

Pharmaceutical policy in Italy: towards a structural change?

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Abstract

Italian pharmaceutical policy has recently moved towards a “two lanes” approach, with regulation differing according to a drug’s patent status. This study analyses the Italian regulatory framework, focusing on policies related to “off-patent” drugs. Three main regulatory innovations have been examined: (i) generics, introduced in Italy for the first time in 1996; (ii) the reference pricing (RP) scheme, under which consumers pay part of the cost of high-priced products; (iii) pharmacists’ right of substitution, supported by a regressive margins system.

The recent reforms are already producing some worthwhile results, at least in terms of competitive pressure on the (few) substances that run out of patent protection. However, further intervention could be required to achieve long-term sustainability. © 2004 Elsevier Ireland Ltd. All rights reserved.

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1. Introduction

Every country in the European union (EU) has some sort of control over pharmaceutical pricing, reimbursement and dispensing. Most health care markets have been regulated according to the “public insurance approach” typical of Europe. Differences in regulation stem from the types of health care system adopted, the historical structure of the domestic industry and, more in general, local attitudes.

In Italy, the pharmaceutical market has usually been a favourite target for cost-containment interventions in the health care sector. The authorities find it easier to intervene on pharmaceutical expenditure since most of the health care budget consists of fixed costs (e.g.,

hospital services). As a consequence, regulatory authorities have aimed at short-run savings by imposing price cuts on reimbursable drugs [1]. These features are still typical of the Italian case. However, the most recent reforms seem to lead towards a “two lanes” approach in the market, by both increasing competition in off-patent products and supporting industrial R&D efforts through “premium prices” recognised for innovative drugs. This general model seems to fall in line with other European countries’ experience, like France, Germany, Spain, and the UK.

This paper, updates information on pharmaceutical policy in Italy. The first part examines Italian pharmaceutical policy during the last decade, briefly summing up the main issues that have contributed to the present structure of the system. The second part specifically focuses on the policies towards off-patent products. The recent introduction of generics and the reference pricing (RP) scheme will be analysed from both the

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regulatory and economic points of view, to assess their main consequences.

2. The Italian pharmaceutical policy: an overview

2.1. General framework

Introduced in 1978, the Italian national health service (INHS) is a public system funded by general

taxation which provides universal coverage and comprehensive health care, free at the point of delivery. The INHS has three institutional levels. The first is the department of health (DoH), which is responsible for national planning, allocation of financial resources among regions, and pharmaceutical policy. The intermediate tier consists of regional health authorities (RHAs) which are governed by elected politicians and whose activities are similar to the DoH but at regional level. Health care services are provided through local

Table 1
Main pharmaceutical reforms

Year	Law	Description	Notes
1993	Law 537	Average European Price (AEP) <ul style="list-style-type: none"> Based on prices in Spain, France, UK, Germany and on PPPs. Prices higher than AEP fixed at the AEP level Prices lower than AEP phased out to increase in 5 per 1 year tranches 	Applied in February 1994
		Revision of the positive list CUF started a reclassification of the positive list following two criteria: risk-benefit and cost	Revision ended in 1995
		National expenditure ceiling Delisting planned to prevent budget overruns	For 1994
1994	Law 724	Modification of tickets <ul style="list-style-type: none"> From 5,000 ITL to 3,000 ITL for 1 pack prescriptions From 5,000 ITL to 6,000 ITL for 2 or more packs prescriptions 	Applied in January 1995
1996	Law 323	Same price for same drugs Drugs with the same active substance, the same form, and the same route of administration must have the same price per chemical unit	
		Generics Introduced for the first time in the INHS <ul style="list-style-type: none"> Market approval in 120 days from the application Prices at least 20% lower than the innovator 	
	Law 662	New contractual model for pricing new drugs Prices are set through a negotiation between marketing companies and regulatory authorities. Mandatory discount on pharmacists' margin Retail margins are increasingly discounted according to classes of prices in favour of the INHS. Margins are now regressive. Generics are exempted from the INHS mandatory discount.	Applied in May 1997 Applied in January 1997
1997	Law 449	Modification of the AEP The AEP is now based on prices in all the EU countries, Denmark and Luxembourg excluded. Conversion is based on nominal exchange rates.	Applied in July 1998
	Law 450	Payback of market deficit Budget overruns should be covered by the INHS (40%), industry, wholesale and retail (60%)	Never applied
1998	Law 448	Modification of tickets 1000 ITL for each pack.	
2000	Law 388	Abolition of co-payments	Applied in 2001
		Reference price for off-patent drugs Off-patent drugs with the same active substance, the same form of administration, and pack size have the same reference price set as an average price of all drugs considered weighted by volumes sold	Applied in September 2001
		Transparency list The DoH issues the list of off-patent drugs with their actual and reference prices (issued quarterly)	Applied in April 2001
2001	Law 347	Modification of the reference price for off-patent drugs Reference price is now equal to the cheapest price out of the equivalent products on the regional market	Applied in December 2001
	Law 405	Regional expenditure ceiling Set at 13% of overall regional health care expenditure	Not respected
		Pharmacists' right of substitution A pharmacist can substitute a cheaper equivalent drug for prescribed medicines unless the substitution is prohibited by a physician	

