

Original article

A DECADE OF GROWTH IN PUBLIC AND PRIVATE PHARMACEUTICAL EXPENDITURES: THE CASE OF BELGIUM 1990-1999

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ABSTRACT

Objective: To make a systematic, transparent, internationally comparable description of trends (1990-1999) in total, public and private (co-payment + out-of-pocket) spending on pharmaceuticals in Belgium.

Setting: Belgium, a western European country, with a Bismarck-type universal coverage healthcare system

Nature of the study: Descriptive analysis of time-series

Methods: Collaborative data gathering effort between academic and private research institutes and IMS health.

Results: Mean annual growth rate was 3.9% for total, 5.3% for public, and 2.0% for private drug expenditures (expressed in constant 1999 EUR). The ratio of public to private spending shifted from 53.4% to 60.3%. Of the private spending, one third was co-payment for reimbursed medication and two thirds was out-of-pocket payment for non-reimbursed medication.

Conclusion: Co-operation between several data gathering constituencies within one country was necessary to achieve completeness and detail in data collection on out-of-pocket payments for non-reimbursed medicines, and hence in total drug expenditures. Discrepancies were found between the estimate of the public/private mix and OECD health data 2000 for public drug spending.

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INTRODUCTION

In many countries, policy makers try to impose maximum annual growth rates on the different subsystems of health care, and more specifically on the drug budget. Overall growth of the health care budget is the result of a number of complex, poorly understood mechanisms (1-3). Most countries lack monitoring systems, capable of producing data of sufficient sophistication to understand fundamental trends. Without a thorough understanding of these trends, the development of a rational policy to control the quality and the amount of drug spending will be difficult. Moreover, the relationship between health care spending and spending on drugs is not clear. It is not certain that methods to curb pharmaceutical costs will curb health care spending (4).

Within Europe national health and drug policies diverge widely, with regard to pricing, dispensing and

reimbursement. In the US, drug policies vary among Medicaid (the Federal-State health insurance program) and a host of private health insurers. Based on data, collected by the Organisation for Economic Co-operation and Development (OECD), a number of analytical comparisons of health care expenditure figures and policies (2-9) were published. These studies have evolved from cross-sectional to longitudinal comparisons over longer time-periods, and the methodological sophistication of these studies is increasing (10-15). However, their validity has sometimes been questioned, as to the reliability of basic descriptive data on health care and drug utilisation (16-19). Therefore, proposals have been made to enhance the quality of data collection of basic variables on health care utilisation, for the sake of international comparison (20,21).

Published international comparisons of pharmaceutical expenditures exist, but differ in scope (total public expenditures, co-payment) (22,23).

Our aim was to make a systematic, transparent, internationally comparable description of trends (1990-1999) in total, public and private spending on pharmaceuticals in ambulatory care and hospital care in Belgium, a Western European country, and to compare our data with official OECD data on pharmaceutical care.

METHODOLOGY

Data were collected from the official publications from the National Institute for Sickness and Disability Insurance (INAMI-RIZIV), from the research centres of the Belgian Association of Pharmaceutical Companies, from the research centre of the Belgian community pharmacists (APB), and from a marketing research company (IMS Health (International Medical Statistics), Belgium).

Data on public drug spending consist of:

- A. Ambulatory reimbursed specialities (prescribed by general practitioners to ambulatory patients and to elderly patients, residing in nursing homes (only those serviced by community pharmacists), and by specialists to ambulatory patients and to outpatients visiting polyclinics, but not staying in hospitals);
- B. Reimbursed medicines to inpatients (hospital);
- C. Special category reimbursed medicines only delivered by hospital pharmacists to outpatients (predominantly AIDS medication and special oncology treat-

ment). This category also includes reimbursed medicines to elderly patients, residing in nursing homes (only those serviced by hospital pharmacists);

- D. Ambulatory magistral preparations, made in the community pharmacies;
 - E. Various products, predominantly blood products, usually prescribed and dispensed in hospital.
- These data (A-E) were collected through INAMI-RIZIV.

