Volume 6 • Supplement 1 • 2003
VALUE IN HEALTH

Spending on Pharmaceuticals in Italy: Macro Constraints with Local Autonomy

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ABSTRACT

Italy has a national health service (SSN) that is moving toward decentralization and empowerment of local health enterprises (LHEs)—the arms of the regions for delivering health services. Drug policy and spending decisions are both influenced by central government and local authorities. At the "macro" level, the government holds the power to decide the amount of drug expenditure, currently at 13% of total SSN expenditure; the pricing policy, price negotiation, reference price, and price cuts; criteria for reimbursement, inclusion in the positive list, and restrictive notes; and the copayments and exemptions. So far, the government concern has been predominantly on cost containment, and its approach in selecting drugs for reimbursement has been cost minimization. Italy has no centralized office for health technology assessment and this hinders the search for an efficient use of drugs.

At the "micro" level, however, the LHEs are showing a great vitality in fostering a better use of drugs by general practitioners. One of the tools employed is local voluntary agreements between LHEs and general practitioners (GPs) that may be supported by economic incentives, in cash or in kind. In 2000 there were 61 agreements in place, 31% of total LHEs, which concerned the respect of drug expenditure ceilings and the local development and implementation of clinical guidelines (47% of LHEs). A traditional and widespread tool for controlling drug expenditure is providing GPs with regular reports on their drug prescriptions (59% of LHEs). Monitoring, moral suasion, and clinical guidelines are the main incentives for efficiency at local level, but focus on health outcomes is limited. The cost-containment mentality still prevails and the use of drug budget for purchasing better health is at its very early stage.

Keywords: drug budget, drug pricing, cost containment.

Introduction: Controlling and Managing Drug Spending

For pharmaceuticals and for public health spending, in general, concern about cost containment is still predominant in Italy. The use of budgets as a tool to purchase better health for the population or simply cost-effective health services is far from the current mentality. This has not led, however, to strict spending controls, because a "soft budget" mentality prevails. The health expenditure is not particularly high, but Italy has the problem of a huge public debt (110% of gross domestic product [GDP]). Over the past 10 years, this has caused the promulgation of a vast array of measures for constraining health expenditure by the central government and a systematic underfunding of the public health service, in the attempt to limit expenditure through cash flows. However, this policy has resulted in the creation of deficits by the local health authorities (LHAs) and subsequent payoffs by the state. Therefore, at all levels of the system, budget constraints are perceived as "soft." Things are changing, however, and the consciousness about the "value for money" in the health sector is gaining ground.

In this article the most important measures taken in the drug sector will be described and examined at two different levels: the macro level, norms issued and other measures taken by the national and regional governments to control the pharmaceutical expenditure and regulate the drug sector; and micro level, initiatives taken by the LHAs with general practitioners (GPs) to limit drug prescriptions, improve their appropriateness, and raise their consciousness about using the drug budget efficiently.

It will be clear that from a macro perspective, the authorities use rather crude tools—an aggregate drug spending constraint, across-the-board price cuts, and reference pricing—in an effort to contain

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 1098-3015/03/$15.00/S31 S31–S45

drug spending, with little regard for the best allocation of resources between drugs and other types of health care and among different drugs. In turn, these macrodecisions provide little basis to encourage physicians to make wise (i.e., cost-effective) drug prescribing decisions. At the same time, the decentralization of control provides the regions and the LHAs with considerable autonomy to find solutions to obtain value for money in their drug spending.

Organization of the SSN

The Italian National Health Service ("Servizio Sanitario Nazionale" or SSN) was established in 1978 and became effective in 1980. Afterward, it underwent two main reorganizations. The first in 1992 to 1993, when the LHAs from public bodies became public enterprises (LHEs, Aziende sanitarie locali), major hospitals were split from LHAs and transformed into hospital enterprises (HEs, Aziende ospedaliere), to introduce partial forms of privatization and competition. The second reorganization took place in 1999, when the entire system was reorganized in the direction of "planned competition." During this period there were also some major changes in financing mechanisms, including the adoption of the remuneration of hospitals based on diagnosis related group (DRG) tariffs in 1995 (like the DRG system for Medicare hospital payment in the US).

The SSN is "the complex of functions, structures and activities devoted to promotion, maintenance and recovery of physical and mental health of all population" (article 1, law 833/1978). It is not a public body on its own, but a complex articulation of powers and responsibilities at different levels of government.

The SSN is organized on three tiers of responsibilities: state (national government), regions, and LHEs. Initially, it was organized in a rather hierarchical way with the regions and LHAs being considered as arms of the state, but now they enjoy considerable autonomy. The state is responsible for framing and promulgating laws, setting the budget of the SSN and allocating it among regions, planning, controlling, financing, and as a last resort, paying off the debts of the regions and the LHEs. The state is also responsible for negotiating and setting the prices of ethical drugs, and tariffs on health services (hospital, specialist, rehabilitation), negotiating SSN employee labor contracts and self-employed physican contracts (for GPs and specialists), and introducing and varying copayments. In moving more and more toward the federal perspective, the ultimate responsibility of the state will be to steer the SSN in shared responsibility with the regions—a ground yet to be explored.

The regions are responsible for managing their health service through promulgation of laws on organization, including subdivision of territory in LHEs; accounting, financing, and sharing resources among LHEs; planning, controlling, and appointing top managers of LHEs and HEs; authorizing LHEs for their recruitment plans and sales of real estate; and ultimately paying off their debts (together with the state). Their role is most like that of a holding company. According to their own interpretation of the last reform law, they may act as "negotiators," vis-à-vis LHEs, hospital enterprises, and private hospitals, or as "regulators" of the internal market, within which all providers compete. As fiscal subjects, they are empowered to collect regional taxes and to vary their rates, within established limits.

The LHEs are responsible for delivering health services, either directly, that is, with their own facilities, or through contracts with private accredited providers. In 1995 they were transformed from public bodies into public enterprises, with their top managers appointed by the regional government. According to the last reform, they are granted "entrepreneurial autonomy" and can act according to the civil law, a difficult compromise between their public nature and the need to behave as a firm, to gain flexibility. They adopt private accounting schemes and are constrained to balance their budget, making up losses or retaining surpluses for investment or incentives to their employees. Major hospitals, owing to certain strict requisites, are allowed—if the region wants—to become hospital enterprises, separated from the LHEs. The other hospitals are "integrated" in the LHEs and are considered as their "factories." At the moment there are 197 LHEs in Italy, with an average population of 290,000 inhabitants, ranging from 82,000 to nearly 600,000, and 96 HEs (Table 1).