Table 1 (Continued)

2002	Law 112	Reduction of CCP duration One year reduction every two years	Applied in 2003
		Cut of expenditure for pharmaceutical congresses in 2003 50% of 2001 expenses	Applied in 2003
	Law 178	Revision of the national positive list	Applied in January 2003
		Modification of prices for reimbursable drugs under patent protection Prices are recalculated on annual turnovers and DDDs and are set equal for the me-too drugs in the same therapeutical class	Applied in January 2003
	Law 289	Cut of expenditure for pharmaceutical congresses in 2004–2006 50% of 2003 expenses for years 2004–2006	For 2004–2006
		Modification of the INHS discount on pharmacists' margin 3.75% for prices < € 25.82 6% for € 25.83 – € 51.65 9% for € 51.66 – € 103.28 12.5% for € 103.29 – € 154.94 19% for > € 154.94	Applied in January 2003
		INHS discount exemption for off-patent products priced at the reference level	Applied in April 2003
		Premium price for innovative drugs The total budget available (0.1% of the total pharmaceutical expenditure) will be shared among manufacturers of new innovative drugs who invest in R&D in Italy	For 2003
2003	Law 326	Modification of the regional expenditure ceiling Overall pharmaceutical budget (pharmacies + hospitals) is set at 16% of regional health care expenditure.	For 2004

Abbreviations: PPP: purchasing parity power; ITL: Italian Lira; CCP: certificate of complementary protection; DoH: department of health; INHS: Italian national health service; R&D: research and development; DDD: defined daily dose; CUF: national drug committee.

health authorities (LHAs) and hospital trusts, i.e. the local tier of the INHS.

In the last decade, the INHS has been extensively reformed, mostly inspired by two major trends [2]:

- (1) *Increasing regional autonomy*: more autonomy in health care policy was devolved to the 20 regions, which are now allowed to collect local taxation and finance extra health care services in addition to the essential levels of care provided by all of them. Since 2001 RHAs are also financially accountable for any possible deficits (law 388/2000), pharmaceuticals included.
- (2) *Injecting managerial skills at local level*: initially LHAs were administered by local politicians, so they were open to political strategies and ambitions. Since the early 1990s, they have been run by General Managers appointed by RHAs, with renewable rolling contracts (D. Lgs. 502/92 & 517/93). This managerial trend was aimed at widely disseminating a local

budgetary approach, targeted also to pharmaceuticals.

2.2. A decade of reforms

After huge scandals came to light in the early 1990s [1,3], radical reforms were introduced in the whole public sector. The first important reform in the pharmaceutical sector was in 1993. Since then, pricing schemes, co-payment rules and the positive list have continuously changed. The main policy laws passed in the last ten years are summarised in Table 1.