Data on private drug spending consist of:

- F. Over-the-counter medicines (OTC). Data were collected through IMS Health. The annually revised sales data were used, not the monthly published data;
- G. Non-reimbursable medicines on prescription in ambulatory care (also available from IMS Health);
- H. Reimbursable medications in ambulatory care that were not accepted for reimbursement. This complex remaining group consists of drug spending by Belgians not covered by the not completely universal health insurance system, by foreigners, not covered by the national insurance system, and by Belgians for drugs potentially reimbursed in the prior approval system (f-medications), but deliberately paid fully out-of-pocket (e.g. because the patient does not want to undergo a diagnostic procedure required in the prior approval system). The expenditures in this heterogeneous remaining group were calculated by subtracting the two previous subcategories (F+G) from the sum of all non-reimbursed sales in ambulatory care (available from IMS Health). This category will be labelled in the tables: reimbursable but not reimbursed.
- I. Co-payment for reimbursed ambulatory pharmaceutical specialities (available from RIZIV-INAMI as the difference between "Bruto" and "Netto" ("gross" and "net") data);
- J. Co-payment for reimbursed ambulatory magistral preparations (also available from RIZIV-INAMI);
- K. Co-payment for drugs in hospital (a lump sum of 0.61 € per hospital day), whatever the actual drug consumption;
- L. Out-of-pocket costs for non-reimbursed drugs in hospital. Based on the results of a survey in a sample of hospital pharmacies, we estimated this item with a calculation of 10% of the public spending in hospital (B+C+E).

Notes: There exists a special, small category of OTC-drugs, which can be reimbursed only when prescribed by a physician (e.g. a fungicide cream). Sales in this category are under A and I, when prescribed and under F, when not prescribed.

There are no reliable data sources on a minute subcategory of non-prescribed and non-reimbursed magistral preparations (mainly pharmacy-made cough syrups). As this subcategory is estimated to be below 10 €/day in the average pharmacy, it was disregarded.

In this article we reserve the term “co-payment” for the private contribution towards the cost of *reimbursed* medicines (I+J+K). The term “out-of-pocket payment” is reserved for private drug spending by patients on drugs with no reimbursement at all (F+G+H). The total of “private spending” is the sum of co-payments and out-of-pocket payments.

Cross-validation of data

Financial data on the expenditures of reimbursed medicines in ambulatory care are available from the accounting records of the National Health Insurance Institute (INAMI-RIZIV), at the Ministry of Social Affairs. In addition, the government has set up a data collection system of detailed consumption data of reimbursed medicines (called “Farmanet”), based on data from all billing offices, since 1966. Furthermore, the main pharmacists association in Belgium (APB) has its own data collection system, through the Institute of Pharmaco-epidemiology of Belgium (IPHEB-IFEB), based on data from its billing offices (75 % of the community market), since 1966. In this study, data from the accounting system of INAMI-RIZIV have been used to cover the decade, but the data from the three sources has been used to cross-validate the overlapping years.

For the expenditure data in hospitals (mostly fully reimbursed), we also used in this study the accounting system of the INAMI-RIZIV. In addition, the INAMI collects more specific consumption data since 1994, but because of poor classification, only data on antibiotics have been analysed. Furthermore, IMS Health has a tracking system of hospital drug consumption covering approximately half of the hospital beds in Belgium. No cross-validation with these sources was possible because the latter source of data was not available.

Data on total drug spending were calculated as the sum of private and public spending, and checked with the turnover data of the pharmaceutical industry in Belgium, provided by AGIM-AVGI (The Belgian Pharmaceutical Industry Association). This procedure assures the inclusion of parallel import (very limited in Belgium in this decade) and the exclusion of export trading from the total sales.

Limited expenditures of small populations of beneficiaries (war veterans, army personnel and ex-colonialists) were not given as a separate category. These

expenditures are incorporated indirectly in the categories of private spending. All data from INAMI-RIZIV before 1996 were slightly adjusted (multiplied by 1.0252) to compensate for the absence of consumption data of a small sub-population of railroad workers, integrated into the national system only from 1996 onwards. The multiplication factor was calculated by AGIM-AVGI, based on a long-term analysis of the drug consumption of this sub-population).

The historical spending data in Belgian Francs were recalculated in EUR at the official rate of 40.3399 BEF for 1 EUR. The minor fluctuations of the exchange rate with the ECU from 1990 till 1996 were not taken into account, as all the data were converted into constant EUR, taking into account the Belgian index of consumer goods (official index).

Trends in public and private spending were graphically visualised by polynomial smoothing.

Further background information on the Belgian health care system and pharmaceutical market

To foster a good understanding of the data presented below, we refer to the report of the EUR-ASSESS project on Health Technology Assessment in Health Care, comparing health care policies of 16 European countries (26,27) and to publications focussing on the financing mechanisms (28-30).