Organization of Primary Care Services

In Italy, like in the British National Health Service (NHS), all residents must be registered to a GP (if over 14 years) or a general pediatrician to have access to health services. The national contract between the SSN and the GPs provides that in each district there should be 1 GP per 1000 adult population or 1 pediatrician per 600 children, with a ceiling of 1500 patients (800 children) per doctor. (The District is a subarea of the LHE.) The GPs are paid a per-capita amount for each patient, regardless of

Table 1 Main characteristics of the regional health systems, year 2001

Region	LHEs				Hospital enterprises	Population per LHE	% integrated hospitals*
	Integrated	Mixed	Separated	Total			
Piemonte	18	4	—	22	7	195,188	45.4
Valle d'Aosta	1	—	—	1	—	119,224	100.0
Lombardia	3†	1	11	15	27	597,245	7.8
Prov. Bolzano	4	—	—	4	—	113,583	82.1
Prov. Trento	1	—	—	1	—	464,398	71.0
Veneto	19	2	—	21	2	212,038	68.8
Friuli V.G.	3	2	1	6	3	197,707	32.2
Liguria	3	2	—	5	3	330,145	43.7
Emilia Romagna	8	5	—	13	5	302,917	49.4
Toscana	9	3	—	12	4	293,723	57.0
Umbria	2	2	—	4	2	207,479	51.4
Marche	11	2	—	13	4	111,354	65.4
Lazio	9	3	—	12	3	434,764	27.7
Abruzzo	6	—	—	6	—	212,278	78.7
Molise	4	—	—	4	—	82,674	90.1
Campania	8	5	—	13	7	445,027	39.4
Puglia	7	5	—	12	6	340,641	48.3
Basilicata	4	1	—	5	1	121,572	66.3
Calabria	8	3	—	11	4	188,560	49.1
Sicilia	0	9	—	9	17	566,756	30.3
Sardegna	7	1	—	8	1	207,869	69.2
All of Italy	135	50	12	197	96	291,680	42.0†

*The difference includes HEs (28%), other public hospitals (4%), and private hospitals (26%).
†In February 2002 hospitals were split from the LHEs and became HEs.

his/her age, plus a variable quota for specific services or linked to programs and objectives. In Italy there are at present 47,148 GPs (1 GP per 1,059 adults) and 7,155 pediatricians (1 pediatrician per 1,080 children) [1]. Most GPs practice on a solo basis, although group practice, GPs "in association," is gaining ground.

Regional Models of Health Systems

The Italian SSN is rapidly evolving toward a form of so-called "health federalism," the full content of which noone yet knows. The organization and supply of health services differ markedly among the Italian regions—19 regions and two autonomous provinces. In fact, there are 21 models of regional health services. Since the 1999 reform, the former National Health Service has become a network of regional health systems. The regional systems differ in three main respects: the institutional organization (purchaser/provider split), the models of internal markets and competition, and the public–private mix in the supply of health services.

Different regions made different choices in the past, with regard to the split of hospitals from the LHEs. At one extreme, Lombardia has completely separated hospitals from LHEs. At the other extreme, most regions have divided (Abruzzo, Molize) or very few (Veneto, Toscana, Emilia-Romagna, Lazio) hospitals. Therefore, most hospitals remain integrated as simple "factories" of the LHEs (Table 1).

In principle, the regions and LHEs have the power to selectively contract hospitals, public and private, among those accredited and to reduce the DRG-related tariffs below their usual level, which is considered a maximum, but in practice they do not do it. So, after separation, Lombardia has chosen a "yardstick competition" model, where all hospitals compete for patients under fixed prices, and other regions (e.g., Emilia-Romagna, Toscana), a planned competition model, where quantities of services are negotiated at regional level and tariffs are trimmed if providers exceed the agreed quota. But most regions still run a "command and control" model, where hospitals are integrated in the LHEs. The region governs the health system through norms and decrees and "internal" hospitals are still financed on a historical basis, instead of DRG-related tariffs [2] (Fig. 1).

The "public–private mix" in the supply of health services varies considerably across regions. On average, the SSN relies on private contracted providers for 38% of health services delivered, including GPs and drugs, but this percentage reaches 51% in Lazio, 46% in Campania, and 42% in Sicily and is generally higher in the southern regions. Conversely, the proportion of health services directly owned and managed by LHEs is 70% in Tuscany

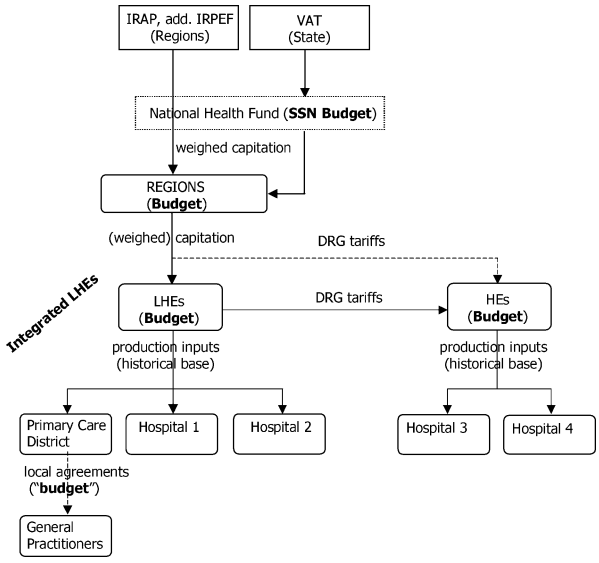

Figure 1 The SSN budgeting process.

and 68% in Emilia-Romagna and Veneto and is generally higher in most of the northern regions.

Financing of the SSN

The Italian SSN is financed 97% by general taxation, 3% by copayments paid by patients, and to a different extent in the various years, by current deficit (e.g., 16.2% in 1990 and 7.2% in 2000). Taxes are collected 50% by the central government and 47% by the regions. Regional taxes are IRAP, 4.25% on production value, paid by firms, self-employed, and public administration, and "addizionale" IRPEF, a surtax, composed between 0.9 and 1.4% of personal incomes. After the 2000 tax reform, the central government contributes to fund the SSN mainly through a value-added tax (VAT) share (47%) and the excise on mineral oils (3%). In principle, these funds are not considered transfers by the government (although in practice they are), but participation to national taxes. The participation of regions in national VAT revenues is currently 38.55%.

Patients contribute to the financing of the SSN by copayments on outpatient services and other charges on services provided in the private interest. Copayments on drugs were abolished in 2001, but many regions reintroduced them in 2002. These funds are gathered locally by the LHEs.

The SSN is also "ordinarily" financed through deficits. Since 1981, expenditures have always exceeded revenues (with 1980 being the exception). Deficits were paid off through state bonds and long-term loans from banks, secured by the state or regions.

All four sources of financing—the share of VAT, IRAP, IRPEF surtax, and copayments—determine the SSN annual budget, which then is shared among the regions. In the past, these resources fed the National Health Fund, which was recently suppressed, but in effect it still defines the annual SSN budget.