2.2.1. Pricing

In 1993, prices were recalculated according to a new scheme, the average European price (AEP). Since then, many modifications and further pricing schemes have been introduced, sometimes overlapping. In 1997, a contractual model for prices of new drugs registered through the European centralised procedure was introduced and then extended to mutual recognition approval from 1998 [1]. Through this mechanism,

prices should be negotiated with the DoH and take account of the economic evaluations of products and of industrial investment. In 2003, however, all the prices of existing under-patent products were completely re-defined in line with a defined daily dose (DDD) based criterion applied to therapeutic groups [4]. An equal price is set for the active substances clustered in the same therapeutic group, calculated as an average daily cost for each group. The daily cost calculation is based on annual turnovers divided by the number of DDDs reimbursed by the INHS (law 138/2002). According to public estimates, this has led to a 5% price cut on average.

2.2.2. Budget ceilings

In 1994, the Italian government introduced a national drug expenditure ceiling for the first time. In 1998, it was agreed that any pharmaceutical budget overspending should be covered 40% by the INHS and the remaining 60% by pharmaceutical companies, wholesalers, and pharmacists (law 450/1997). Although industry and distribution did not pay their share of the deficit at that time, the scheme will be reintroduced in the budget law for 2004.

Since 2001, financial responsibility has been at regional rather than national level. RHAs are now accountable for their pharmaceutical budgets and are expected to cover deficits from their own sources. Thus, budget ceilings are now fixed for each RHA. In 2003, regional pharmaceutical expenditure through pharmacies should not exceed 13% of the regional overall health care expenditure (law 405/2001). As of 2004, the regional pharmaceutical budgets will include both pharmacy and hospital expenses to take into account the possible switch due to direct distribution (see below) and will be set at 16% of the regional overall health care expenditure (law 326/2003).

2.2.3. Co-paying

Co-payments and charges were introduced in Italy at the start of the INHS in 1978. After some modifications in 2000, the outgoing government abolished any form of co-payment and charges on drugs (law 388/2000), suspiciously just before general elections. This led to a steep rise in public pharmaceutical expenditure in 2001 (Table 2). To curb this

trend the newly elected government has continuously attempted to boost regional financial accountability rather than reintroducing national co-payments which could prove very unpopular. However, following the decentralisation trend, some regions have gone back to co-payments (law 405/2001). Currently, half of the 20 RHAs collect flat charges on prescriptions.

2.2.4. Pharmacists' margins

Starting from 1997, the retail margin, traditionally fixed as a proportion of the public price on reimbursed drugs (25.5% at present, VAT excluded), has been discounted in favour of the INHS according to defined classes of price to achieve a regressive effect. Hence, the more expensive drugs are now charged with a higher percentage. At present, discounts range from 3.75% for prices <€ 25.82, to 19% for prices >€ 154.94.

2.2.5. Direct distribution

In 2001, regions were allowed to use the so called "direct distribution" for a limited list of drugs (Law 405/2001). The aim is to reduce pharmaceutical expenditure by cutting down dispensing prices through public procurement. In practice, two different strategies have been implemented. In both of them, drugs are directly purchased by LHAs, but distribution channels are different. In one case, drugs are dispensed directly by LHAs and hospitals, thus, bypassing intermediate and retail distribution. In the other wholesalers and pharmacists agreed to dispense LHA-purchased drugs at much lower margins in order to limit their losses. At present, 14 RHAs extensively exploit this option; one of them claimed a saving of around 15% of the expenditure related to the list of drugs directly distributed in the first nine months of 2003 compared to the same period in 2002 [5].

2.2.6. GP prescribing

The 1993, reform made it possible for LHAs to introduce expenditure targets and saving incentives to GPs. However, there is no evidence that such measures were ever applied. In 1997, a Parliamentary commission created to check the macroeconomic compatibility of social expenditure re-launched the need to

Table 2
Public and private pharmaceutical expenditure in Italy (millions of Euro)