Belgium has a rather strict definition of the concept “medicine”, reflecting the definition in the EEC Directive 65/65 on January 26, 1965 (31). Medicines are exclusively distributed through community pharmacies and hospital pharmacies. Pharmaceuticals, not registered as medicines (with a formal interdiction on making therapeutic claims), such as homeopathic medicines or phyto-pharmaceuticals are also sold in pharmacies, with an estimated yearly turnover of 175 million € in 1999; food supplements in pharmacies account for approximately 64 million € (MEur) per year; sales of vitamins and food supplements outside pharmacies are limited (less than 50 MEur/year in 1999) (32).

Details on registration, pricing and reimbursement procedures (33) are updated at the web site of the Belgian Pharmaceutical Association and the Minister of Social Affairs (34,35). The national list of reimbursed drugs available on the Belgian market, their prices and their reimbursement status can be consulted on the web at the site of the INAMI-RIZIV (<http://www.riziv.be> in

Dutch en <http://www.inami.be> in French) and the National Drug Information Centre <http://www.bcfi.be> (in Dutch) or <http://www.cbip.be> (in French), updated monthly.

Of the 4,770 available presentations in 1999, 1,468 are OTC, and 3,302 POMs, of which 292 products that are only reimbursed when used in hospital care. Of the 4,770 products, 20 % are fully reimbursed in class "A", 75% are in class "B" (intermediate reimbursement), and 5% in "C" classes (low reimbursement).

Patients pay a percentage of the public price per package (25% to 60% according to the class of the drug and the social status of the patient). Co-payment per package is however limited to a maximum of 9.30 € (6.20 € for socially deprived patients) for class B medicines, and 15.49 € (9.30 € for socially deprived) for class C products. Patients on chronic therapy with prescription medicines need to go and see the doctor in order to obtain a repeat prescription. The usual amount prescribed to patients on chronic therapy is a 1-3 month supply. Repeat prescriptions by practice assistants are not allowed and non-existent. Twenty-percent of the reimbursed ambulatory medicines are prescribed by specialists (hospital based and in private practice), and 80 % by general practitioners. Over-the-counter (OTC) products are mainly cough syrups, medication for common cold, pain relief (including some OTC-NSAIDs), medicines for digestive or intestinal complaints, vitamins, minerals, tonics, products for skin, eye, nose, ear and mouth care. Non-reimbursed medicines on prescription compose an important group and include hypnotics, tranquillisers and medications commercialised for cerebral and peripheral vascular diseases. Newly registered medications, awaiting reimbursement categorisation, are a growing part of this subcategory. Sometimes companies have to position new medicinal products in this group aiming at better prices and less controlled market volumes.

During the nineties, drug budget control was predominantly operated through turnover taxes, package taxes, across the board price freezes and cuts, and reimbursement cuts.

In Belgium, the market share of generics was limited (compared to our neighbours), as there is a high degree of brand loyalty among physicians. Price differences between brands and generics were generally limited to 20 % or less. In 1999, the market share of reimbursed generics (DCI-generics and branded generics) was less than 3% and the share of copies (sold at a price similar to the original) was less than 10 %.

Most of the important innovative pharmaceuticals of the last 10 years with an expected significant impact on market share have been subjected to the prior approval (Bf) system that means that a physician of the sickness fund of the patient has to approve the reimbursement. The total market share of prior approval medicines rose from 12.3 % in 1990 to 23.0% in 1999 in constant 1999 EUR. In 1990, only H2-antagonists and ACE-inhibitors had an important market share. By 1999 proton-pump inhibitors, lipid-lowering drugs (fibrates, statins), hormones (gonadorelins, somatostatins, anti-androgens), vaccines, anti-HIV drugs, cytokins (colony stimulating factors), and a new group of antihypertensives agents (sartans) had joined the ranks.

RESULTS

Trends in pharmaceutical spending

In table 1, the overall picture of 10 years of pharmaceutical spending in Belgium is given.

Total drug spending rose from 2,666 MEuro in 1990, to 3,753 MEuro in 1999, with a mean annual growth rate of 3.9 % and an index growth from 100 to 141, in line with the growth rate of healthcare expenditure.

Public spending rose from 1,422 MEuro in 1990 to 2,262 MEuro (mean annual growth rate 5.3%; index growth 159).

