% to 19%. The cost of this extra benefit differential was approximately $1.7 million. See Appendix II.

337 *Example Three*

- The PTC recommended that a significantly lower-priced new medicine within a therapeutic sub-group should serve as the benchmark for all other medicines within the sub-group. Although the Department initially considered benefit reductions, they did not eventuate.
- The following year, a further lower-priced new medicine was added to the sub-group. The PTC recommended that this new medicine should serve as the benchmark and that benefits across the group should be reduced.
- In response, the Department selectively made benefit decreases and also incorrectly applied the uniform subsidy policy. As a consequence, there was no uniformity in the levels of benefit in relation to the respective therapeutic effectiveness of the medicines.
- The Department's action achieved significant savings of approximately $5.7 million. However, the failure to fully implement the initial recommendation has to date cost the Government approximately $3.9 million. See Appendix III.

Conclusions

338 The Department has, without explanation, not fully implemented all PTC recommendations and has, as a consequence, forfeited significant savings in PBS expenditure.

PTC Meeting Arrangements

Background

339 The PTC meets three times each year. Meeting dates are determined in advance and there is provision for the committee to meet more regularly if its workload warrants.

340 We expected the Department's PTC secretariat to have prepared, given the Department's negotiating policies, an agenda which allowed a comprehensive and systematic review of all the major expenditure therapeutic groups. This would allow the PTC to identify all therapeutic sub-groups and recommend appropriate adjustments in subsidy levels.

Discussion and Findings

341 The PTC's function of reviewing benefits within therapeutic groups and sub-groups was reactive and constrained by the timetabling of its three meetings a year.

342 At the PTC's April 1991 meeting, the opportunity was identified to review the benefits for two related therapeutic sub-groups that amount to $62 million in PBS expenditure. The opportunity arose from the entry of new cheaper medicines, whose inclusion in the Tariff could potentially reduce benefits within the whole therapeutic group. A reduction of 5% in benefit levels in this therapeutic group is, in our opinion, plausible, based on limited previous PTC reviews, and would amount to savings of $3.1 million per annum.

343 Consideration of that benefit review was deferred until the next scheduled committee meeting four months later, at which time a decision was further delayed due to a lack of information.

344 Waiting for scheduled meetings to consider this matter has delayed reductions in benefits that could have saved $1.5 million over the period of the delay.

Conclusions

345 The PTC is an important source of advice upon the appropriate level of medicine benefits. Its advice, however, is sought in a reactive manner and is unnecessarily constrained by the timetabling of the committee meetings.

Pricing and Supply of Generic Medicines

Background

346 Generic medicines[1] regularly enter the medicines market. Generic medicine suppliers can offer significant price reductions relative to "brand-name" suppliers.

347 Before a supplier can sell a new generic medicine it must first obtain the Department's approval and registration for the new generic medicine. This regulatory process can take 12 to 24 months.

348 The entry of a lower-priced generic medicine allows the Department to lower the benefit for the initial brand-name medicine and other medicines within the relevant therapeutic group. The use of generic medicines can therefore result in

[1] See paragraph 501 for a description of a generic medicine.

considerable savings in PBS expenditure. One supplier has, since 1989, introduced five new generic medicines to the market at prices lower than the existing medicines. This has resulted in savings to the PBS of approximately $13 million per annum.

349 The Department can give higher priority to an application for medicine registration when a generic medicine supplier offers to reduce the final market price relative to the existing brand-name medicine, thus generating savings in benefit payments.

350 We expected the Department actively to identify generic medicine registrations and negotiate reductions in the generic medicine supplier's intended market price in return for priority consideration. We also expected the Department to confirm that a generic medicine supplier had sufficient stocks of medicine to ensure that it could meet market demands, which is a condition for a medicine being subsidised from the PBS. That confirmation would prevent predatory pricing behaviour by generic medicine suppliers, and would ultimately ensure that the supplier's price is one at which that supplier can sustain market supply.

Discussion and Findings

351 Giving priority consideration to the registration of generic medicines that offer significant price reductions can result in large cost savings. For example, in one case the Department estimated that savings of $600,000 per annum would be achieved.

352 The Department's decision to give priority consideration to a generic medicine registration is usually in response to a supplier's offer to reduce the medicine's price. The Department does not actively identify generic medicine registrations for priority consideration in return for the suppliers lowering the intended selling price. Furthermore, the Department does not negotiate with suppliers which make price reduction offers, in an attempt to seek further price reductions.

353 The Department has no power to prevent a generic medicine supplier distributing a copy of a brand-name medicine where the initial brand-name medicine is in the Tariff and its patent has expired. Other than giving priority consideration to medicine registrations, the Department has no discretionary powers to persuade generic medicine suppliers to lower their new medicine's intended price.

354 On one occasion, the Department had been rigorous in its efforts to ensure that a generic medicine supplier offering a significant price reduction had sufficient stocks to meet potential market demands. However, our review of the Department's files showed that it usually makes no attempt to determine a generic medicine supplier's stock levels. As a consequence, we found an example of a supplier offering a significant price reduction of 33%, and then, 18

days later, discontinuing supply. We found other examples of the same supplier being regularly out of stock of several generic medicines.

Conclusions

355 The Department has not maximised the possible financial advantages from prioritising generic medicine registrations.

356 The Department has not consistently ensured that generic medicine suppliers which offer price reductions have sufficient stocks to meet market demands.

Comparison of New Zealand Medicine Prices with Overseas Medicine Prices

Background

357 In 1988, the Audit Office undertook preliminary investigations into the Department's management of the PBS. One of the questions posed at that time was:

> "What does the Department do to ensure that pharmaceutical prices, on which subsidies are determined, are internationally competitive?"[2].

358 This question was raised because a review of the ten top selling medicines in New Zealand showed that the same medicines were selling in Australia at an average of 37% less than the New Zealand price.

359 We expected the Department, on a regular basis, to systematically compare New Zealand medicine prices with international medicine prices, particularly Australian prices.

Discussion and Findings

360 In 1988, the Department established a medicine subsidy negotiation unit. The unit, when it was first established, stated that it would begin paying increased attention to the comparative prices of medicines in overseas markets. That year, the benefit for a particular medicine was reduced on the basis that its price in the United Kingdom and Australia was considerably lower. But, since 1988, the Department has not systematically monitored international medicine prices and compared them to New Zealand prices.