The Health and Pharmaceutical Expenditure

According to the ISTAT (National Institute of Statistics), public and private health expenditure amounted to €91,925 million in 2001, corresponding to €1,589 per capita. Its share of GDP was 7.6%, of which 5.8% is for public and 1.8% for private expenditure (Table 2). Public expenditure is the main component (76.5% of total), although its percentage is not high compared with the other EU countries. In the late 1980s and early 1990s its share of the GDP was steadily rising, from 5.5% to 6.3% of GDP in 1991 to 1992, and the government was compelled to adopt drastic measures—the most severe of which were applied to the pharmaceutical sector (in 1992, Italy came out of the European Monetary System). In 3 years it dropped by 1% of the GDP and at present, despite the recurrent deficits of the SSN, it seems under control.

Within the European Union (EU), Italy holds a middle position. In 2000 per-capita total health expenditure amounted to $1932 (in US$ purchasing power parities), compared to $2386 (in 1998) in Germany, $2290 in France, $2136 in the Netherlands, $1686 in the United Kingdom, and $1516 in Spain. However, in terms of GDP share, Italy (7.7%) is surpassed not only by Germany (10%) and France (9.2%), but also by Portugal (7.9%) and Greece (7.8%). The Netherlands is aligned (7.7%), while the UK is below (6.9%).

In 2001, according to the IMS Health, the total pharmaceutical expenditure was €17,156 million, of which €11,591 million for public (67.6% of total) and €5,565 million for private drug consumption. These figures are slightly different from those of national accounts, but more detailed (Table 2). Per-capita drug expenditure was €297. The share of pharmaceuticals of total SSN expenditure was 16.5% in 2001. For 2002, the government imposed a ceiling of 13%. Copayments on SSN gross drug expenditure were 9% in 2000.

Total drug expenditure in 2001 is made up of 72% of SSN reimbursable (€12,308 million) and 28% of other ethical and over-the-counter (OTC)

Table 2 Total health and pharmaceutical expenditure, years 1992 to 2001

	€ Lira and € millions					
	1990	1992	1995	1999	2000	2001
Population (on 1.1.)(000)	56,694	56,757	57,269	57,613	57,680	57,844
Total health expenditure	50,088	59,861	64,709	81,271	88,304	91,925
Public	41,381	48,110	47,410	59,592	65,919	70,282
Private	8,707	11,751	17,299	21,679	22,385	21,643
Breakdown (%)						
Public	82.6	80.4	73.3	73.3	74.7	76.5
Private	17.4	19.6	26.7	26.7	25.3	23.5
Share of health expenditure of GDP (%)						
Total	7.3	7.6	7.0	7.3	7.6	7.6
Public	6.1	6.1	5.1	5.4	5.7	5.8
Private	1.3	1.5	1.9	2.0	1.9	1.8
SSN drug expenditure (% of public health expenditure)	17.6	15.6	10.7	12.8	13.3	16.5
Copayments (% of SSN gross drug expenditure)	10.8	16.3	13.4	9.7	9.0	0.1
Reimbursable drugs	NA	9,611	6,538	9,290	10,542	12,308
SSN (1)	7,290	7,504	5,090	7,599	8,756	11,591
Copayments (2)	883	1,462	787	819	869	14
Private purchases (2)		645	661	881	917	704
Class A		887	5,817	8,537	9,736	11,454
Class B		8,724	721	752	805	854
Not reimbursable drugs (3)	NA	1,317	3,420	4,655	4,715	4,848
Class C (ethical)		523	1,867	2,673	2,689	2,733
Nonprescription drugs*		794	1,553	1,982	2,025	2,115
OTC drugs (4)					1,241	1,275
Total drug expenditure	9,410	10,928	9,958	13,944	15,256	17,156
Ethical drugs (classes A-C)		10,134	8,405	11,962	13,231	15,041
Nonprescription drugs*		794	1,553	1,982	2,025	2,115
Public expenditure (1)	7,290	7,504	5,090	7,599	8,756	11,591
Private expenditure (2 + 3)	2,120	3,424	4,868	6,354	6,501	5,565

*OTC drugs and other products (e.g., diagnostic agents, anti-infectives).
Source: For total health expenditure, ISTAT; for drugs, calculations by Osservatorio Farmaci CERGAS on (1 and 3) IMS health data, (2) Department of Planning, Ministry of Health until 1996 and Federfarma from 1997, and (4) Anifa.

drugs, as seen in Table 2. Ethical drugs represent 88% of total purchases, and nonprescription drugs the remaining 12%. OTC drugs are a small portion of the total; 7.4% in 2001, equivalent to €1275. Class A, or "essential" drugs, account for 68% of total consumption, class B for 5%, and class C for 16%.

The SSN Budgeting Process

The budget of the SSN is determined by the finance law, for a 3-year period, and updated annually. Its amount is fixed by the Ministry of the Economy, formerly the Ministry of Treasury, jointly with the Ministry of Health, and agreed upon with the regions in the so-called "State and Regions Permanent Conference." For the next 3 years it is as follows: 2002, €75,597 (+6.0%); 2003, €78,564 (+3.5%); and 2004, €81,275 (+3.9%).

The budget is shared among the regions according to an allocation formula. Over the past 20 years this formula changed five times in its methodological approach and many more times in the parameters employed each year.

The present allocation formula is made up of four main steps. The description is based on the 2000 procedure, which was maintained also for 2001 and 2002:

1. Division of the total budget in three "levels of care" (macro areas), according to planned shares for each of them; these are (with the 2000–1 percentages shown in parentheses): public health (5%); primary and outpatient services (49%); and hospital services (46%).
2. Calculation of regional funds, through simple or weighed population formula (capitation). Weights are ratios of health expenditure by age groups, where the middle-age group equals 1. The seven expenditure functions, within the three levels of care are public health (5%), general practitioners (12.2%), specialist care (12.2%), drugs (12.6%), elderly care (5%), residential care (7%), and hospital services (46%).
3. Redress of regional shares through various indicators of need (e.g., cube root of the standardized mortality ratios).

4. Algebraic addition of compensation funds for regional cross-boundaries flows of patients, so-called "health mobility," that accounts for approximately 1.5% of total budget.

After these operations, funds are allocated to regions as a global sum and, together with other possible resources, make up the Regional Health Fund budget that is shared among the LHEs according to each region's criteria, in most cases according to weighed capitation. The LHEs in turn get a global sum; they are free, in principle, to assign to the different items of the budget, according to their preferences and priorities.

Although the resource sharing, or "budgeting," process is very analytical, the shares allocated to the seven types of expenditures do not represent separate budgets—except in some regions, for example, Lombardy, where a budget exists only for hospital expenditure. The same principle applies to the drug expenditure, which is not constrained at the regional and local levels. However, during the past decade, a series of national laws imposed national ceilings on drug expenditure, constituting a budget for drugs.