Private spending rose from 1,244 to 1,492 MEuro in 1999 (mean annual growth rate 2.0%; index growth 120).

Analysis of public spending

In ambulatory care the most important subcategory is "ambulatory specialities". Reimbursement rose in ten years from 918 MEuro to 1,580 MEuro (mean annual growth rate 6.2%; index growth 172). Magistral preparations dropped by a mean annual rate of -7.5%.

Drug spending on reimbursed medicines in hospital in-patients rose from 280 MEuro to 395 MEuro (annual growth rate 3.9%; index growth 141). Delivery from the hospital pharmacy of special drugs to severely ill out-patients (AIDS and cancer patients) is a smaller but fast-growing subcategory.

TABLE 1. Pharmaceutical expenditures in Belgium (1990-1999)
In millions of 1999 constant EUR (MEuro) (1 EUR = 40.3399 Belgian Francs)

	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	Index 1999 (1990=100)	Mean Annual Growth rate
PUBLIC SPENDING (RIZIV-INAMI)												
A Ambulatory Specialities	918	1 029	1 102	1 083	1 152	1 182	1 311	1 376	1 456	1 580	172	6.2%
B Hospital In-patients	280	308	325	341	358	363	400	369	383	395	141	3.9%
C Hospital Ambulatory patients	41	55	67	75	84	87	106	118	132	147	354	15.1%
D Magistral prepar. (Ambulatory)	112	118	108	94	91	91	93	61	51	55	49	-7.5%
E Various (blood...)	71	74	74	71	69	71	78	72	78	85	119	2.0%
Subtotal Public Spending (1)	1 422	1 584	1 676	1 665	1 754	1 795	1 988	1 996	2 101	2 262	159	5.3%
PRIVATE SPENDING												
F OTC (Ambulant)	380	393	408	441	433	447	449	473	478	474	125	2.5%
G Rx, not reimbursed (Ambulant)	225	219	228	253	261	263	267	323	336	367	164	5.6%
H Reimbursable, not reimbursed (Amb.)	215	227	208	222	135	209	143	125	144	145	68	-4.3%
I Co-payment Amb. Reimb. Specialties	348	380	398	395	411	412	438	383	407	416	120	2.0%
J Co-payment Amb. Magistral Prepar.	19	19	18	24	22	22	22	15	13	13	72	-3.6%
K Hospital forfait	18	17	16	15	14	14	14	13	13	13	72	-3.6%
L Hospital not reimbursed ^a	39	44	47	49	51	52	58	56	59	63	159	5.3%
Subtotal Private Spending	1 244	1 298	1 323	1 398	1 327	1 420	1 392	1 388	1 451	1 492	120	2.0%
GRAND TOTAL ^b (2)	2 666	2 883	2 999	3 063	3 081	3 215	3 380	3 384	3 553	3 753	141	3.9%
Public/private mix in % (2)/(1)	53.4%	55.0%	55.9%	54.3%	56.9%	55.8%	58.8%	59.0%	59.1%	60.3%		
% of total drug spending in GDP^c	1.4%	1.4%	1.5%	1.5%	1.5%	1.5%	1.6%	1.5%	1.6%	1.6%		
% of public drug spending in GDP	0.7%	0.8%	0.8%	0.8%	0.8%	0.8%	0.9%	0.9%	0.9%	1.0%		
Per capita total pharmaceutical expenditures (in EUR/year)^d	267.5	288.1	298.5	303.7	304.5	317.1	332.8	332.4	348.2	367.0		

Sources : Heymans Institute of Pharmacology, RIZIV-INAMI, AVGI-AGIM, BIGE-IBES, IMS Health

^a à ratio of 10 % of hospital reimbursed drugs (B+C+E).^b NOT INCLUDED : Homeopathic drugs / Not reimbursed and not Rx magistral preparations.^c Gross Domestic Product^d Expenditures in ex-pharmacy purchasing prices.**TABLE 2: Relevant background data for Belgium (1990-1999)**