Year	1997		1998		1999		2000		2001		2002	
	Value	Index	Value	Index	Value	Index	Value	Index	Value	Index	Value	Index
Public pharmaceutical expenditure	7,284	100	7,917	109	8,758	120	10,038	138	12,134	167	12,630	173
Private pharmaceutical expenditure	4,919	100	5,332	108	5,640	115	5,382	109	5,141	105	5,090	103
Public health care expenditure	54,855	100	56,773	103	59,778	109	63,631	116	74,130	135	78,479	143
Gross domestic products	1,026,285	100	1,072,873	105	1,107,779	108	1,165,677	114	1,216,694	119	1,281,786	125
Co-payment and charges/public pharmaceutical expenditure	10.4%		10.2%		9.3%		8.7%		0.1%		2.7%	
Public pharmaceutical expenditure/ total pharmaceutical expenditure	59.7%		59.8%		60.8%		65.1%		70.2%		71.3%	
Public pharmaceutical expenditure/ public health care expenditure	13.3%		13.9%		14.7%		15.8%		16.4%		16.1%	
Total pharmaceutical expenditure/ gross domestic product	1.2%		1.2%		1.3%		1.3%		1.4%		1.4%	

impose some kind of “mild” budget restrictions on GPs. Even so, most efforts are still in the direction of more information between LHAs and GPs, rather than explicit targets [4].

2.2.7. R&D incentivess

As part of the strategy to launch a new industrial policy and turn Italy into an attractive country for R&D investment, in 2001 the government introduced a “premium price” for innovative drugs. This budget, which should have amounted originally to 0.1% of the total pharmaceutical expenditure, will be distributed among manufacturers of newly approved innovative drugs who invest in research in Italy. The broad budget has already been restricted to 10.2 million Euros for 2003. Thus, the “premium price” scheme may not be enough to enhance R&D investments in Italy. It is also worth noting that the slack in research investment in Italy does not involve only the pharmaceutical sector. Italy suffers from a historical lack of research oriented industry [6]. In the absence of serious attempts to improve and integrate academic and industrial efforts, the lack of spill-over between various sectors may well always penalise R&D investments in Italy compared to other countries.

3. Off-patent drugs

3.1. Regulation

The market of “off-patent” drugs in Italy is still very small, mainly for historical reasons. In addition to the usual 20 years patent, the Italian Complementary Certificate of Protection (CCP) on pharmaceuticals, introduced in 1991 (just before approval of the European Supplementary Protection Certificate) [7], permitted prolongation of patent rights for a further 18 years. Despite all recent attempts to abolish it by Parliament and Government, the CCP is still in force. The only compromise so far is a gradual reduction of the CCP period starting from 2003—every two years the CCP duration will be reduced by one year (Law 112/02) until Italy is aligned with the other EU countries.

Despite this limit, in the last few years the policy for “off-patent” products has followed a different path

from under-patent drugs. Three main regulatory innovations have been introduced.

3.1.1. Generics

The term “generic drug” was first introduced in Italy by the Law 323/1996, which specified that generic medicines are to be marketed under the International Non-proprietary Name (INN) followed by the manufacturer’s name, at a price at least 20% lower than the original drug [7]. Starting from 2002, prices of generics approved through mutual recognition in Europe have been also subject to negotiation with the DoH, like prices of specialities (see Section 2.2).

A main characteristic of the Italian “off-patent” system is the contemporary presence of both copies and generics. Copies are drugs with the same active substance and packs marketed with their own brand name. Copies flourished in Italy mainly for two reasons. First of all, Italy lacked patent protection for a long time; the Italian High Court included pharmaceuticals among products on which patent rights could be applied only in 1978. Copies marketed before 1978 were allowed to stay even after patent introduction. Secondly, Italy is the only EU country where “co-promotion” (i.e. the same brand sold by different companies) is forbidden. However, the practice of marketing the same active compound as different brands under the originator licence (i.e. “co-marketing”) has been a common practice and helped to increase the number of copies even after patent introduction.

Some studies have analysed the Italian pharmaceutical market considering copies as equivalent to generics [8], although there is little in common between generics and copies from a marketing point of view. Here we shall distinguish the two categories clearly: the term “generics” will refer only to products marketed under the INN followed by the manufacturer’s name.