361 We compared the Australian and New Zealand dispensed prices for comparable medicines, as at April 1991. The medicines chosen for this comparison were the 42 top selling New Zealand medicines plus 32 of their associated formulations (i.e. standard and long-acting tablets, capsules, suppositories, etc), all of which were also available under the Australian Pharmaceutical Benefits Scheme. These 74 medicines account for approximately 41% of medicine expenditure in New Zealand.

362 The New Zealand prices for 58 of these medicines were greater than for the same Australian medicines, with 27 medicines being over 50% more expensive in New Zealand than in Australia (range +50.15% to +178%). Sixteen New Zealand medicine prices were less than in Australia, with one of these being only 50% of the Australian price.

Conclusions

363 Although we are aware of some unique features of the Australian medicines market (for example, a Government research and development subsidy to

[2]Parliamentary Paper B.1 [Pt.II], *Report of the Controller and Auditor-General on the Public Accounts for the year ended 31 March 1988,* page 30.

manufacturers), we believe that the more extreme medicine price differences cannot be justified. The price differences should have been investigated by the Department and benefits appropriately adjusted.

PBS Management Information

Background

364 The Department has a computerised prescription pricing system, which became partially operational in November 1990 and has been fully operational since April 1991. This computer system is based at the Department's Wanganui Prescription Pricing Office. This office processes the prescription forms received from pharmacists and arranges payment of the benefits.

365 The Department expected the computer system to reduce prescription pricing administration costs. Expenditure on developing and implementing this system was also, in part, justified in terms of management information which the system would ultimately provide to the Department for price and benefit negotiations and monitoring of prescriber behaviour. The capital and operational cost of the computer system over five years was estimated to be $23.41 million. In 1990, the Department recognised that the Government's desire to contain PBS expenditure heightened the need to have timely access to quality management information, which the proposed computer system was expected to provide.

366 We expected the Department to have promptly instituted measures, such as adequate staff training for the medicine subsidy negotiating staff and procedures, to ensure that maximum advantage was derived from the management information generated by the new computer system.

Discussion and Findings

367 During the period of our audit fieldwork (July to August 1991), the management information available was not being fully and systematically utilised as intended. No strategy had been implemented to ensure that staff were fully trained and that maximum use of the information was achieved.

368 For instance, the determination of the respective average daily dose (ADD) of medicines is critical in determining the benefits for them. Collecting and monitoring ADD information is an important PBS management control because it enables comparison of the actual ADD with the ADD which was the basis for determining the benefit for a medicine at the time of including it in the Tariff. Where discrepancies are detected, this would allow the Department to adjust benefits accordingly. Prior to the implementation of the computer system, the Department would occasionally sample prescriptions over a period of five days to determine the ADD of medicines within particular therapeutic groups.

369 The Department should have been able to provide the sample ADD information to the PTC for its 1991 April and August meetings. However, this was not done.

370 We utilised the computer system to obtain information to calculate the ADD of a sample of medicines in the Tariff. In a sample of two therapeutic groups which we estimate will have a cumulative 1991-92 benefit expenditure of $41.5 million, we calculated the ADD for the medicines in each group.

371 We found that the ADDs were generally different from those utilised to determine medicine benefits by the Department and the PTC. The ADDs varied from −21.9% to +33.5%. This variation means that the basis upon which the PTC and the Department have determined benefits is now erroneous, with some medicines having a lower benefit than intended and others having a higher benefit than intended.

372 On the basis of the actual ADD, we calculated, for our sample of two therapeutic groups, the impact of medicine benefit adjustments, in order to restore the intended level of average daily cost for each of the medicines concerned. If the Department had acted promptly, it could have reduced net expenditure in the two therapeutic groups by an estimated $957,000 per annum.

Conclusion

373 The Department has not maximised the potential benefits of the management information generated by its computer system.

Chapter Conclusions

374 The purpose of the Department's price and benefit negotiations is to contribute to minimising the cost of the PBS. Since 1988, the Department has significantly reduced the rate of growth in benefit expenditure. This can be attributed to the Department's refusal to raise benefits and the partial transfer of PBS-related costs to the public by imposing a standard charge for every prescription dispensed.

375 The other means of restraining PBS expenditure is appropriate application of the Department's negotiating policies. The application of these policies has been variable. We have identified, from a limited sample, savings of approximately $13.5 million which could have accrued to the Government if negotiations had been effectively and efficiently managed within existing administrative resources.

376 The Department has failed to:

- Comprehensively specify its negotiating policies and ensure that they are complied with promptly and fully;
- Ensure that the PTC's recommendations are fully implemented and the committee's advice actively sought to identify cost-saving opportunities;

- Maintain adequate documentation of negotiation processes and outcomes to allow an effective managerial review of the negotiations;
- Maximise the benefits from its new prescription pricing computer system; and
- Follow up instances where there are significant price differences between the same New Zealand and Australian medicines.

377 We can give no assurance that the Department's subsidy negotiations are ensuring that the level of medicine benefits is being minimised.

4

PARALLEL IMPORTING

Introduction

401 This chapter reports on a major initiative by the Department to lower the price of medicines. The expected outcome was that up to $70 million per annum would be saved in medicine expenditure (see paragraphs 406–407). This would be achieved through the "parallel importation" of medicines from Australia.

402 Medicines in Australia generally sell at lower prices than in New Zealand[3]. The Department sought to take advantage of this situation by proposing to purchase medicines in Australia and selling them in New Zealand through medicine wholesalers. The imported medicines would undersell the same medicines on the New Zealand market and allow the benefits for them to be reduced.

403 In order to implement the scheme, an amendment to the Medicines Act 1981 was required. This was enacted on 31 July 1989. It was found necessary to make further legislative amendments in 1990. No medicines have yet been imported under this scheme.

404 Given the size of the expected savings from the proposal, we expected that it would be well researched and would accurately identify the medicines on the Australian market that offered opportunities for savings.

The Estimated Savings from Parallel Importation

Background

405 In 1988, research by the Department led it to believe that 38 leading brand-name medicines were selling on the Australian market at much lower prices than exactly the same medicines being sold in New Zealand. For example, an asthma medicine on sale in Australia for $NZ4.50 was being sold in New Zealand for $NZ8.24.