The three-level budgeting process is depicted in Fig. 1. The key actors at each level of this process are: First, in the Ministries of Economy and Health, the former determines the availability of resources, whereas the latter—in agreement with the regions—establishes the criteria and parameters for sharing resources; Second, the 21 regional councillors responsible for budget finance and health, who determine the amount of funds for the regional health service, the regional tax increase—if necessary—and the criteria for sharing the Regional Health Fund among the LHEs; Third, the top management of the 197 LHEs allocates resources to different health services and determines the priorities of expenditure; Fourth, the General Director is jointly responsible for primary care in the health districts; Fifth, the representatives of GPs can sign local "additional agreements" on primary care budgets. The top management is made up of a triad: the General Director, the Medical Director, and the Administration Director. Of course, all these actors share a common responsibility, with an emphasis placed on resources or health outcomes, depending on their principal commitment.

The Drug Budgeting Process

The example of funds allocated to drug expenditure may highlight in detail the budgeting process. In 2000, the drug expenditure share was established at 12.6% of the total national fund. After that, the regional populations were weighted according to these parameters (age bands, weights): <1, 1.000; 1–4, 0.969; 5–14, 0.695; 15–44 men, 0.693; 15–44 women, 0.771; 45–64, 2.105; 65–74, 4.176; and 75+, 4.290. The fund for pharmaceutical expenditure (Italian lira bn 14,421) is allocated by multiplying per-capita national expenditure times weighted regional population.

Most of regions conform to these criteria in sharing resources among their LHEs, although using own weights for population. At the local level, the LHEs allocate funds to the item "pharmaceutical care" of the annual budget on a historical basis, without consideration of priorities for diseases or patient groups. Their effort to control drug expenditure is based on a mix of tools, which in some cases appeal to incentives, but which, in any case, lack sanctions.

The Macro-Level Cost-Containment Measures in the Drug Sector

In the past decade Italy experienced a vast array of measures for controlling the pharmaceutical expenditure of the SSN. Some of these measures were also partly dictated by the scandals that ravaged the political system and the drug industry in the early 1990s, the "clean hands" period. Since then, the drug sector in Italy continues to be under "special surveillance" and this explains the number and strength of the many measures taken.

The tools designed to control the drug sector can be summarized as follows:

1. Pricing policy and price cuts;
2. Reference (reimbursement) price;
3. Positive list of drugs: criteria for classification, restrictive notes, and delisting;
4. Copayments and exemptions;
5. Ceilings to total drug expenditure;
6. Direct delivery of drugs by hospitals and LHEs.

After a new drug, or a new formulation of an existing drug, is approved by the European Agency for the Evaluation of Medicinal Products (EMEA), for example (the majority of cases) or the National Drug Committee (Commissione Unica del Farmaco or CUF), the next step is pricing and admission to "reimbursement," that is, inclusion in the SSN list of deliverable drugs. Although drugs delivered by the public health service are often called "reimbursable," there is no reimbursement by the SSN, because patients do not pay in advance. In principle, there should be two distinct phases: pricing and admission to reimbursement. But actually there is a

single process, because if the manufacturer does not accept the reimbursement price, the drug cannot be entered in the positive list.

Pricing Policy

In Italy, the retail prices of drugs, whether ethical or OTC, are the same all over the country. Law sets wholesalers' "and pharmacists'" margins, and they decrease in percentage terms as price increases.

Government sets the prices of ethical drugs, according to the so-called "average European price" (AEP) method. This "reference pricing" model for price setting was introduced in 1994, together with a radical change in the regulatory environment, aimed at a more transparent, rational, and cost-containment-oriented system of administered prices for drugs.

According to the AEP original method, prices could not exceed an average value calculated with reference to four countries, France, Germany, the United Kingdom, and Spain. To identify the products equivalent to the Italian ones, a similarity criterion was adopted: same active ingredient, route of administration, dosage, and pharmaceutical form. Generics were included in the calculation and purchasing power parities (PPP) were used to convert foreign prices into lira. As a result, prices above their AEP were lowered immediately, while those below were allowed to reach the AEP in five equal annual steps. Actually only two steps were authorized, the first in 1994 and the second in 1997. The impact of the new pricing method has never been evaluated. Farmindustria, the Italian association of drug manufacturers, estimated an initial 17% to 18% reduction in total drug expenditure.

The AEP legislation was modified in 1998, because the Council of State declared the use of PPP illegitimate. The new AEP calculation is based on all EU countries, provided that the drug is marketed in at least four countries, including two countries with some form of price control, and foreign prices are converted using nominal exchange rates. As a consequence of this new AEP, most products should have been awarded price increases, but again the government required the immediate cut of prices above their AEP, while providing for six annual equal steps toward the AEP for the prices below. These steps have not been regularly implemented. In 1999 the AEP method was extended to all new drugs not subject to price negotiation.

Price negotiation. In 1997 a new model for setting prices of innovative products was adopted: prices of new products approved by EMEA through the centralized procedure are to be negotiated between the manufacturing company and the regulatory agency (CUF). The parameters considered are prices in other countries; industrial commitments, such as investments, employment, and exports; market forecasts; and pharmacoeconomic evaluations. Also, from 1998, new products authorized by the EMEA, through the mutual recognition procedure, fall under the price negotiation. If an agreement cannot be reached, the new product is excluded from reimbursement by SSN, but can be sold privately.

In 2001 some changes were introduced: 1) only for more innovative products is pharmacoeconomic evidence recommended (a specific part of the negotiation dossier form is devoted to this matter); 2) a budget impact analysis (i.e., the consequences of the new product reimbursement on the total SSN drug spending) must be produced; 3) the company can obtain higher prices for the new product if it accepts a reduction in the prices of older products; and 4) if the actual market sales of the new product exceed the original company's forecast, after some time, generally a couple of years, the regulatory agency can ask for a price cut.

Price cuts. To help regions to respect the 13% ceiling on pharmaceutical expenditure, during 2002 the government applied a 5% price cut on the sales to the SSN. The same measure has been reiterated for 2003 and is expected to produce a saving of €600 million per year.

Reference (Reimbursement) Price

In Italy there is a single payer of drug expenditure: the SSN. The reimbursement decisions of the National Drug Committee are based on the principles of efficacy, clinical novelty, needs, and costs. Pharmacoeconomic data are recommended only for the most innovative products.

Until 1993, the retail price was fixed by the Comitato Interministeriale Prezzi (CIP), the former body charged for administering prices, according to a pricing method, that resulted in the assignment of different prices to the same active substances, with same form and route of administration. The most important restructuring of the positive list took place in 1993 to 1994 by the newly set up CUF. Reimbursed drugs were grouped in two classes. The guiding principle was a simplified version of the cost-minimization analysis: drugs were entered in class A if the unit cost of the active substance was the same as that of an equally effective comparator.

Higher cost drugs were placed in class C, for example, not reimbursed, unless companies agreed to lower the price. Many companies cut their prices to avoid losing market share.

A similar principle was at the root of two subsequent reforms: the reference price for 1) off-patent drugs (2001) and 2) for homogeneous therapeutic groups (2002).

Reference price for off-patent drugs (generics). The Italian legislation ignored generic drugs until 1996, when a definition of "generic" was introduced: "a product no longer protected by patent . . . with the same bioequivalence, form and indication of the registered product, marketed under the International Non-proprietary Name, which can be followed by the manufacturer name." Law sets the price of a generic drug at least 20% below the price of the original product.