(Monetary data in constant 1999 EUR)	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999
Gross Domestic Product (in Billions of EUR) ¹	196.8	200.6	203.8	200.8	206.9	212.0	214.0	221.6	227.6	231.9
% Total Health spending of GDP ¹	7.4	7.8	7.9	8.1	7.9	8.2	8.6	8.6	8.8	8.8
% Public Health spending of GDP ¹	6.6	6.9	7.0	7.2	7.0	7.3	7.6	7.7	7.9	7.9
Consumer Goods Index (1990 = 100) ²	100.0	102.8	106.5	110.4	112.4	114.5	115.8	117.3	119.2	120.4
Belgian Population (in millions) ²	10.0	10.0	10.0	10.1	10.1	10.1	10.2	10.2	10.2	10.2
% Elderly (65+) ²	15.1	15.2	15.4	15.5	15.7	16.0	16.2	16.4	16.6	16.7
% Belgians on National Insurance (major risks) ³	97.0	97.0	98.9	98.6	98.3	98.8	99.4	97.0	97.9	98.7
% Belgians on National Insurance (drug costs) ⁴	86.4	86.5	90.7	89.4	89.3	89.4	89.4	89.6	90.4	90.6
Hospital days (in millions) ⁵	25.4	24.9	24.0	23.7	23.1	22.7	22.0	21.5	20.9	20.4
GP patients contacts (in millions) ³	47.2	48.6	49.2	48.6	47.1	48.8	48.6	48.3	48.7	49.1
Life expectancy (in years) ²	76.0	76.4	76.4	76.8	77.2	77.3	77.7	77.9	77.9	77.9
Infant mortality (/1 000 live births) ¹	8.0	8.4	8.2	8.0	7.6	7.0	6.0	6.3	5.9	5.6

Sources : ¹ OECD-2000 ² BELGOSTAT (midyear population) ³ RIZIV/INAMI ⁴ IFEB-IPHEB ⁵ Ministry of Public Health

Note : 1 EUR = 40.3399 Belgian Francs (BEF)

Data in italic : estimates

Monetary data in constant 1999 EUR

Analysis of private spending

In ambulatory care, over-the-counter medicines rose annually by 2.5%, and not-reimbursable medicines on prescription by 5.6%.

Reimbursable but not reimbursed medicines on prescription dropped by -4.3%. Co-payment for ambulant reimbursed ambulatory specialities rose by 2.0%.

In hospital care, the evolution of the lump sum for hospital drugs co-payment (from 18 MEuro to 13 MEuro) reflects the drop in the number of hospitalisation days.

Within private spending for drugs, co-payment for reimbursed medicines is but a third. At the beginning of the decade, co-payment accounted for 31% of private spending, rising to 34% in 1996 and then falling again to 30% in 1999.

Perspectives in drug spending

Overall hospital spending decreased from 20.2% to 18.1% of the drug spending market share in Belgium.

In ambulatory care, the market share (in spending) of OTC medication dropped slightly from 20.6% to 18.4%. For the segment of ambulatory medicines on prescription, the market share (in spending) of non-reimbursed medicines decreased slightly from 31.5% to 24.8%. The market share in ambulatory care of magistral preparations dropped from 10.3% in 1990 to 3.4% in 1999, through a policy of discouragement (i.e. restriction of reimbursement), mainly in 1992 and 1997.

Relative evolution of public and private spending

In fig. 1., a polynomial smoothing of the annual growth percentages of public and private drug expenditures is shown. The growth of public spending was larger than the growth of private spending. Hence, the relative part of public spending in overall spending rose steadily from 53.3% in 1990 to 60.3% in 1999. Growth rates regressed in the mid-nineties, but the pace of expenditures accelerated again by the end of the decade, especially for public expenditures.

Trends in general economical, demographic and health care indicators

In Table 2, the evolution from 1990 till 1999 is given for important economic and demographic data. The Belgian Gross Domestic Product (GDP) increased in ten years to an index of 143 in current EUR, while the Index of Consumer Goods rose to 120. In constant EUR, the GDP rose to 118. The percentage of total health care cost slowly climbed to 8.8% of the GDP, while the percentage of public health care costs levelled off at 7.9% of the GDP. The Belgian population remained stable at 10.2 million inhabitants, and the percentage of elderly people (+65) rose from 15.1% to 16.7%. There was a slow downward trend in the number of hospital days, but the number of patient contacts made by general practitioners was stable, despite a growing number of doctors (1 active general practitioner per 781 inhabitants in 1999). The density of community pharmacies was quite high with one community pharmacy per 2000 inhabitants. Life expectancy was also stable at about 78 years, and infant mortality dropped from 8.0 to 5.6 deaths per 1000 live births.