3.1.2. Reference pricing

Starting from 2001, reimbursable off-patent products have been subject to a reference pricing system: if a drug price is higher than the reference limit, the patient is expected to pay the difference. At the real beginning the reference level was calculated as an average price (weighted by volumes of sales) of all the equivalent drugs whose price did not exceed that of the most expensive generic. As the DoH considered

the reimbursement limits calculated according to this method as too high, since the end of 2001 the reference limit has become the lowest price among the equivalent products available in the regional distribution network. Thus, reimbursable prices may slightly differ from one region to another, depending on local supply.

Differently from other, RP schemes in the EU [9], in Italy the RP is applied to the same pack size of equivalent products rather than to the same chemical or therapeutic group. As a consequence, the reimbursement limit can considerably differ from one pack to another of the same active component, depending on the different competitive pressure and consequent pricing strategies of manufacturers. A paradoxical example is offered by acyclovir (ATC: J05AB01). Two packs with the same administration form (oral) and the same dosage strength but different numbers of units (25 tablets and 35 tablets \times 800 mg) have at present reimbursement limits of € 67.23 and € 40.00 respectively, the larger costing about two thirds less than the smaller one.

A step towards a wider awareness of RP has been recently taken by issuing the so called “transparency list”, i.e. the list of reimbursable off-patent medicines and their reference prices. The list, issued first in 2001, is now published quarterly.

3.1.3. Pharmacists' margins

In 2001, the DoH introduced the pharmacist's right of substitution. A pharmacist is now allowed to substitute the cheapest available equivalent medicine for the prescribed drug, unless a physician indicates on the prescription form that substitution is prohibited, with the patient's agreement.

One substantial financial incentive to encourage substitution with generics by pharmacists has been the removal of the INHS mandatory discount on pharmacists' margins. At first all generics were exempted but to induce more price-sensitive pharmacists' behaviour, since 2003 the tax relief has been limited to those products (i.e. generics and copies) whose price does not exceed the reference level. It is worth noting that in most cases this rebate system hardly compensates the pharmacist's loss due to lower prices of generics and copies compared to originators. In cash terms, pharmacies can still earn more by dispensing the more expensive brands.

3.2. Market overview

The introduction of RP clearly aimed at containing demand for highly-priced products by cutting down reimbursement prices. Fig. 1 shows prices and volumes for the commonest packs of the top three active substances in terms of revenue, with at least one generic version: ticlopidine (thrombocyte antiaggregant, ATC: B01AC05), nimesulide (NSAID, ATC: M01AX17), and ranitidine (histamine-2-receptor antagonist, ATC: A02BA02).

The RP's effect on prices is clear from these three cases. In all three, the prices tended to fall. In particular, there were steep drops for nimesulide and ticlopidine at the end of 2001, when the reimbursement limit was redefined, while ranitidine prices started falling at the beginning of 2002, after the launch of the first generic. Generics gained market shares in all three cases with a greater increase where the price gap between generics and originators (and/or copies) is wider. The impact of RP on the total sales volumes of the three substances is more uneven, depending on the different competitive “arenas”, which include under-patent me-too drugs. For instance, the sharp drop in total volumes of ranitidine may be explained by the availability of many in-patent drugs with the same therapeutic indication (e.g. omeprazole and its derivatives), energetically promoted by companies to avoid price competition.

Despite these successful examples, the overall market for reimbursed generics is still under-developed in Italy, their share of public pharmaceutical expenditure being only 1.2% in 2002. The generic market is also very small compared only to “off-patent” products (17% in 2002), which includes copies and originators. Thus, low penetration of generics can not be related only to the long patent protections.

The awareness of the positive effects of generics in containing pharmaceutical expenditure should encourage RHAs to promote local initiatives aimed at supporting generic diffusion. However, there is scant evidence of regional measures in this sense. At present, only one region (Sicily) is planning to introduce an explicit incentive, by cutting down co-payments for generic products. This lack of support might explain why the generics' share, although uneven, is still very limited in all the Italian regions, varying from 4 to 1% in volumes (Fig. 2).