406 The Department estimated that direct savings of $37 million per annum of benefit payments were possible if it were to undertake parallel importing of such medicines. This estimate was arrived at by comparing the price of a number of lower-priced Australian brand-name medicines with the same medicines in New Zealand and multiplying this difference by the expected quantities to be used in New Zealand. Allowance was also made for importation costs, etc. It was recognised that parallel importation was only worthwhile for those medicines that were significantly cheaper in Australia

[3]See paragraphs 357–363.

than in New Zealand. The Department's analysis was on the basis that the largest price differences were in patent-protected medicines.

407 Further, "flow-on" savings were expected, although the Department acknowledged that it was hard to estimate the exact extent of such savings. Bringing lower-priced medicines into New Zealand would result in the benefits for other medicines being reduced as medicine suppliers lowered prices to compete with the imported medicines. This was estimated to raise total savings to $50 million per annum. It was further estimated that savings in the cost of hospital medicines would be $20 million, giving total savings of $70 million per annum.

408 Because of the estimated savings, in 1989 the Department advocated a reduction of $50 million per annum in Vote Health.

Discussion and Findings

409 The 38 medicines identified by the Department in fact were not all available in Australia. We identified at least four that were not. Importation of these four medicines had been estimated by the Department to save $2.3 million.

Conclusions

410 The Department identified a potentially significant opportunity for savings to PBS expenditure and felt able to recommend to the Government an overall reduction to Vote Health of $50 million per annum. However, the Audit Office questions the adequacy of the Department's research of the proposal. Some of the medicines intended to be purchased in Australia in fact were not available there and the possible direct savings were overstated by $2.3 million.

Mechanics of the Scheme

Background

411 The Department intended to purchase the medicines in Australia and re-sell them to New Zealand medicine wholesalers based on orders already placed with the Department. The proposal was to purchase annually $72 million worth of medicines, representing about one-fifth of the New Zealand prescription medicines market.

412 All the medicines were to be purchased from one of the largest Australian medicine wholesalers. Obtaining the medicines from such a large wholesaler would, in the Department's view, reduce the risk of Australian manufacturers refusing supply in order to avoid their medicines being onsold to New Zealand.

413 We expected that a trading proposal of this magnitude would be developed and documented so that all the parties involved would fully understand their obligations.

Discussion and Findings

414 No written agreements were entered into between the Department and the Australian medicine wholesaler. The Department said that the understandings between them were oral.

415 The Treasury, on three occasions prior to the planned implementation of the scheme on 31 July 1989, raised with the Department the issue of security of supply. However, we can find no record of the Department checking the supply arrangements with the Australian supplier until three days after parallel importation of medicines was made legal on 31 July 1989. This check revealed that the supplier's understanding was that the Department intended only to purchase medicines for one or two hospitals.

Conclusions

416 The Department was proposing to embark on a major purchasing operation on the basis of oral understandings. In our view, more formal arrangements should have been entered into between the Department and the Australian medicine wholesaler, so that both parties had a clear understanding of their obligations before any orders were placed. At the minimum, there should have been an exchange of letters.

The Consultative Process

Background

417 The Department's analysis of existing laws that could prevent the legal parallel importation of medicines pointed to the need to over-ride provisions in the Patents Act 1953, the Trade Marks Act 1953, and the Copyright Act 1962, and possibly other legislation, such as the Customs Act 1966 and the Commerce Act 1986. Section 32A of the Medicines Act 1981 was drafted so as to overcome restrictions in these or any other Acts of Parliament and was enacted on 31 July 1989.

418 Parallel importation is a practice of international concern. It raises issues relating to possible infringement of trademarks, copyright and patent rights. These rights are known collectively as "intellectual property rights". There are several international agreements to protect these rights. New Zealand is a signatory to those agreements.

419 Given the potential interest of other Government departments which administer laws and agreements relating to intellectual property rights, we

expected that, in formulating proposals on parallel importing, the Department would have consulted with those other departments.

Discussion and Findings

420 The Ministry of External Relations and Trade (MERT) had advised the Department in early-1989 of the sensitivities of the United States of America on intellectual property rights, the relevance of international conventions protecting intellectual property rights, and the possible implications for New Zealand legislation protecting intellectual property rights in pharmaceuticals. This advice was in connection with the Department's proposal on generic substitution. However, the Department did not consult the MERT on the parallel importation proposal prior to the 31 July 1989 implementation date.

421 There was consultation with the Treasury. The Treasury was concerned that the parallel importation proposal had a substantial risk of not proceeding. In particular, the Treasury questioned:

- Whether the Department would be able to obtain the necessary documents on the imported medicines to demonstrate safety;
- Why the sole Australian supplier identified by the Department should be willing to jeopardise its own supply of medicines in order to supply New Zealand; and
- Why the Department should be exempted from provisions of the Patents, Commerce and Copyright Acts.

422 Despite these concerns being expressed in several reports on the proposal, the Treasury supported parallel importation.

Conclusion

423 The Government was not sufficiently alerted to the international implications of parallel importation.

Current Situation

Background

424 The Government decided that section 32A of the Medicines Act had to be amended, and that other legislation needed amending in order to avoid the domestic and international implications created by section 32A. These changes were effected in late-July and early-August of 1990.

425 The effect of the amendments is to restrict parallel importation to brand-name medicines for which patent protection has expired and to generic medicines. Even so, the Department estimated that parallel importation of medicines from Australia could still save $40-$50 million per annum. To date, the Department has not parallel imported any medicines.

426 To avoid reliance on one supplier, the Department decided, in late-1989, to try and establish purchasing arrangements with a number of Australian wholesalers. In its advice to the Minister of Health in 1990, the Department said that it had located one further wholesaler willing to supply New Zealand.

Discussion and Findings

427 The Department has approached other Australian medicine wholesalers. However, it has not secured any written agreements as to supply arrangements.

428 In Australia, at least one medicine manufacturer has arranged a supply agreement between itself and medicine wholesalers which prohibits the onselling of medicines to other countries. It is thought that other medicine manufacturers have done likewise.

Chapter Conclusions and Recommendations

429 Given the differences in Australian and New Zealand medicine prices, parallel importation of legally-manufactured medicines offers the potential to exert downward pressure on New Zealand medicine prices. There are major areas of uncertainty as to how the parallel importing proposal would operate in practice, particularly in light of any international implications (including trade sensitivities).

430 We believe that, in any future negotiations to import medicines, the Department should obtain formal confirmation as to supply and availability of the medicines.