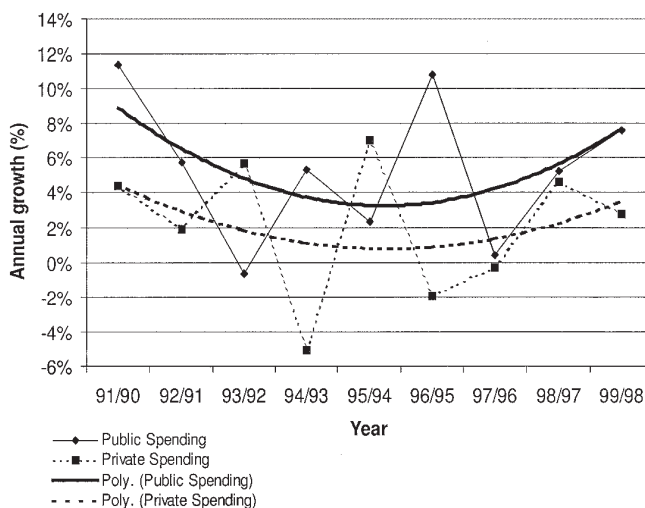


Figure 1. Annual growth of public and private drug expenditure (constant 1999 EUR) in Belgium.

Comparison with OECD health data 2000

We found an interesting discrepancy in the estimation of the ratio of public to private spending on pharmaceuticals between data of the present study and OECD health data 2000 (see table 3). Whereas we estimated that the results for total pharmaceutical spending only were slightly higher (1.6% of GDP in 1999) than OECD health data 2000 (1.5% of GDP in 1999), the results for public drug spending diverged considerably between our data (1.0% in 1999) and OECD health data 2000 (0.6% in 1999).

TABLE 3. Data on 1999 Pharmaceutical Expenditures in Belgium

	OECD* Health Data 2000	Our Data
Total pharmaceutical expenditures (in % of GDP)	1.5	1.6
Public pharmaceutical expenditures (in % of GDP)	0.6	1.0
Public/Private Mix (in %)	40%	60%

* OECD data include "other non-durables (bandages, elasticated stockings, incontinence articles, condoms and other mechanical contraceptive devices)"

DISCUSSION

Limitations and strengths

There are several limitations in this collaborative effort of experts working for various institutions, such as market research organisations, university departments, scientific associations, and government institutions. Data were collected in segments of years. The procedures of starting and closing (fiscal) years may not have been consistent from year to year within a single source, and between sources. However, the validity of the long-term trends over 10 years is most plausible.

Some smaller categories (e.g. private drug spending in hospital) stem from estimated rather than measured data. Limited expenditures of small populations of beneficiaries (war veterans, army personnel and ex-colonialists) were not given as a separate category and incorporated indirectly in the categories of private spending. A minute detail (non-reimbursed magistral formulations in the community pharmacy) was left out. The public/private mix of a very limited number of OTC-

medications, which are reimbursed when prescribed, was not considered.

Web trading of medicines, mail order dispensing, and parallel trading were insignificant in Belgium throughout the nineties and hence did not need to be taken into account in this study. Coverage of the national health insurance was almost universal and private reinsurance of private drug costs was limited in Belgium, except perhaps among employees of a small number of companies and among personnel of international organisations. As the distribution system gets more complex and private insurance may emerge, it will be more complicated to paint a comprehensive picture of the next decade.

The data still predominantly relates to financial developments (available from 1990 till 1999) and not to volume trends. There are still no direct data available on population exposure to medicines.

The strength of this collaborative data collection effort lies in its comprehensiveness, detail, and transparency over the years and in the quantification of the out-of-pocket expenditures for OTC products, and for prescribed but not reimbursed medicines. The latter are often not incorporated into international comparisons, because of the difficulty in quantifying them, resulting in flawed estimation of total drug expenditures and of the public/private mix.

Evolution of total expenditures

The total spending on medicines in Belgium per capita per year rose from 268 €/person/year in 1990 to 367 €/person/year in 1999 (constant 1999 EUR). The Belgian pharmaceutical market is a relatively high volume, relatively low price, and average expenditure market. We prefer to wait for similar detailed descriptions of national pharmaceutical systems, before engaging in hazardous international comparisons.

The evolution of private drug spending

Belgian citizens spend in 1999 149 € per year on private expenditure for medicines. The percentage of private spending in total drug expenditures decreased from 46.7% in 1990 to 39.7% in 1999. However, in absolute values (as perceived by the patients), private spending rose from 124 Euro/year to 149 Euro/year in one decade.

