The Drug Budget Silo Mentality: The Dutch Case

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ABSTRACT

This article provides a broad outline of developments in the Dutch health-care policy related to the costs, budgeting, and reimbursement of pharmaceuticals. In-hospital drugs costs are part of hospital budgets, whereas for the main part of costs, nonhospital drugs, no strict budget exists. The government sets a goal for the annual cost increase of nonhospital drugs, but has only limited means to enforce that goal. Two measures were implemented to reduce drug prices: a reference price system and a price law. Both measures had a modest and temporary impact on drug prices during the 1990s.

In limiting the utilization of drugs, the package of reimbursed drugs has been restricted. This led to a shift from public to private costs and possible substitution of cheaper not reimbursed drugs by more expensive reimbursed drugs. An electronic prescription system was implemented to encourage rational prescription. Although 70% of the Dutch general practitioners reported to use the system, the estimated savings on drug costs appear to be modest and far less than expected.

The use of economic evaluation for reimbursement decisions will increase. From 2005 onward a pharmacoeconomic study and budget impact analysis is formally required for new nonclustered drugs seeking a premium price. Furthermore, in the future the health-care insurers will get a more prominent role in limiting the costs of drugs and enhancing the efficient use of drugs within their overall budgets. Health-care insurers may choose which drugs to purchase and reimburse and they can negotiate drug prices with the pharmaceutical industry, wholesalers, and local pharmacists.

Keywords: drugs, budgets, health-care policy, cost-effectiveness, economics.

Introduction

In many European countries, the costs of drugs increase at a larger pace than the costs of other parts of the health-care system. National governments are concerned by this structural phenomenon, which relates to the general problem of financing increasing health-care expenditures and which may be reinforced by the aging of populations in the coming decades. For example, based on aging alone, Dutch drug costs are expected to increase 1.2% per year compared to 0.9% for hospital care [1]. This article provides a broad outline of developments in the Dutch health-care policy related to pharmaceuticals. It describes the policy measures used, such as budgeting, prescription control, price regulation, and reimbursement criteria. Furthermore, we will analyze the inherent incentives in this health-care policy, and drug policies in particular, to see how these influence the efficiency and costs of the delivery of pharmaceuticals in the Dutch context. This article will also describe the expected developments in drug policy and the possible role of pharmacoeconomic evaluation in the nearby future.

The Dutch Position

The Netherlands has an intermediate position in both health-care and drug costs among European countries. For 2000, health-care expenditures were responsible for 8% of the Dutch gross domestic product. The share of drug costs in total health-care costs for 2000 amounted to 12%, which is relatively low compared to the OECD average of 16% [2]. The Dutch drug prices are relatively high, but the utilization of drugs is relatively modest. For example, the opposite situation holds for France.

The health-care system in the Netherlands is predominantly financed through health-care insurance premiums. Every citizen pays compulsory income-related premiums (AWBZ) for “ uninsurable” long-
term care: 38% of health-care finance. Additionally, approximately half of the health-care budget is funded by insurance premiums: 36% sickness fund and 15% private. Approximately two-thirds of Dutch citizens and their employers pay income-related and fixed sickness funds premiums from the public sector, which are set by the government. The package of health-care services covered is also publicly decided. The rest of the population is privately insured, to which they are ineligible to join the sickness fund, and pays risk-related premiums and additional solidarity premiums that are transferred to the public sector. Most privately insured have an insurance coverage comparable to the sickness fund package. The amount of out-of-pocket spending in the Netherlands is modest (6%), especially compared to other countries. Finally, only 5% of the health-care budget is paid for through general taxes (e.g., public health programs).

**Health-Care Budgeting Process**

Since the 1980s, all parts of hospital care, primary care, and long-term care in the Netherlands have been strictly regulated by budgets, annually set by the government. The rate of annual budget increase is the result of political negotiation and is determined by expected economic growth and the targeted share of health-care expenditure in national income. For example, hospitals get budgets based on functional parameters that reflect the amount of the adherent population, the type of facilities, the number of beds, and production parameters such as the number of bed-days and outpatient visits. The level of activity is negotiated with insurers, and the result is an input into the calculation of the hospital budget. Since the 1990s, the insurers also have had budgets. There are no explicit regional budgets derived from the national annual budget, although budgets of local health-care providers are related to the size of the population that are served by their health-care facilities.