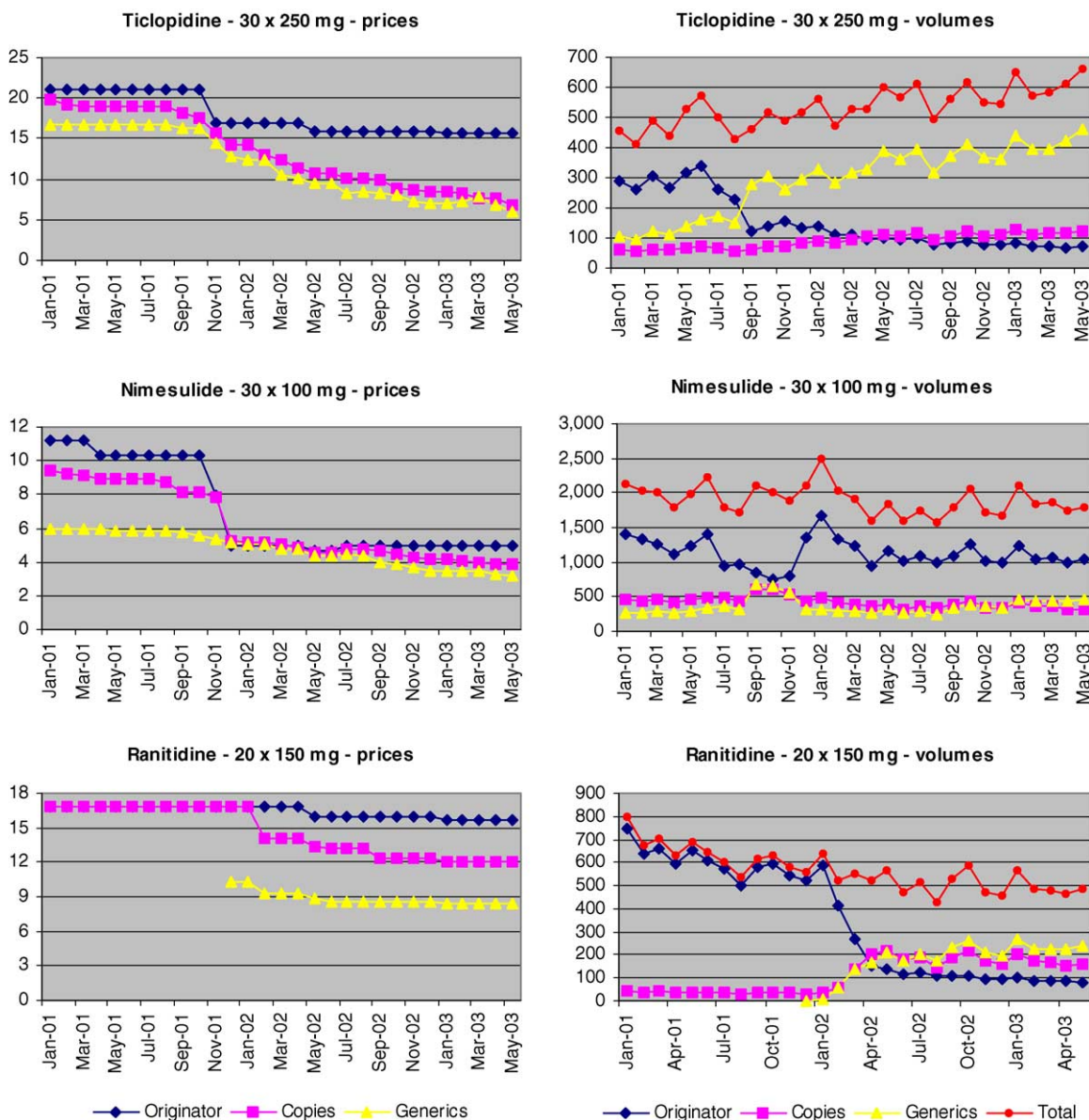


Fig. 1. Prices (Euros) and volumes sold (thousands of packs).