Of the private spending, 107 € (approx. 2 thirds) was spent on out-of-pocket payments for OTC products, for prescribed but not reimbursed for commercialised medicines such as hypnotics, sedatives, spasmolytics, peripheral and central vasodilators, for medications not accepted by prior approval and for new medicines not (yet) reimbursed.

Co-payment for reimbursed medicines was 42 € per year per capita in 1999. The percentage of co-payment in the expenditures for reimbursed pharmaceutical specialities in ambulatory care dropped from 26 % to 21 % over the decade. This occurred mainly because of the growing market share of newer, highly priced medicines, for which co-payment per package is limited by a ceiling (in most cases co-payment is not higher than 9.30 € per package - see method section). This ceiling mechanism is the fundamental reason for the smaller growth rate of private versus public expenditures. At the end of the decade, larger pack sizes of expensive innovative medicines were admitted to the market, with slightly lower sale prices, and significantly reduced co-payment, further increasing the effect of the ceiling mechanism.

An average co-payment of 42 €/capita/year is still higher than in a number of other European countries (e.g. the Netherlands, where nearly full coverage of reimbursement spreads much wider over the range of therapeutic products). Most Belgians do not have private insurance or employee benefits for these private expenditures. The distribution of this private spending is heavily skewed, as a minority of patients on high intensity treatments pays much higher amounts, sometimes up 10 % or more of their personal budget. The precise impact of co-payment and out-of-pocket charges on the extent and the quality of drug utilisation and on equity in healthcare is still under debate (36-41), but there is evidence in Belgium that the utilisation declined in therapeutic classes where reimbursement was stopped or diminished (42).

The pace of annual growth for private expenditures has picked up again at the end of the decade. During these 10 years, wages and allowances were frozen and inflation of other goods was rather limited. This probably contributed to the sharp rise in awareness of pharmaceutical cost among Belgian citizens. It was translated in a political commitment to prevent a further rise in private spending for pharmaceuticals. In the last years of the decade there were no new proposals accepted to shift public spending to private spending by abolishing reimbursement of therapeutic classes with efficacy claims under scrutiny.

Recently, annual co-payment for reimbursed medicines was levelled off to a individual maximum of 372 € per year per person.

The evolution of public drug spending

During the first eight years of the nineties, the Belgian government targeted the yearly growth rate of public health and drug expenditures at 1.5 % (excl. inflation) to respect the criteria of convergence in the Maastricht Treaty. The observed mean annual growth of public drug expenditures was 5.3% (constant EUR) in the nineties.

Budget targets were adapted in 1999 to 2.5% and more recently to a more realistic 5% annual growth.

The pace of growth seems to step up again by the end of the decade (see fig. 1). The smoothing procedures in fig. 1 obscure the strong jumps in annual growth rate of the different categories, reflecting the susceptibility to expensive, innovative medicines with a fast market penetration, but also possibly reflecting budget policy measures or the effectiveness of drug utilisation review actions.

Restraints on pharmaceutical spending in Belgium

The most important expenditure control measure was the reclassification and declassification of important therapeutic classes, with abolished or strongly reduced reimbursement. This operation was conducted in October 1992 and completed at a lower level of impact in July 1997. In addition, price freezes, price cuts and price referencing kept the pharmaceutical prices down. These measures were responsible for the initial reduction of growth of drug expenditures. Furthermore, the pharmaceutical industry was taxed to help pay for the drug bill. The erosion of the distribution margins (because maximum cuts per package for wholesalers and pharmacists were not adapted) also helped to reduce public expenditures, as mainly more expensive reimbursed medicines were affected. The prior approval system for most of the new therapeutic classes possibly limited the number of users of certain therapeutic classes (e.g. in peptic ulcer disease), albeit at the expense of major diagnostic costs for endoscopy (43). By the end of the decade, prior approval criteria for peptic ulcer and asthma medications were loosened or lifted.

Despite all these measures, annual growth of public and (to a less great extent) of private drug spending seems to pick up again at the end of the decade.