This budget system resulted in a significant slowdown in annual cost increase during the 1980s. In the subsequent decade the budgets acted more and more as a rationing vehicle. Waiting lists emerged and grew substantially in many health-care sectors; the number of dissatisfied patients and physicians showed a parallel increase. Many plans for implementing regulated competition between insurers as well as providers were discussed in the Dekker reforms and the Simons plan to introduce more incentives for efficiency and quality improvement [3]. Although steps have been taken to introduce more competition in the insurance and provider markets, the government has been reluctant to simultaneously withdraw the current budget and supply side regulation. This regulation incorporated many disincentives to efficient health-care provision and is generally blamed for the bad performance of many health-care organizations.

Drug costs have continued to rise more rapidly than the other components of health-care expenditure. For hospital drugs the costs are a part of the hospital budget. Hence, at the central level, hospital drugs are not strictly budgeted, but hospitals should monitor drug costs carefully as part of their total hospital budget. There are several examples of new very expensive drugs (e.g., EPO®, AZT®, Reopro®, Taxol®, and Remicade®) that caused problems with hospital drug budgets. Currently a discussion is being held on whether and how these drugs can be financed in the future (e.g., using an earmarked subsidy as was done with EPO and Taxol in the past) taking into account the planned change in hospital financing toward a diagnosis-related groups-type system. For nonhospital drugs there is no strict budget. The government sets a goal for the annual cost increase of nonhospital drugs, but has only limited means to enforce that goal. For expensive “borderline drugs,” when diseases can be treated as inpatient or outpatient, the hospital has an incentive to shift the costs to the outpatient setting to nonhospital drugs. In contrast, the health insurance companies bear 100% risk for nonhospital drugs and approximately 20% for hospital costs, so they have the opposite incentive.

**Pharmaceutical Budgeting and Use**

The pharmaceutical budget, or better the target for total nonhospital drugs costs, is determined in the political arena, as the total health-care budget is. As all costs, pharmaceutical costs consist of a price component and a utilization component. The Dutch government has made many efforts to influence both components of cost increase. The following analysis concerns only the nonhospital drugs, responsible for the lion’s share of the Dutch drug costs.

**The Price Component**

With respect to the price component, the reference price system (GVS) was introduced in 1991. This system works as follows: if a new drug has the same therapeutic effectiveness, a combination of efficacy, side effects, and secondary characteristics of the drug, as existing drugs, and the manufacturer does
not want a premium price, the reimbursement level is set at the cluster's average level. If a new drug cannot be clustered in GVS and the manufacturer wants a premium price, the therapeutic value and the cost consequences for the drug budget of the introduction of the new drug should be documented. If the cost consequences for the drug budget would be substantial, the drug may not be approved or only approved at a lower price. This restriction to the drug budget only, instead of an analysis of the costs for total health care, is an example of what we call a drug budget silo mentality. The GVS system has two targets: it would decrease drug prices as a result of price competition and it would encourage the use of generic drugs, because if brand products would have a higher price than the reimbursement limit, the patient would have to pay the difference out of his or her own pocket.

In 1996/1997 a price law was introduced that sets the maximum reimbursement/price of a drug cluster at the average price of four neighboring countries: Belgium, France, Germany, and the United Kingdom. The maximum prices are reviewed each 6 months, based on price changes, exchange rate changes (United Kingdom only), and changes in the reimbursement packages.

In 1998, the government reduced the wholesale bonuses of pharmacists by means of a generic reduction of the reimbursement of purchase prices of local pharmacies by 3.5%, a claw-back measure.

The Utilization Component

A formal budget restriction on the quantity of drugs prescribed does not exist. In the Netherlands, a physician does not experience a strict financial ceiling or financial liability when prescribing a drug. Since 1993, however, the package of reimbursed drugs was restricted in several phases. Most drugs that were excluded from reimbursement were relatively cheap, as patients were expected to be able to afford to pay for these themselves.

In 1993 it was observed that pharmaceutical expenditure rose sharply again as a consequence of many expensive drugs being listed which could not be clustered in the GVS. Therefore, to contain costs, many new ambulatory drugs that could not be clustered, and for which the manufacturer wanted a premium price, were put on a waiting list during the period 1993 to 1999. New drugs were only approved if they served a disease that was not treatable before by drugs or if the new drug could replace another more expensive new drug. In 1999, when the procedure was reopened, all waiting lists were judged on therapeutic effectiveness and cost consequences, and most of these drugs were approved for reimbursement.

More Efficient Prescription

Many initiatives such as local and national formularies and pharmaco therapeutic discussions to support prescription protocols (FTO) have been taken. General practitioners (GPs) are recommended to prescribe generic drugs, also supported by the introduction of electronic prescription systems. Pharmacists are financially stimulated to substitute “specialités” (brand products) with generic drugs.