5

GENERIC SUBSTITUTION

Introduction

501 As discussed in the associated Audit Office report Department of Health: Medicine Safety, when a medicine is invented and patented, patent law prevents other medicine manufacturers from copying the medicine. When patent protection expires, and the medicine can be legitimately copied, the copied version is referred to as a "generic medicine". Usually, the generic medicine is initially offered for sale at a lower price than the original medicine, with the consequence that the price of the original medicine is reduced to the same level.

502 When a pharmacist dispenses a prescription, the medicine named by the doctor must be dispensed. Hence, even though there may be a less expensive generic version of a medicine available, if the more expensive medicine is specified in the prescription it must be dispensed.

503 The Department is proposing to seek amendment of the Medicines Regulations 1984 to allow substitution of less expensive generic medicines. This proposal is known as "generic substitution".

504 Because the brand of medicine named by the doctor is the brand that must be dispensed, doctors are seen as the "gatekeepers" in determining the quantities of which brand of medicine is sold. For this reason, doctors have been targeted by medicine suppliers to prescribe their brands.

505 With generic substitution, the nature of the pharmaceutical market would change. The pharmacist would decide which brand of a medicine is to be dispensed and would thus become the "gatekeeper" to increased sales rather than the doctor.

506 In preparation for generic substitution, the Department has arranged a thorough programme of reassessing the registration files for generic medicines to ensure that they are equivalent to the medicines for which they may be substituted.

507 We expected that the benefits of such a scheme would be clearly identified and that the Department would have specified the mechanisms necessary to ensure that the potential benefits were realised.

Discussion and Findings

508 In July 1991, only 118 original medicines, out of over 3,000 medicines in the Tariff, were sold at a higher price than the equivalent generic medicines. This means that most original medicines sell at the same price as the generic

medicine. On the basis of current price differences, there would be only limited opportunities for pharmacists to substitute a cheaper generic medicine.

509 The Department estimates that savings to PBS expenditure from generic substitution could amount to $25 million per annum, but it has not been able to provide us with a comprehensive analysis to support its estimate.

510 The assumption underpinning the estimated cost savings is that, when generic substitution is allowed, generic medicine suppliers will be willing to lower prices in the expectation that their medicines would sell in greater quantities. Hence, any initial losses by a generic supplier from lower prices would be more than recovered from increased sales. If prices are lowered, the Department would also lower the benefit for all related medicines with consequential savings on benefit payments.

511 We have seen no evidence to indicate that generic medicine suppliers will necessarily lower prices. Indeed, since prescription medicines are in the main paid for by the Government, there is little incentive for either suppliers or pharmacists to be concerned with prices, except as between themselves. Ways other than reducing prices are open to suppliers seeking to actively maintain or increase market share. For example, a supplier may discount the purchase price of a medicine to pharmacists by offering "three for the price of two", an effective 33% discount on the unit price recognised by the Department and on which the benefit is based. With the pharmacist in the position of "gatekeeper" to increased sales, such inducements are likely to be influential in the choice of generic substitute. But they will not contribute to a reduction in PBS expenditure, because the Government is precluded from sharing in the financial gain from them.

512 The generic substitution scheme proposed is in advance of many other countries. For example, EEC countries do not have generic substitution. As mentioned in paragraph 420, there are some concerns about the scheme possibly breaching intellectual property rights. While these concerns may be overstated, the Department will need to ensure that there is complete consultation with other interested Government departments. This is to ensure that the Government is fully advised of any possible trade repercussions that might arise from generic substitution.

Chapter Conclusions and Recommendations

513 Generic substitution has the potential to reduce the cost of the PBS. But savings will arise only if prices are reduced and benefits are commensurately reduced. Given the possibility that pharmaceutical suppliers may act to increase their market share by means other than reducing prices, the Department needs to ensure that generic substitution procedures take account of this.

6

PRESCRIBING BY GENERAL PRACTITIONERS

Introduction

601 In this chapter, we discuss what the Department has done to ensure that there is cost-effective prescribing of PBS medicines. This has taken the form of providing information to General Practitioners (GPs), who prescribe the bulk of PBS medicines, on their patterns of prescribing.

602 GPs prescribe medicines that they consider the most appropriate to treat a patient's condition. No review is carried out as to the appropriateness of individual practitioners' patterns of prescribing, such as whether a particular medicine is being over-or under-prescribed.

603 In 1990, the New Zealand Medical Association and the College of General Practitioners submitted a proposal to the Minister of Health to fund the operation of a "New Zealand Preferred Medicines Centre" (PreMec). Funding of $443,000 was approved for 1991–92. PreMec has a staff of four and works under the overall direction of an advisory group of senior medical practitioners.

604 PreMec aims to provide GPs with independent information on the safety and efficacy of medicines, and advice on their prescribing patterns and cost-effective prescribing. In essence, it is a quality assurance programme to assist GPs with their prescribing decisions. PreMec has invited GPs to register for use of its services. Registration is voluntary and free to GPs.

605 GPs registering with PreMec can have the prescriptions which they have written analysed to provide details of their most prescribed medicines and the cost of their prescribing. They can also obtain information which compares their pattern of prescribing with that of other GPs registered with PreMec. Such comparison is seen as useful because it allows GPs to reach a consensus on the "preferred" medicines to be used to treat the more common medical conditions. The development of preferred medicine lists is seen as providing GPs with reliable and independent information to assist their prescribing.

606 A scheme to provide GPs with information on their prescribing, comparison with colleagues, and development of preferred lists was tested in the Nelson area during 1989. The outcome was a 5% reduction in the cost of medicines prescribed. The study also showed a wide variation in the cost of prescribing among GPs. Over a one-month period, this cost ranged from $1,200 to $24,000, with the average being $11,000 per GP.

607 Given the variations in prescribing patterns, we expected the Department to ensure that there would be analysis of the prescribing patterns of all GPs.

The PreMec Contract with the Department

Discussion and Findings

608 PreMec's contract with the Department requires it to have, by 30 June 1992, 400 GPs registering their interest in the service. By the same date, PreMec is required to have produced 250 individual GP prescription analysis reports and to have developed four local preferred medicines lists.

609 GPs were first invited to register for PreMec services in August 1991, and 700 have now done so.

610 Voluntary registration is consistent with the PreMec philosophy that improved practices are best developed through discussion and consensus. GPs are told that the Department cannot have access to PreMec information either to take disciplinary action or to coerce them in any way. This is to provide assurance that no action by the Department will follow any analysis of prescribing.