A number of expenditure driving factors in pharmaceutical care in Belgium may be responsible, but they have not all been quantified. Expenditures have grown because of the shift in prescribing in some major therapeutic classes from older, inexpensive medicines to newer, expensive medicines (e.g. from beta-blockers and diuretics to ACE-inhibitors and calcium-antagonists in hypertension; or from tricyclic antidepressants to SSRI's in depression (44)). The growth of consumption (volume expansion) is another driving force. The impact of demography (growth of the population - very limited in Belgium- and the ageing of society) was estimated to account for a 1.92 % growth in annual public spending (45). The small, but significant growth of the population covered fully by the National Institute for Sickness and Disability Insurance (from 86.4% in 1990 to 87.6% in 1999) was not taken into account in previous analyses. It is not yet possible to quantify this small but relevant extension of coverage as to its impact as a driving factor of spending. Influx might come from non-insured independent workers who became seriously ill. There was the arrival of major therapeutic innovations in cancer, asthma, immunological therapies, HIV infections. Primary and secondary prevention with medicines extended in new areas (e.g. osteoporosis) or in traditional areas where the threshold criteria for risk assessment are sharpened (e.g. cholesterol, hypertension (46)). Prevalence of some diseases (e.g. asthma, heart failure) was on the rise. In a number of diseases (diabetes, asthma, heart failure), there was a clear call for more aggressive therapy.

The co-operation of all bodies will be needed to assure the quality in the innovation adoption process (separating fake from real innovation) and the balance between quality of care and equity, as we might be approaching a new era of increased growth in pharmaceutical expenditures (47).

New initiatives in national drug policy (33,48-49) have been taken. Only a joint effort of policy makers and prescribers will enable a nation to absorb the growing cost of innovation, and its optimal exploitation. More sophistication is needed in the development of drug utilisation monitoring systems, capable of measuring disease-specific drug exposure (50,51), longitudinal research (52,53), co-medication research (54), and the study of prescriptions by sources (55). Drug policy would also benefit from increased expertise in target

setting for the health care budget (56-60), from a reorganisation of the distribution sector (61,62), from innovation management and implementation of evidence-based medicine (63), and from evaluation of drug policy measures (64-66).

Aligning pharmaceutical spending trends with general trends

In the wealthy state of Belgium, GDP and pharmaceutical spending increase further from an already high level, although drug and health care expenditures growth rate exceeds the growth rate of the economy. The rise of drug expenditures occurs in a country with a stable population and a large (and slightly increasing) proportion of elderly, but also with a stable (and in hospital even somewhat decreasing) high offer of care, with limited organisational restraints. Rising drug expenditures do not correlate with rising life expectancy but might be related with an improved quality of life. A slight drop in already low infant mortality may be caused by other factors than drug spending. Studying one country will not suffice to shed light on the interaction between the health care indicators. A comparison between a greater number of countries, based on a valid longitudinal data collection of a comparable set of indicators, and with contrasting data, is more likely to bring valuable insights.

Comparison with OECD health data 2000

The observed discrepancy in the estimation of the public spending ratio on pharmaceuticals and GDP, between our data (1.0% in 1999) and OECD health data 2000 (0.6% in 1999) is presumably caused by taking into account only the reimbursed *ambulatory* pharmaceutical specialities in the OECD database.

Moreover, we would like to remind that the 2000 revision of the OECD longitudinal data for health spending in % of GDP revealed a substantial change for Belgium from 7.8% (1997) in the OECD health data 1999 to 8.6% (1997) in the OECD health data 2000. This is probably related to newer, more sophisticated methods of data collection (System of Health Account). Unfortunately, the actual implementation of this system varies from one country to another. This should be more studied and taken into account when interpreting international comparisons (22).

CONCLUSIONS

This study is to our knowledge the first published, comprehensive, longitudinal overview of pharmaceutical spending in a Western European country over a period of 10 years (1990-1999). Co-operation between several data gathering bodies was necessary to achieve comprehensiveness, detail, and consistency over time in the description. Only then was it possible to establish the correct total of expenditures and the correct delineation of the public to private mix.

Where total drug expenditure in Belgium rose at the same rate as health expenditures (mean annual growth rate 3.9%), the ratio of public to private spending shifted from 53.4% public expenditure to 60.3%, because public spending had a mean annual growth rate of 5.3% and private spending only 2.0%. Of the private spending, one third was co-payment for reimbursed medication and 2 thirds was out-of-pocket payment for non-reimbursed medication.

Interesting discrepancies were discovered between our data and the official OECD data for public drug spending. Special care should be taken in the development and the application of internationally accepted accounting methods of health care expenditures in general and pharmaceutical spending in particular.

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