Despite some incentives provided by the law, the generic market was negligible in Italy, less than 1% of the total, and came to existence only when an effective reference price system was introduced in September 2001. It was preceded by a 5% price cut of off-patent drugs from February 2000 (this measure concerned 2000 types of packs) and again another 5% from February 2001. The reference price was established as the weighted average price of similar products, whose price is not higher than the maximum price of generics. In some cases the companies decided to lower the price of the original product. It was estimated that the market of off-patent products accounted for 12% of reimbursable market in 2000. Therefore, since December 2001, for the off-patent drugs the SSN reimburses the lowest price of the available generic drug and the pharmacist is allowed to change the package from the branded drug to the generic one; otherwise the patient pays the price difference, because generics are not very widespread, and they are often unavailable.

At present, some measures aimed at promoting generics have been implemented, both at the local and at the central level, such as physician and patient information and a transparency list. In some LHEs, financial targets, within a cost-containment action, have been implemented in primary care. However, such measures have not produced the expected increase in the generic market, whose amount in 2002 is estimated around 1% to 2% of reimbursable drugs. According to the Association of Generic Drug Manufacturers, the expenditure for generics accounted for €77 million in the first 10 months of 2002.

Reference price for therapeutic groups. The most recent measure taken under this respect concerns the extension of the reimbursement price principle, least expensive active substance, to an entire therapeutic group. The law states that in each of the ATC (anatomic, therapeutic, and chemical) groups, the reimbursement price should be that of the most cost-effective drug. The revision of the SSN drug list took place in September 2002 and the CUF followed this new method:

1. For each drug in the ATC group (fourth level) the cost per defined daily dose (DDD) was calculated, weighted by the number of packages sold in 2001, and ranked in increasing order.
2. The reference price was set at the level where jointly a) the cumulated number of DDD consumed was 60% and b) the cumulated SSN expenditure was 50% of total market.
3. When a single active substance covered 50% of market, the reference price was calculated as the average price of the cheapest active substance, increased by 15%.
4. The prices of drugs exceeding the reference price were to be reduced to that level; otherwise drugs were placed in class C, while those below remained unchanged.
5. No one manufacturer could be penalized by a reduction higher than 10%.

The reference price is actually a cutoff price. The mandate of the committee was to reduce drug expenditure to meet the fixed limit for 2002, but without destabilizing the whole market. The expected savings were estimated at €440 million.

Positive List of the SSN Drugs

The list of drugs supplied by the SSN is called "*Prontuario Terapeutico*" and is divided in three classes (and from January 2003 only in two classes, A and C): class A, drugs considered to be "essential," because they are clinically effective and treat "relevant pathologies" (i.e., serious or most common illnesses); class B, all other drugs that are "nonessential" and were subject to patient charges until 2000 (50% of the price) (this class was split in classes B.1 and B.2 by the drug committee in December 2001 and regions were allowed to charge copayments; however, from January 2003 drugs pertaining to these classes will be either included in class A or C); and class C, includes drugs that 1) have no clinical documentation of their efficacy, 2) are more costly than class A drugs, 3) are used to treat minor or inexpensive illnesses, or 4) do not

require a medical prescription. These drugs receive no reimbursement.

A fourth class, H, includes drugs that can only be used in hospitals. Some drugs of the national formulary are accompanied by the so called "restrictive notes" (note limitative), issued by the CUF, that contain precise indications about what pathologies or under which conditions the drug can be prescribed by a general practitioner or a specialist doctor. These notes, which are periodically revised, are seen as a surrogate for clinical guidelines. There are at present 57 restrictive notes.

Copayments on Drugs

Italy was one of the last countries in the European Union to introduce patient charges for drugs and perhaps the only one that has abolished them so far. They were introduced in 1978, a few months before the law on the SSN was passed, and abolished from January 1, 2001. They are still paid on outpatient specialist services, including laboratory tests and diagnostic imaging.

Copayments were paid in different ways: as a lump sum per package (e.g., €1.5) or prescription (€2.6), a percentage on each package (50%), or with or without a ceiling (€20.6). They could vary according to the therapeutic class A or B [3].

Different categories of people were exempted from copayments: low-income social groups, patients with chronic conditions, pregnant women, the young (0–6 years), and the elderly (>65 years, but under €36,000 of income). Some 25% of people were exempt from charges on drugs and specialist services.

Since its national abolition, which caused a 12% increase in drug expenditure, however, the regions are free either to apply charges within their territory or to delist some less essential drugs (the former class B) from the *Prontuario Terapeutico*. The cumulative effect of abolition of copayments and some restrictive notes, together with the price increase owing to adjustment to the AEP method, was 32%. As of October 2002, 12 regions had reintroduced copayments, 4 had excluded some drugs from the positive list, and 5 had taken no action (Fig. 2).

Figure 2 Regions that have introduced copayments and d-listing from 2002 (October 2002). Black, copayments >€2 per package; dark gray, other copayments; gray, delisting of drugs; white, no copayments or delisting. *Source:* Federfarma.

Ceilings on Drug Expenditure

Another possible form of control over pharmaceutical expenditure is by imposing a cap on its growth. The "ceiling approach" has a long tradition in Italy. It was first introduced in 1994, after the CUF restructured the *Prontuario Terapeutico* with a massive delisting, and was thereafter reiterated until 2000. Its first impact was strong, because it limited the growth of drug spending to a mere 9.9% in 3 years (1994–1996). After that, the expenditure started again to rise, also because VAT on drugs was increased from 4% to 10% in 1997 and exceeded the ceiling by 17% to 18% in 1999 and 2000.

The 1998 finance law provided that any excess should have been paid 60% by the drug industry, wholesalers, and pharmacies and 40% by the state and regions. A complex mechanism was set up for monitoring the quarterly expenditure trends and for sharing the burden of payback among the individual drug producers. The dispute between the drug industry and the government went on for some years, when in 2001 the ceiling and payback were abolished, in exchange for a moderation in price increases.

Despite the poor cost-containment results achieved in the past, a new ceiling was introduced again by the new government in 2002 and made "structural"—that is, until its abolition by a future law. The ceiling was set at 13% of total SSN expenditure, both at the national (€9,830 million) and at the regional level. In the year before, the drug expenditure amounted to €11,590 million (Table 2) and the envisaged reduction (–15.2%) seems rather large. However, both the central government, through a set of concomitant measures, such as the 5% price cut and the reference price for therapeutic groups, and the regions, through the reintroduction of copayments and the delisting of class B drugs, are

striving to respect the ceiling. It seems plausible the expenditure will reach the same level as in 2001. According to Federfarma, the Italian association of pharmacies, from January to July 2002, the cumulated expenditure increased by 2.7% over the same period of 2001 (–0.3% in July) and a 0 growth is expected for the whole year.