Data for Prescription Analysis

Discussion and Findings

611 All data for the prescription analysis by PreMec is provided by the Department's Prescription Pricing Office at Wanganui. The Pricing Office collates the prescription data over a 3-month period and provides it to PreMec on a computer disc. PreMec re-arranges the data into a report format to be provided to each GP.

612 The Pricing Office already has the computing capacity to provide analytical and reporting services on prescribing practices for all GPs. The ability to analyse and provide a reporting service was one of the reasons for the Department deciding to spend $23.41 million, over a five-year period, on a computerised prescription pricing system. The system has the capacity to extract and provide in report form details of the pattern of prescribing, such as most frequently prescribed medicine, total cost of a practitioner's prescribing, and average cost of a prescription. This information can be provided for every medical practitioner prescribing PBS medicines.

613 There are approximately 2,600 GPs. The resource cost for the Pricing Office to collect prescription data for all GPs is approximately $210,000 per annum. No

estimate of the cost of also analysing this data and presenting it in report form has been made.

Conclusions

614 The Department has the ability, with the provision of extra resources, to analyse the prescribing patterns for all GPs. Such analysis is not being carried out.

615 The decision was made to establish PreMec on the basis that GPs choose whether or not to register with PreMec, and that the Department would provide PreMec with prescription data. The voluntary nature of PreMec, and the information it provides to GPs, has been shown to reduce PBS expenditure. While none of the prescription analysis carried out by PreMec cannot be performed by the Department, the demonstrated interest in PreMec indicates that medical practitioners trust and accept PreMec services.

Prescribing Information for Other General Practitioners

Discussion and Findings

616 There can be large variations in the patterns of prescribing. The study referred to in paragraph 606 demonstrated a cost of prescribing that ranged from $1,200 to $24,000 per month.

617 There are approximately 1,900 GPs not enrolled with PreMec. The Department has no assurance that there is no inappropriate prescribing of PBS medicines by these GPs.

Chapter Conclusions and Recommendations

618 The Department needs to be satisfied that there is no wasteful prescribing of PBS medicines. The Department should therefore analyse patterns of prescribing for those GPs not registered with PreMec, and should consult with those GPs whose pattern of prescribing is considered to be inappropriate in comparison to other GPs.

7

TREATMENT PROTOCOLS

Introduction

701 A treatment protocol is a document aimed at advising medical practitioners on how to diagnose a particular medical condition and suggesting appropriate methods of treatment. Not all treatment methods necessarily involve the use of medicines. Protocols may be developed to provide advice to all practitioners or to selected groups of practitioners.

702 This chapter deals with a major initiative by the Department to provide a national treatment protocol on hypertension. Development of this treatment protocol was to serve as a model for similar protocols for other conditions, such as asthma.

703 It has been estimated that about 180,000 people receive regular medication for hypertension (raised blood pressure). The cost of benefits for these medicines is currently about $98 million per annum. One estimate quoted by the Department of possible savings in benefit payments from improved prescribing for hypertension was $30 million per annum.

704 There is no general agreement that prescribing medicines for patients with mild hypertension is the most effective treatment. There is concern that many patients with hypertension are treated unnecessarily with expensive medicines when cheaper alternatives are available.

The Treatment Protocol on Hypertension

Discussion and Findings

705 In 1988, the Department convened a group of health professionals to draft a treatment protocol for hypertension. The first meeting of the group was held in October that year. The group completed its work and delivered a report and the draft protocol to the Department in December 1989.

706 The report recognised that the medical profession has a duty to keep the costs of anti-hypertension treatment as low as possible, subject to the requirements of good clinical care. Recommendations in the report reflect that recognition.

707 For example, the report recommended that, if raised blood pressure is confirmed, lifestyle factors which influence blood pressure should first be identified and modified. The report suggested that this is usually a matter of dealing with conditions of overweight, high alcohol intake, too little exercise, and smoking. If blood pressure remains elevated, treatment with medicines is then recommended. Less expensive medicines were recommended as the first

stage in treatment, with more expensive medicines recommended for use in certain defined situations. The report also recognised that this is an area of rapid change and suggested that the Department should review recommendations in the report within two years.

Action by the Department

Discussion and Findings

708 It was our expectation that, having set up the group, the Department would quickly distribute the report to GPs once it was received. However, when the report was received by the Department, no action was taken to pass it on.

709 The only immediate taken by the Department was to issue press statements that inaccurately described the contents of the report. As a result, the Department was reported as stating that the treatment protocol would mean that GPs would be encouraged to wean established patients off blood pressure medicines where appropriate, and that this process would involve full consultation with patients. It was also reported that about 60,000 patients would be taken off blood pressure medication, and that "People who have been on drug medication for long periods become wedded to it. They may require extensive counselling to be convinced that they do not need that safety blanket".

710 These reported comments caused concern among members of the group, as it seemed that the Department had drastically altered the report's recommendations without their consent or knowledge. The group had advocated a gradual approach but assumed from the reported comments that the Department had changed the report to recommend that medication for tens of thousands of patients should be stopped.

711 On the other hand, the concern expressed by group members was interpreted by the Department to mean that there was disagreement between members over the contents of their report. The Department therefore felt that, before the report could go any further, it had to be sure that all members would put their names to the report.

712 Group members were accordingly approached to confirm their agreement with the draft report. One member suggested small changes to two paragraphs of the report which were agreed to by the other members.

713 The Department then could not decide whether to have the full report or just a shortened version published in the New Zealand Medical Journal. Parts of the report were by now becoming obsolete and in early-1991 the report was again discussed with the original group members. Amendments to update the report were agreed on.

714 In July 1991, the Department decided to refer the amended report to PreMec, the intention being that the report would be distributed directly to all GPs by

PreMec, with the Department paying for the publishing costs. That has not yet been done, but it is intended to distribute a revised and updated protocol.

Chapter Conclusions and Recommendations

715 The Department believed that providing guidance to doctors on more appropriate diagnosis and treatment for hypertension would benefit patients and reduce PBS expenditure. Setting up a group to draw up a treatment protocol for hypertension was an important initiative by the Department.

717 It is now two years since the Department received the treatment protocol report and it has still not been made available to medical practitioners. Given the potential savings from providing better information to practitioners, action should now be taken to distribute an updated protocol.

718 If the Department is to proceed with the development of further treatment protocols, it should develop a strategy for ensuring that completed protocols can be quickly distributed.