LHAs too should be interested in initiatives to encourage the use of generics locally, although their political dependence on RHAs is likely to affect their attitudes. A recent survey of 11 LHAs (from eight Italian regions), selected among the most active in supporting generics, did not give encouraging results [10]. All these LHAs organised public meetings on

generics and distributed information, i.e. leaflets and advertisements, among GPs, pharmacists, and the population. While seven LHAs regularly provided GPs with a list of locally available generics, only two of them sent GPs reports on their prescription patterns, highlighting the generics' share, but none introduced any specific incentive. As Fig. 3 shows, there seems to

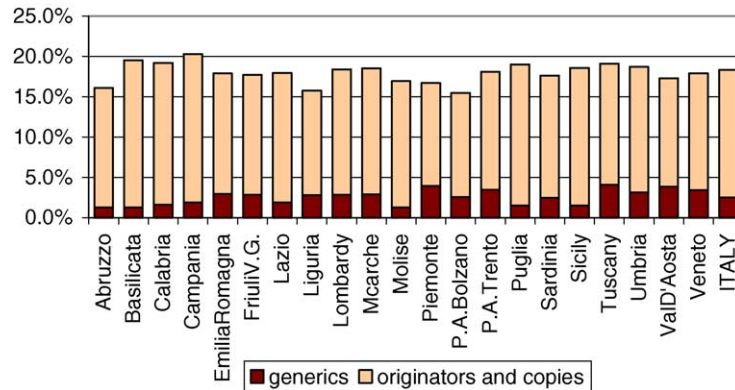


Fig. 2. Share of “off-patent” products on regional pharmaceutical volumes of reimbursed packs (2002). *Source:* IMS Health.

be no evidence that informative action alone enhances the spread of generics: in none of the 11 LHAs in our sample did the share of generics substantially exceed the regional average -in five LHAs it was in fact lower.

4. Discussion

In most EU countries, the decision to ensure a universal coverage for all basic health needs has created serious financial problems. On account of the many political and practical difficulties in reforming the whole health care systems, one favourite target for

cost containment policies has been the pharmaceutical market. In Italy, public pharmaceutical expenditure has traditionally been regulated in a very centralised way, mainly through rigid price schemes and continuous reviews of the positive list. In the last few years, the approach has shifted slightly, also following what is happening in other EU countries. Italian pharmaceutical policy seems to be moving towards a “two lanes” approach, depending on the patent situation of reimbursable products. Most of the main recent structural reforms involve off-patent active substances and aim at increasing competition among equivalent products. This seems an important turning point in the Italian regulator’s approach to pharmaceutical policy. In this

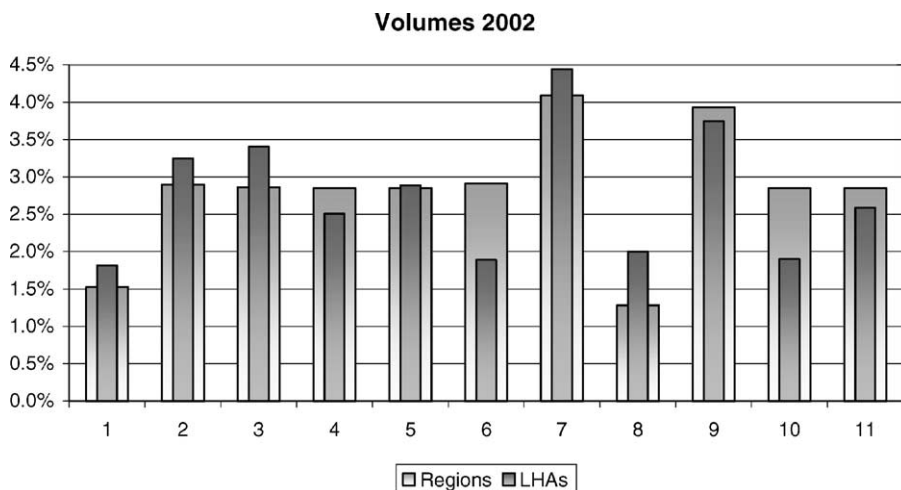


Fig. 3. Comparison of the 11 LHAs’ generics shares and the corresponding regional averages, in volumes. *Source:* Martina et al., 2002.

study we focused on the regulation and on the main consequences of these new policies.