In the Netherlands economic evaluation of health-care programs and medical technology assessment has become quite common in assisting health policy. However, for drug policy it has not been used in a systematic way thus far. Until now, for new drugs for which the manufacturer wants a premium price, the therapeutic value and the cost consequences for the drug budget of introduction of the new drug were documented by the committee for pharmaceutical care, and consequently the Minister of Health was advised on reimbursement by this committee. From 2005 onward, a pharmacoeconomic study and budget impact analysis is formally required for new drugs, seeking a premium price, a higher price than the reimbursed cluster price. During 2002 to 2004, the pharmacoeconomic study is still voluntary. Such study must be carried out and submitted by the manufacturer. In 1999 guidelines for the pharmacoeconomic part of such submission were issued by the “College voor Zorgverzekeringen” [4]. These stipulate that the study should take a societal perspective, including all medical and nonmedical costs involved, a move beyond a drug budget mentality. Furthermore, a cost–utility study is preferred, using a discount rate of 4% for both costs and benefits. The reimbursement decision may incorporate both a price/reimbursement and a utilization component, restricting the indication within label use or setting a possible budget for a specific drug. The Ministry of Health is also considering the application of risk sharing schemes as applied in France and Ontario, Canada, where agreements are made on sales, utilization, or off-label use after reimbursement between the government and manufacturers.

Cost-Effectiveness as Criterion in Reimbursement

Since the mid-1980s there has been a policy of financing economic evaluation studies of major new health-care programs and using the results of these studies to inform decisions on public reimburse-
ment of such programs. All major public health pro-
grams have been evaluated in that way before the
decision to introduce them and some major curative
programs such as all transplants programs have fol-
lowed the same procedure. In addition to this from
1988 onward, academic hospitals could acquire
funds to finance new health-care programs condi-
tional upon the execution of an economic evalu-
ation. Health authorities are required to consider the
outcomes of these studies when deciding on the
actual implementation of these new programs. A
number of examples can be given that suggest that
the results of the economic evaluation studies have
been influential in shaping policy on new health-
care programs, but also other arguments have
entered the debate such as “budget impact” or “the
burden of the disease to the patient” [5]. For
instance, the determination of the target population
and the invitational scheme for the national pro-
gram for breast cancer screening in the early 1990s
were based on the results of an extensive economic
evaluation study [6]. The same was true for the pol-
cy of restricting the number of in vitro fertilization
attempts in the case of infertility to three attempts
because the fourth and further attempts were shown
to be associated with strongly increased marginal
cost-effectiveness.

It is difficult to predict how important cost-effec-
tiveness will be in relation to budget impact when
deciding on reimbursement and what other criteria
will be taken into account. Very cost-effective inter-
ventions have not acquired access to public funding
(e.g., Viagra®, cost-effectiveness €6,100 per qual-
ity-adjusted life-year [QALY]), while relatively inef-
ficient programs like lung transplantation (cost-
effectiveness €71,000 per QALY) were added to the
basic health insurance package [7,8]. This is not
surprising as the relative efficiency of a new tech-
nology is not the only criterion for reimbursement.
 Others are the necessity of treatment for the indi-
vidual, related to the severity of the disease, the
degree of collective versus individual responsibility
(should we pay collectively for “lifestyle products”
such as Viagra and antiobesity drugs?), and the
efficiency of insuring the service. With respect to
Viagra, the problems with off-label use make
reimbursement even more complex for decision
makers.

It may be that these criteria—necessity, responsi-
bility, and cost-effectiveness—should not be consid-
ered successively but rather simultaneously. Maybe
the relative efficiency criterion should be applied
differently when the disease problem is more or less
disabling to the patient: health gains for patients
that are more severely ill would then be weighted
more than the same health gains for patients who
are initially in a better health state. This idea is
brought forward in an advice of the College voor
Zorgverzekeringen, and this may be implemented in
future decisions on reimbursement of pharmaceuti-
cals [9].

Economic Implications of the Budgeting and
Allocation Process

Price Component
The direct effect of the GVS system was an initial
price decrease of 5% on average of drugs that had
prices above the reimbursement limit and a price-
limiting effect on newly introduced drugs. This
price effect was temporary and the GVS did not
affect the structural rise in the utilization of drugs.
The price law also had a temporary impact during
the period 1994 to 1997. This same holds for the
pharmacy bonus reduction measure mentioned
above.
The GVS system also had some negative impli-
cations for drug costs: setting guaranteed reim-
bursement ceilings for clustered drugs provided no
incentive for manufacturers to set a price below the
ceiling level. In fact, the prices of several generic
drugs were raised toward the maximum reimburse-
ment level [10]. Competition between manufactur-
ers and wholesale companies was aimed at the
pharmacist through bonuses and discounts rather
than at the consumer or the insurance company.
The GVS also provided an incentive to present
drugs that were in fact almost identical to existing
drugs as innovative new drugs to avoid clustering
and to get a premium price, which put an upward
pressure on prices.