8

EXPENDITURE ON MEDICINES IN SPECIAL CASES

Introduction

801 There are cases where a medical practitioner believes that a patient would benefit from a medicine that is not in the Tariff, and is therefore not ordinarily eligible for a benefit, but which should be prescribed at no cost to the patient. In such cases, special application must be made to the Department.

802 If the application is approved, the arrangement is the subject of a special direction by the Minister under section 99 of the Social Security Act, and the patient is then able to obtain the medicine from a public hospital pharmacy. The hospital is fully reimbursed by the Department for the cost of the medicine.

803 The medicines involved in these special cases are usually those considered by the Department to be very expensive. Issuing the medicines through hospital pharmacies enables the Department to both set and monitor appropriate conditions on the use of the medicine.

804 The Department is concerned at the cost of these special case medicines. Expenditure on them was $10 million in 1990-91. The Department has stated that the average cost of a special case prescription is $547, whereas the average cost of Tariff medicine prescriptions is $30.

805 We expected that, in the case of medicines likely to be expensive to use, the Department would have in place measures to control their price and quantity. This expectation was tested in relation to two medicines identified by the Department as being very expensive.

Measures to Manage Prices

Discussion and Findings

806 Because medicines that are the subject of special case applications are requested by medical practitioners and supplied by hospital pharmacies, the Department is only able to consider the merits of each case on the basis of whether it is prepared to recommend to the Minister that the full cost of the medicine be met, whatever that cost might be. The Department has no control over the price of the medicines since it has no dealings with the commercial suppliers.

807 In June 1991, the Minister of Health approved a Department proposal that expensive medicines currently obtained under a special direction should be

included in the Tariff. A new "written approval only" category was created in the Tariff for these medicines, and medical practitioners would continue to apply to the Department for approval. However, creation of the new category enables the Department to exercise its negotiating powers over the price of the medicines and therefore influence the amount of the benefit payable.

Measures to Manage Quantities

Discussion and Findings

808 We audited the Department's actions in managing the expenditure of two particularly expensive medicines subject to "special direction".

809 In 1989, an application was made to list a cholesterol-lowering medicine in the Tariff. However, the Department estimated in January 1990 that this expensive medicine (with an average prescription cost of $240) would be widely used and expenditure could be up to $150-$200 million per annum. The PTC recommended that the medicine be the subject of special direction by the Minister. Conditions as to the use of the medicine were imposed, such as specifying the minimum cholesterol level at which treatment can start. The Department estimated that, even with these restrictions, use of the medicine would cost $25 million per annum. Based on the Department's prescription records, our estimate of expenditure is that use of the medicine will cost $2 million per annum.

810 Another expensive medicine (with an average prescription cost of $1,215) was approved, in late-1990, as a special direction medicine. This was a medicine used in the treatment of patients with kidney failure and who were anaemic. Use of this medicine avoids the need for the patients to have a regular blood transfusion. The Department's estimate for expenditure on this medicine, even with the controls placed on its use to qualify for benefit, was $10 million per annum. Our estimate of the expenditure on this medicine is $700,000 per annum.

811 Various controls were placed on the use of this medicine. For example, it would be restricted to patients who suffered severe reactions from having a blood transfusion. Further steps to control usage were also taken. The Department tracks the number of approvals issued and, when the number exceeds the number of patients which the Department estimates should be using the medicine, it stops approval of any new applications.

812 However, the Department is using the wrong measure of use. The number of approvals in this case far exceeded the number of patients actually using the medicine, because some patients no longer required the medicine and were

therefore not using it. Instead, the Department should be tracking usage through the Prescription Pricing Office to determine if there is over-use.

Chapter Conclusions and Recommendations

813 The decision to list some expensive new medicines in the Tariff, and to retain the same conditions as to their use, will allow their prices to be negotiated.

814 The Department has been rigorous in controlling the use of expensive medicines. However, it needs to review its methods of controlling the usage of special direction medicines to ensure that, when it refuses new applications, the decision is based on correct usage information. Otherwise, patients will unnecessarily be deprived of the medicine they need.

9

FEES PAID TO PHARMACISTS

Introduction

901 Patients collect the medicine prescribed by their medical practitioners from retail pharmacies. In recognition of the professional services provided in dispensing the medicines, pharmacists are paid a fee for each prescription they dispense. The dispensing fee paid depends upon the type of prescription dispensed.

902 Pharmacists are also paid a nominal "mark-up" of 15% on the cost of the medicine ingredients that are dispensed. This is in recognition of the costs incurred in stocking medicines.

903 It was our expectation that the Department would seek to minimise these distribution costs.

Pharmacist's Professional Fee

Background

904 The current basis for determining the professional fee was approved by the Government in 1979. The Government also decided that annual adjustments would be made to the professional fee based on:

- 70% of the fee being indexed according to a formula that uses the Consumer Price Index and average ordinary hourly rates of pay in the private sector; and
- The remaining portion being subject to negotiation, taking into account factors such as the cost of stock holding and changes in the earnings of other professional groups.

Discussion and Findings

905 There are eight rates of dispensing fee, ranging from $2.43 to $33.61 per prescription. A prescription that involves "compounding" a medicine (i.e. mixing several ingredients together) attracts a higher fee, because of the work involved compared with dispensing a pre-packaged medicine. The average dispensing fee per prescription is $2.70, reflecting the preponderance of prescriptions for pre-packaged medicines.

906 In 1990, the Department suggested establishing a working party with the Pharmacy Guild to define the services that pharmacies can provide for the Government and the cost of provision. The Guild has argued that the present

scale of fees does not adequately recognise the expert advice that pharmacists provide to patients about medicines.

Conclusions

907 The proposed working party should be set up and should in particular define what exactly the Government is paying for when it pays a professional fee for each prescription. A review of this nature will allow the Department to advise the Government whether the basis for determining fees continues to be appropriate.

Mark-up on Medicines

Background

908 In 1970, the pharmacists' nominal mark-up on medicines was reduced from 50% to 20%. In 1979, the mark-up was further reduced to 15%. When purchasing medicines from wholesalers, pharmacists may receive a discount on the price agreed with the Department. The probable average level of discount was assessed by the Department in 1979 as 6.47%, and it reduces the nominal mark-up paid by half of the assessed average discount. This is intended to allow the Department to share the financial benefit gained by pharmacists from discounts. The effective mark-up on medicines is therefore 11.28%. The value of the deductions can amount to $12 million per annum.

Discussion and Findings

909 A mark-up of 11.28% is modest in comparison to some other countries. For example, a survey of seven EEC countries showed an average mark-up on medicines of 30%.