Monitoring of expenditure ceilings. A joint commission between the Ministry of Health and Federfarma and other representatives issues a report every 3 months on drug prescriptions and expenditures in which drug expenditure limits are monitored. These documents are the basis for adjusting—if necessary—the budget for drugs. However, since the late 1980s, Federfarma has been publishing monthly reports, by region, on drug prescriptions, expenditure, and copayments, that are based on the list of prescribed medicines that the regions or LHEs reimburse to pharmacists. According to Federfarma, this monitoring system is unique in Europe.

Direct Delivery of Drugs by Hospitals and LHEs

A recent form of drug cost containment is direct delivery of drugs by public hospitals and LHEs. The reason for this lies in a 1976 norm that imposes at least a 50% price cut to drug manufacturers for direct sales to hospitals. Patients needing a drug treatment after their discharge from the hospital may acquire their drug at the hospital pharmacy. The norm applies also to very expensive drugs. There are no official statistics on these "sales," but hospital pharmacists report that this distribution channel is increasing and becoming important.

The Micro-Level Allocation of Spending on Drugs

The incentives for physicians to use drugs cost-effectively are far from being widespread or consolidated. However, some steps forward have been taken.

The gradual acquisition of incentives and mentality for more efficient use of drugs by physicians can be represented as a three-stage evolution that started in the early 1980s and was: 1) a simple control process over GPs' drug prescriptions, made by some LHEs in the north of Italy, through recurrent reports on their drug expenditure, compared to the average of LHE, with no sanctions or incentives associated; 2) the first voluntary agreements, in the mid-1990s, between LHEs and GPs over an individual or group "virtual budget" for drug expenditure, entailing monetary incentives; and 3) the present agreements aimed at developing clinical guidelines by GPs themselves for a better use of drugs, diagnostic services, and hospital services, with regard to some of the most diffuse or costly diseases. GPs manage no budgets for drugs: the LHE simply records their expenditure. This description of the drug budget mentality therefore considers three aspects: reports on drug prescriptions by GPs, agreements on drug expenditure ceilings, and development of primary care clinical guidelines.

The diffusion of the budget mentality among GPs is documented by a recent national survey carried out by the "Osservatorio nazionale sulla Medicina Generale" (OsMeG) of the Bocconi University of Milan [4]. The survey was carried out during 2000 through a mail questionnaire. Of 196 LHEs, 162 (83%) responded to the questionnaire. Presumably, nonresponding LHEs have no experiments ongoing, because most of them are in the south and are less sensitive to such initiatives. Unfortunately this report gives only a description of the projects under way, without making an evaluation of the impact of the many initiatives undertaken by LHEs. Furthermore, the data are connected to the LHEs, whose dimension varies greatly, not to the number of GPs involved, nor the population served.

Reporting on GPs' Drug Prescriptions

The beginning of a focus on drug budgets can be traced back in the 1980s, when the LHAs were given responsibility to control the increase of health expenditures. The information needed to control drug expenditure is probably the easiest to obtain, because every month the pharmacies send to the LHEs the list of medicines acquired by patients for reimbursement. Before paying, the LHE, or the region on their behalf, must check a percentage of total prescriptions, whose number is very high. Therefore, many LHEs make use of electronic devices, or contract out data entry, which in turn produces a significant amount of information regarding drugs, patients, and GPs.

Some LHEs started sending to each GP a quarterly or monthly report, with very simple information on the average number of drugs prescribed per patient, the average expenditure, and a comparison with the LHE or region averages, showing the percentage of deviation. Some LHEs used to contact doctors who overprescribed, to discuss their prescription habits. It was and is assumed that the simple fact of feeling scrutinized by the health authority would have induced GPs to more virtuous behavior. No sanctions were imposed, in any case, nor were incentives assigned. The prevailing mentality at that time was that of control and cost containment. Sig-

Table 3 Reports on drug consumption sent by LHEs to GPs, year 2000

	No. of LHEs	%
Regular reports	116	59
Monthly	39	20
Quarterly	43	22
Every 6 months	19	10
Other	15	8
Occasional reports	46	23
Nonrespondents	34	17
Total LHEs	196	100
Reports on		
Drugs	114	98
Specialist care	24	21
Hospitalization	36	31
Total	116	100
Information to GPs on drugs		
Per-capita drug expenditure, packages, or prescriptions	122	107
Comparison with average LHE or region	114	100
Expenditure by producer	15	13
Expenditure by ATC classes	92	81
First 10-20 active substances prescribed (by expenditure)	75	66
Prescription/expenditure of drugs with restrictive notes	57	50

Source: Our calculations based on OsMeG [4].

nificantly, a law in those years called doctors as "orderers of expenditure."

The reporting system is now very widespread and is extended also to other expenditures. According to the OsMeG survey, 59% (n = 116) of LHEs send regular reports to GPs and 23% occasional reports (Table 3). LHEs forward about 20% monthly reports and 22% quarterly reports. Nearly all reports (98%) concern drug expenditure; in addition, they inform on specialist services prescriptions (21%) and referrals to hospitals (31%).

All reports inform each GP on his/her average per-patient drug expenditure or packages or prescriptions, compared with the LHE or regional average (Table 3). Most of them also give information on pharmaceutical expenditure by ATC class (81%), on the first 10 to 20 prescribed active substances (66%) and on prescriptions or expenditure of drugs with restrictive notes (50%).

The monitoring system is mainly concentrated in the northern regions, where 85% of LHEs have in place a regular reporting process, while in the center 66% and in the southern regions only 22% of LHEs report to GPs.

Unfortunately, there is no systematic evaluation of these experiences. It is questionable whether the cost of these operations, especially in the past when personal computers were not so common, is offset by the benefit. Generally, a reduction of prescriptions is observed at the beginning of monitoring, but in the long run doctors tend to resume their practice, after learning or knowing that no sanction is enforced. However, in the LHEs where cases of overprescription are regularly discussed with GPs, drug expenditures are more likely to be under control.

Agreements on Drug Expenditure Ceilings

The first step in attempting to encourage better management of drug spending by GPs can be found in the finance law for 1997, which linked part of the "variable quota" of GPs capitation to the attainment of 1% reduction of regional health expenditure, over the previous year. This norm gave rise to local agreements between LHEs and GP representatives to set objectives, indicators of result, incentives, and methods of distribution.

The concomitant national contract with GPs, which is for 3 years and signed in 1996, supported this point and issued guidelines for developing local agreements. Because such agreements provide monetary incentives that are gained from savings in health expenditures, for example, drugs and referrals to hospitals, and make up a sum to be shared among GPs, usually they are referred to as "budget agreements," but in no way are they meant to be similar to the drug budgets in, for example, the English experience of GPs fund holding.

There are different types of decentralized agreements on GPs "budget" that concern respect of ceilings on expenditure, planning of GPs' activities, for example, home visits for elderly and care for chronically ill, and attainment of qualitative results, such as reduction of waiting lists and application of clinical guidelines.