Utilization Component
The package restriction led to a shift from public to
private costs and probably not to a reduction in
overall drug utilization. An unforeseen negative side
effect of this measure was that drugs that were no
longer reimbursed were sometimes replaced by
reimbursed drugs and more expensive drugs were
prescribed.
The waiting list procedure for new drugs during
1993 to 1999 had a limiting effect on the cost of
new drugs as the introduction of these drugs was
postponed. In contrast, it may have increased the
cost increase in other parts of health care, especially
the hospital sector, because new drugs may reduce
the rate and/or length of hospitalization compared
with standard therapy. It probably limited the diffusion of some new innovative drugs temporarily during the period 1993 to 1999. The possible consequences for patients' health are unknown.

More Efficient Prescription

During the 1990s, the market share of branded medicines decreased from 70% to 50% while the market share of generic drugs rose substantially. The benefits of this shift, however, fell to the pharmacists who got higher discounts for generic drugs, while the insurance companies paid prices for generics, which were almost equal to those for specialties. The electronic prescription system for physicians was evaluated in 2002. Although 70% of the Dutch general practitioners reported to use the system, the estimated savings on drug costs appear to be modest: €7 to €15 million, compared to the expected €139 million reduction in costs [11]. The evaluation concludes that the electronic prescription system may have more positive impact on the quality of drug prescription than on the cost of it. It may be concluded that the policy measures in all three domains had only temporary success in containing pharmaceutical costs and did not provide the right incentives for more efficient use of drugs in health care.

Options for Reform and Improvement

As we have seen, current policy on pharmaceuticals is not effective. This has been acknowledged generally and the new policy is to gradually abandon the GVS system and make way for a more active role of insurance companies with a move toward more competition in both the insurance and the health-care market. As a first step, the cholesterol lowering drugs and gastrointestinal drugs will exit the reference price system in 2003. Health-care insurers may purchase these drugs directly from pharmaceutical companies or contract for large bulks with wholesalers and local pharmacists. As patents expire for some of the products, in these two areas insurers can expected to be especially eager to cash in as much as possible from consequent price reductions.

In the future the health-care insurers will get a more prominent role in limiting the costs of drugs and enhancing the efficient use of drugs within their overall budgets. Health-care insurers may choose which drugs to purchase and reimburse, provided that a comprehensive range of drugs for all diseases is available for each patient, and they can negotiate drug prices with the pharmaceutical industry, wholesalers and local pharmacists. Some insurance companies have bought pharmacies to start competing with existing pharmacies to decrease prices or, at least, to retrieve some of the benefits from substitution by generics.

Dutch health insurers nowadays bear a large part of the risk for outpatient and drug costs, so for these costs they have a clear incentive to act as cost-containing agents. The fraction of risk for health insurers with respect to the hospital budget, currently about 20%, will increase in the near future, so the risk of shifting drug costs to the hospital will diminish. For health insurers the degree of integration of budgets will rise, lowering the risk of perverse incentives. If a health insurer succeeds in lowering total costs, the nominal premium for its clients can be lowered, making the health insurer more attractive from a client perspective.

Two issues seem to be important to sort out: are health-care insurers adequately equipped with information to negotiate successfully with drug providers and what exact set incentives will stimulate insurers to provide an optimal effective and affordable range of drugs?

For the moment, the Dutch Ministry of Health is facing rising drug costs, a substantial slowdown in economic growth, and no short-term effective policy instruments. Therefore, in November 2002, the Minister of Health announced an extension and differentiation of the existing claw-back measure. Pharmacists may sell single-source brand products at maximally 91% of their official purchase price. The consumer price for multisource brand products—drugs for which the patent expired and that are supplied by several manufacturers—is limited to a maximum of 60% of the reference price of the original product. It is envisaged that this measure will reduce the costs of drugs with €280 million.

The pharmaceutical therapeutic discussions aimed at establishing prescription protocols are being extended toward all relevant health-care sectors, also involving nursing home physicians, for example, and should produce formularies which cross borders between organizations for health care and are available countrywide.

In general, one can say that in the future reliance will be on insurance companies taking the lead in trying to contain the costs of pharmaceutical expenditure within an overall context of efficient use of their total health-care budgets. Central government remains an important player as the responsible actor for reimbursement and pricing of new pharmaceutical products. These developments con-
tribute to an analysis of drug costs as a part of total health-care costs, a move away from the budget silo mentality as described above. The use of information on cost-effectiveness will be prominent although it remains to be seen whether it will be the dominant criterion in the process of deciding on reimbursement.

References