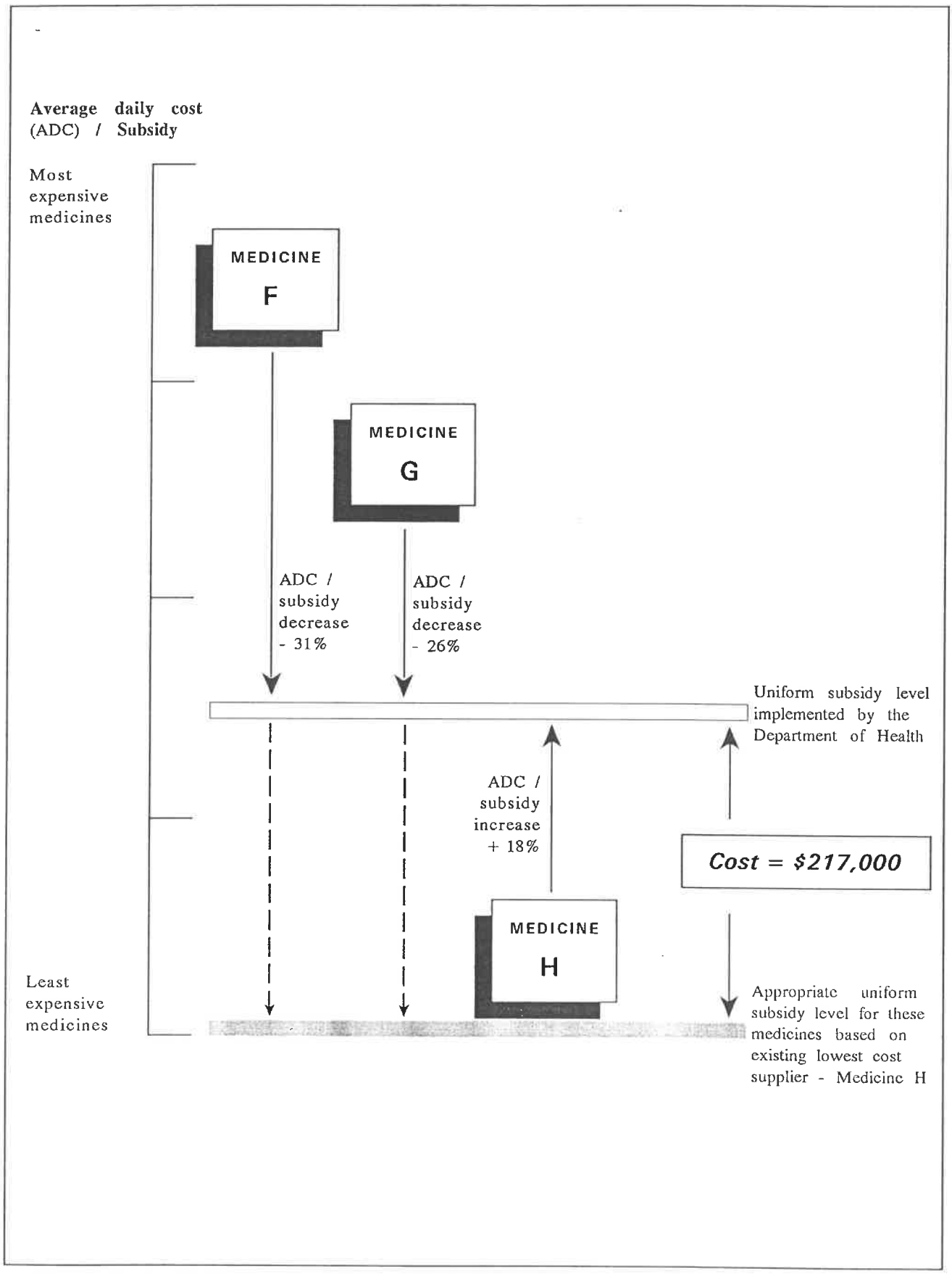
910 The Department believes that discounts greater than 6.47% are being received by pharmacists. For example, the Department has details of one medicine company offering discounts of 30%. In 1989, the Department commissioned an independent study to examine in detail the discounts received by pharmacists. However, the consultants could come to no firm conclusions on the average level of discount received as some of the major companies would not participate in the study. No further action was taken by the Department to ascertain the level of discounting.

Chapter Conclusions and Recommendations

911 In our view, the Department's efforts in negotiating the mark-up on medicines have been effective and have resulted in minimising the amount being paid. However, there is a continuing need for the Department to identify and review the level of discounts received by pharmacists. This is because there are indications that the level of discounting is significantly greater than is currently recognised by the Department.