The results of the national OsMeG survey [4] show a rather disappointing situation: only 31% (n = 61) of LHEs have in place local agreements (Table 4) and they are mainly concentrated in four regions (Veneto, Emilia-Romagna, Toscana, Marche) that account for nearly two-thirds of the total projects. Seven regions, mostly in the south, have not started a single experiment so far. However, 13% of LHEs have already completed one or more cycles of "budgeting" and another 13% are running their first experiment.

Most of the local agreements are concerned with the respect of expenditure ceilings (77% and n = 47), especially on drugs (69% and n = 42), hospitalization (51%), and specialist/diagnostic services (21%). Therefore, while 114 LHEs monitor drug expenditure through regular reports to GPs, only 42 have also signed agreements with them that reward for the respect of ceilings with monetary

Table 4 Agreements of LHEs with GPs, year 2000

	No. of LHEs	%
Local agreements		
Activated	61	31
Project formulation	10	5
Ongoing experiment	25	13
One or more experiments completed	26	13
Not activated	101	52
Nonrespondents	34	17
Total LHEs	196	100
Content of the agreements*		
With respect to expenditure ceilings	47	77
Drugs	42	69
Hospitalization	31	51
Specialist/diagnostic services	13	21
Planning of GPs' activities	28	46
Qualitative objectives	41	67
Other	14	23
Incentives*		
Monetary	31	51
Facilities	5	8
Monetary and facilities	20	33
None	5	8
Total	61	100
Awarding of incentives for*		
Adhesion to project	9	13
Attainment of goals	36	53
Mix of solutions	23	34
Total methods*	68	100
Awarding of incentives to*		
Single GP	19	29
Group of GPs	18	27
Mix of incentives	29	44
Total methods*	66	100

*Number of LHEs and % of activated.
Source: Our calculations based on OsMeG [4].

incentives. The agreements that address drug expenditure in most cases involve other services also: drugs, with 14 LHEs with agreements; drugs plus hospitalization with 16; drugs and specialist/diagnostic services with 1; and drugs, hospitalization, specialization, and specialist/diagnostic services, with 11, for a total of 42 LHEs with agreements.

The control over consumption of drugs and referrals to hospital is the most common of agreements (n = 27). Local agreements tend to be comprehensive, to avoid the risk of "balloon squeezing," namely, that compression of expenditure in a sector increases health consumption in another. Generally, the LHEs that only focus on drug cost containment are the inexperienced ones or those lacking a well-developed information system.

Nearly all agreements (92%) provide some form of economic incentives: in 51% of cases they are monetary; in 8% consisting of facilities, for example, secretary, premises, information, and communication technologies; and in 33% of cases of both (Table 4). Incentives are awarded based on the achievement of results (87% of cases) but in few cases also for the simple adhesion to the project (13%); a mixed solution of ex ante and ex post incentives is employed in 34% of cases. Incentives that are awarded simply for joining the project are intended to stimulate the participation of GPs, who otherwise would be reluctant to "waste" time, for which they are not remunerated.

The local agreements provide incentives either to single GPs (29% of cases) or to GP groups (27%), but most frequently incentives are awarded both to single GPs and GP groups at (44%), as shown in Table 4.

Agreements for Developing Clinical Guidelines

The 1997 finance law that introduced a first embryo of a budget for GPs stated that prescribing doctors should aspire in their habits to the so-called "diagnostic and therapeutic paths," that is, local clinical guidelines that seek to optimize access of patients to health services and their best use. In fact, the Ministry of Health was committed to set up a national committee to issue clinical guidelines for the major diseases that LHEs should implement. The delays and inertia in producing such guidelines led many LHEs to develop their own clinical guidelines.

There is currently a debate whether the best approach should be a top-down—from the Ministry of Health to LHEs—or a bottom-up approach to the local development of guidelines. The first one may rely on the best experts at the national or international level, more resources, and an interdisciplinary method, but the resulting guidelines may be too abstract or distant from the local situations. The main advantage of the bottom-up approach lies in the involvement of doctors, who afterward are called to implement them. On the other side, with local guidelines, there is a risk of duplication, lack of necessary expertise, legitimating of current practices, and moreover, different contents across LHEs.

Although clinical guidelines and "diagnostic and therapeutic paths" are different by definition, the latter involving also organizational aspects, they were considered jointly in the OsMeG survey and were referred to as "guidelines." According to this survey [4], the situation seems encouraging, because nearly half of LHEs (47% and n = 92) have developed local clinical guidelines (Table 5). The vast majority of LHEs have in place up to 5 guidelines and 17% more than these, up to 18. Altogether, 377 guidelines have been developed at the local level. However, the regional situation is patchy: in four regions all LHEs have developed guidelines (Emilia-Romagna, Friuli-V.G., Liguria, Umbria); in three

regions 80% of LHEs have guidelines; but conversely, in seven regions no LHE or only one LHE has guidelines.

The diseases most commonly considered are hypertension and diabetes (60 and 54% of LHEs with guidelines) and respiratory (50%) and vascular diseases (40%); moreover, 72% of them follow guidelines on other diseases. The guidelines are generally concerned with global management of diseases, considering any aspect (67% of LHEs with guidelines), but a large number focus only on drug therapy (52% and n = 48) or diagnostic procedures (42%), as seen in Table 5.

The key actors in developing clinical guidelines at local level are, first of all, GPs (89% of LHEs teams) and hospital doctors (61%). Representatives of LHEs, whether district managers (47%) or central staff (37%), do not always attend meetings on guidelines. In the most significant regional experiences in Emilia-Romagna, Veneto, and Lombardia, 100% of guidelines were developed with the contribution of GPs.

The development and use of clinical guidelines may be fostered by economic incentives or not. According to the survey, nearly half (46%) of the LHEs have developed guidelines without incentives and outside local agreements. Incentives were awarded to GPs in 54% of LHEs that have in place clinical guidelines. This was monetary in 32% of cases, plus facilities in 20%.

Table 5 Development of clinical guidelines by LHEs and GPs, year 2000

	No. of LHEs	% LHEs
LHEs with clinical guidelines by number		
None	70	36
1	7	4
2	20	10
3	19	10
4	15	8
5	15	8
6-10	13	7
11-18	3	2
Total LHEs with guidelines	92	47
Nonrespondents	34	17
Total LHEs	196	100
Number of guidelines developed	377	
Diseases concerned by guidelines*		
Diabetes	50	54
Respiratory diseases	46	50
Vascular diseases	37	40
Hypertension	55	60
Other diseases	66	72
Subject of guidelines*		
Diagnostic procedures	39	42
Drug therapy	48	52
Diabetes	28	30
Respiratory diseases	27	29
Vascular diseases	20	22
Hypertension	33	36
Other diseases	34	37
Disease management	62	67
Other aspects	10	11
Only one subject	39	42
Two or more subjects	53	58
Actors of guidelines development*		
Hospital doctors	56	61
District managers	43	47
GPs representatives	82	89
LHE central staff	34	37
Other	25	27
Incentives and development of guidelines*		
Monetary	29	32
Facilities	3	3
Monetary and facilities	18	20
No incentives	1	1
No local agreements	41	

*Number of LHEs and percentage of LHEs with guidelines.
Source: Our calculations based on OsMeG data [4].