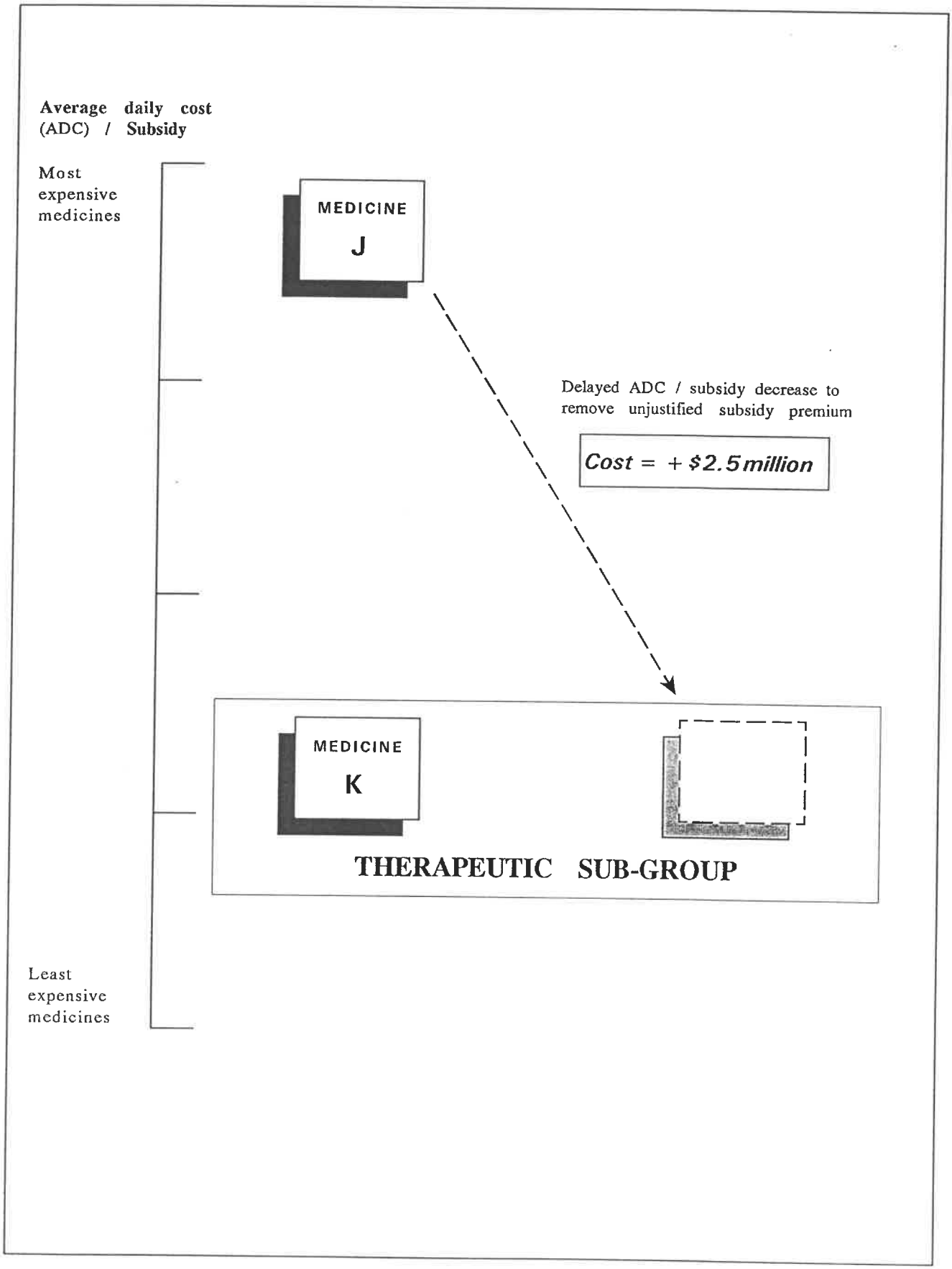
APPENDIX I

(Incorrect determination of uniform subsidy level - paragraph 327)



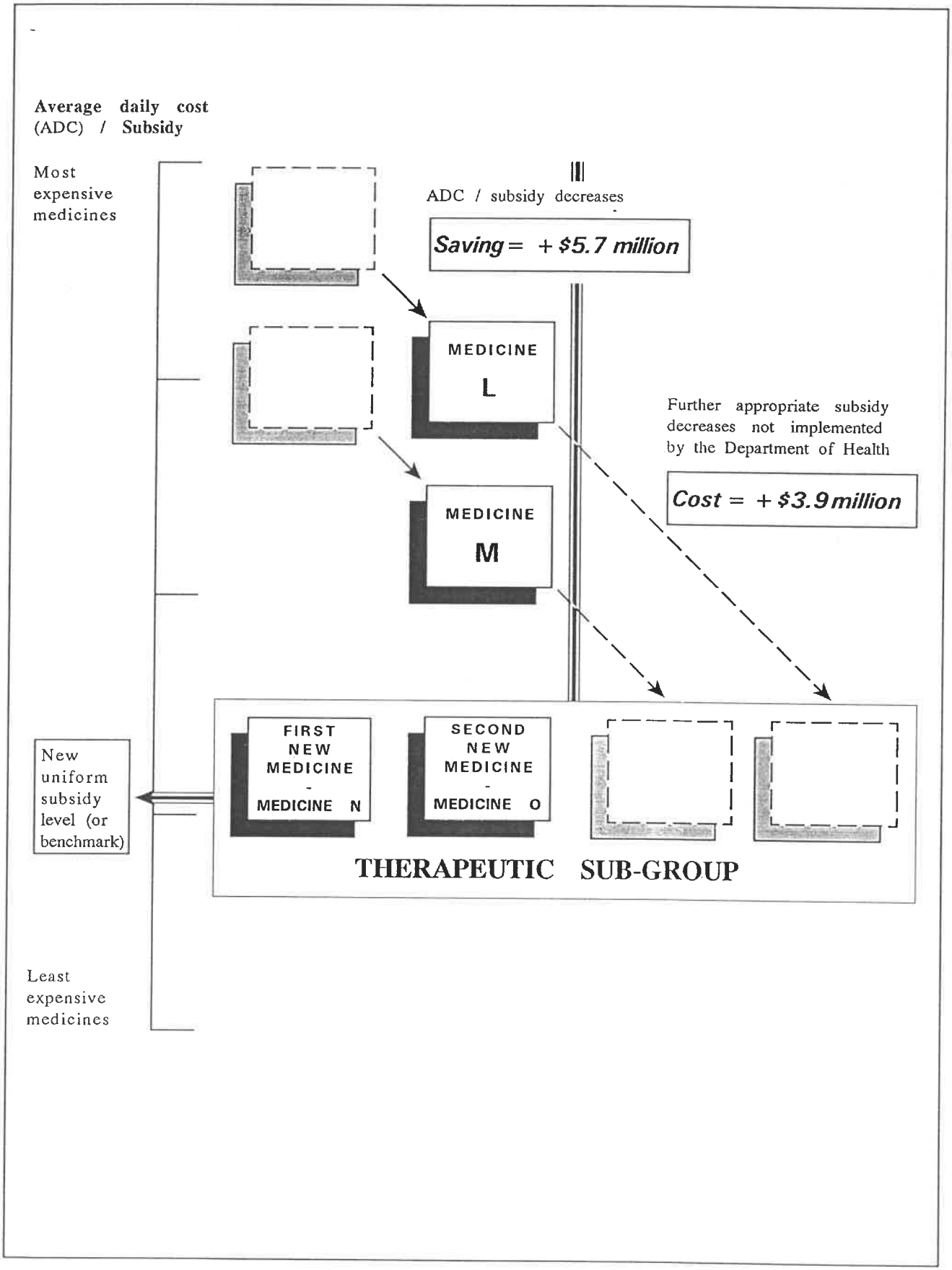
APPENDIX II

(Delayed adjustment of medicine subsidy to appropriate uniform subsidy level - paragraph 336)



APPENDIX III

(Failure to achieve appropriate uniform subsidy level for a therapeutic subgroup - paragraph 337)



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