Conclusions and Prospects of Reform

The control and management of the drug budget in the Italian National Health Service has been examined at two different levels—macro and micro—that correspond to the national and, to some extent, also regional, and local levels. At the macro level, the government sets the annual budget of the SSN and, within it, the budget for drug expenditure—at present, as a constrained amount of expenditure (13%). At the micro level, the LHEs use some managerial tools—ranging from regular reports to GPs on their drug prescriptions to formal agreements with them—to control drug expenditure and make the best use of drugs. Interestingly, the focus on efficient use of drugs versus other health services seems more advanced at the local level than at the national one. The national-level drug policies, by administratively altering and controlling relative prices, affect these local decisions—often in unanticipated ways.

National Level

It seems difficult to speak of a budget for the SSN, because it is currently seen as the simple sum of different sources of finance, half coming from regional taxes and half from shares of national taxes. The SSN budget is formally divided in seven types of expenditures—public health, primary care, drugs, hospitals, specialist care, residential care, and care for elderly—when resources are shared among the regions, but these do not represent "packages of services" that the central or regional governments intend to purchase, nor even expenditure limits. Except for drugs, where recurrent national laws have imposed a ceiling on its growth or amount.

Control over the drug expenditure "budget" is exerted, at national level, through a set of tools

that comprise: recurrent cuts of drug prices, 5% at present; reference prices for groups of products, such as off-patent drugs and therapeutic groups; and reductions of pharmacist margins on the SSN sales and to which the regions have added regional copayments and delisting of less essential drugs.

The pharmaceutical expenditure is regularly monitored by Federfarma and a national committee and issues quarterly reports, on which basis the drug budget might be adjusted upward, as it was in the past.

The drug expenditure is the only sector on which limits are imposed. There seems to be a determined and persistent stance by the national government, past and present, against the drug industry, probably because of the scandals that ravaged the sector in the early 1990s or because of the fact that it is not considered a strategic industry for the country. However, in the past, these overly tight limits were systematically exceeded and the state paid off the debts—not the drug industry and distribution, as provided by the law. Nevertheless, the ceilings helped to slow the increase of drug expenditures.

The government has at its disposal many instruments to control and steer the drug sector, which include pricing policy, management of the positive list, reimbursement policy, and to an even lesser extent, registration of new drugs. However, all these tools do not seem to be used in a manner to proactively achieve economic efficiency in the use of drugs. The pricing and reimbursement of new drugs does not require—except for very innovative drugs—epidemiologic or economic evaluation studies nor assessment of cost impact from adoption of new drugs, as in other countries. Pharmacoeconomic studies are presented sporadically by drug producers to get a higher price and are not viewed by government as a tool to improve allocation of resources. In Italy, so far, there is no public institution in charge of technology assessment, unlike many other countries.

The September 2002 revision of the positive list that entailed a reassessment of prices, according to the principle of reference price per homogeneous groups of drugs, ATC classes, was a simplified version of the cost-minimization analysis; it examined the average cost per DDD, without considering the actual prescribed daily doses and the costs of the whole treatment and drug administration, for adverse events, and for therapy failures. The measure is intended to keep the pharmaceutical expenditure below the mandatory ceiling, and it is questionable whether it will improve the allocation of resources. In the end, the government does not seem to be exploiting all the technical tools available for improving the use of drug budget, nor implementing a proactive policy aimed at "purchasing" health outcomes from the budget for drugs.

Local Level

The concern about getting value for drug spending at the local level is becoming more and more widespread, apparently, not only in hospitals and production centers, but also in primary care services. From a national survey carried out by a parliamentary commission [5], it has emerged that in 1999, 71% of LHEs and HEs had in place a cost accounting system, with regular reports sent to the cost center managers, and budgeting procedures, as it refers to hospitals. In the primary care sector, 59% of LHEs forward periodic reports on drug prescriptions and expenditure to the GPs (Table 3).

The LHEs effort to control drug expenditure is based on a mix of tools, some of which appeal to economic incentives and some to the sense of responsibility, but in most cases are short of effective sanctions. The creation of incentives to manage patient care efficiently at the local level can rely on periodic reporting to GPs on drug prescriptions and expenditure, local agreements with GPs on drug expenditure ceilings, and development of clinical guidelines.

Where agreements are not in place and therefore incentives are not awarded (64% and n = 74 LHEs with a reporting system), the reporting system to the GPs is based on a mix of overseeing power by the district manager, moral suasion, and emulation behaviors. If incentives cannot operate, sanctions are even more difficult to apply. The national contract with GPs provides a very complex and long procedure for inflicting sanctions to the GPs who overprescribe, provided that their sole responsibility can be proved. However, a district manager will never apply a sanction to avoid the risk of losing the collaboration of other GPs.

In 21% (n = 42) of LHEs an agreement has been signed with GPs to reduce in absolute terms, or decrease the growth of drug spending, which provides economic incentives. The little evidence thus far shows that monetary incentives may be given out, even if targets are not reached and reward those doctors who overprescribed in the past. The local agreements focused on the drug expenditure ceilings, euphemistically called budgets, imply a generalized reduction of drug expenditure, no matter what therapeutic group. Selective reductions of drug consumption (e.g., antibiotics) are usually

associated with the development of clinical guidelines or disease management.

The most evolved form of agreement concerns the development and implementation of local clinical guidelines. At present, 47% (n = 92) LHEs are involved in such experiments, of which nearly half operate "spontaneously," out of formal agreements and without incentives, and half with economic incentives (Table 5). The guidelines may concern drug therapy (52% of cases), diagnostic procedures, or the global management of diseases (67%). In most cases, the guidelines on drug therapies are associated with the use of hospital and specialist services, demonstrating a global approach to disease management. Thus, the guidelines are basically comprehensive and seek to avoid the risk of balloon squeezing, for example, squeezing drug expenditure, but increasing hospitalizations.

From the evidence gathered, a move from the traditional cost containment policy to a better use of therapies—in which drugs are seen as but one of components—seems under way. Unfortunately, a north/south divide still persists, where the north and center regions are carrying out the most innovative experiments, while the south regions almost stand still.

Reform Proposals

What else can be done? No reform proposal looms on the horizon, as far as the drug budget is concerned, nor does an evolution toward the fundholding system at the individual physician level, as in the British NHS, look likely. A systematic evaluation of the many experiences carried out so far in Italy would be advisable, if not necessary. There is a common belief that, whatever the results achieved, these experiments with GPs, or virtual budgets, are useful, in any case, and improve their consciousness about the use of drugs and their value: a belief not completely wrong, because Italy, through this mix of macro and micro measures, exhibits one of the lowest per-capita public drug expenditures in the European Union.

We thank Lou Garrison for his helpful comments.

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