Generic medicines still hold only a small share of the Italian pharmaceutical market, for two potential reasons. First of all, patent protection is still largely affected by the extension of patent coverage (CCP). According to recent estimates, the off-patent drugs market (generics, copies and originators) accounts for only 7% in value of the whole sector (16% in volume). This is clearly a strong upper limit to the development of generics, independently of their ability to penetrate the market. Secondly, the presence of many copies, marketed with brand names by domestic companies for many years before the patent expired, raises tougher barriers to entry for generics in Italy than in other European countries.

By limiting the level of reimbursement, the RP aims at containing demand for highly-priced products and creating incentives for price reductions. The case studies shown indicate that prices dropped dramatically after the introduction of RP. However, RP alone, without the presence of generics, may have little impact. A good example of this seems to be nitroglycerine plaster (ATC: C01DA02), i.e. the first off-patent substance in terms of revenues. Because of the lack of “know-how” for manufacturing plasters, no generic version is available and prices are still at the same level as in the past without any variation either in time or between products. Therefore, competition is not effective in this case, even under RP.

More in general, according to the literature [9,11], the relation between the number of generics (a proxy of what could be called “intra-generic competition”) and the average prices of branded “off-patent” products under the RP scheme is negative, i.e. prices drop more where there are more competing generics. This is the case for the Italian market too [12]. Thus, generics play an important role since the long-run sustainability of a policy aimed at undermining strong dominant positions of originators depends on ability of generics to penetrate the market. Therefore, the scheme devised by Italian regulators might prove weak in the long run. In particular, two major problems might arise:

1. The three case studies showed that prices dropped quite quickly. This is probably closely related to

the way RP is set up in Italy. As RP is the lowest price on the market, a steeper downward trend in prices can be expected compared to other countries where the RP is based on a larger subset of products (e.g., Germany, the Netherlands and the UK). This is compounded by the DoH practice of allowing reimbursability of generics approved under mutual recognition only if they enter at prices much lower than the existing RP. Although this might be considered a successful strategy, the authorities must be more careful about boosting too violent “price wars”. The main risk is that prices may drop too far in too short a time, forcing many companies out of the market. Generic manufacturers, with their weak position in a long war of attrition, could be among the first to drop out, leaving the market without the main “inducers of competition” and eventually undermining the regulator’s efforts. In addition, originators could find it worthwhile to play a “limit pricing” strategy [13], dropping their prices to below the manufacturing costs to prevent generics to enter or to force them out. Of course, the success of such a strategy would depend on whether the originators could convince the authorities to raise prices again after the “war” ends. However, in that circumstance their bargaining power would be strong as they would be the only suppliers left.

2. The other issue is related to the “two lanes” approach. Splitting the whole market into two groups according to the patent situation can create some problems in the long run. It is well known that after the first period of RP, public expenditure may pick up again due to an increase in prescriptions of non-referenced products [9,14,15]. Without extending the RP level to the whole set of me-too drugs in a therapeutic group, a successful strategy for big companies has been to switch their promotional efforts on prescribers to similar products still under patent protection, thus, avoiding the problematic competition with generics. In the long run, this can lead to a marked shift of demand towards new and more expensive products.

In conclusion, the Italian “two lanes” policy is just at its beginning. Generics and RP, together with other tools inducing high price-sensitivity in demand, seem

to be a rational move towards higher levels of competition for mature products in a market traditionally featuring heavy regulation and comfortable rent positions. The recent reforms are already producing some worthwhile results, at least in terms of competitive pressure on the (few) substances that run out of patent protection. However, further intervention could be required to achieve long-term sustainability.

References

- [1] Fattore G, Jommi C. The new pharmaceutical policy in Italy. *Health Policy* 1998;46(1):21–41.
- [2] Jommi C, Cantù E, Anessi-Pessina E. New funding arrangements in the Italian National Health Service. *International Journal of Health and Planning Management* 2001;16:347–68.
- [3] European Observatory on Health Care Systems website (<http://www.observatory.dk>).
- [4] Mapelli V, Lucioni C. Spending on pharmaceuticals in Italy: Macro constraints with local autonomy. *Value Health* 2003;6:S31–45.
- [5] Maccani P. Le nuove modalità di distribuzione dei farmaci: l'esperienza dell'APSS di Trento. *Economia e Politica del Farmaco* 2004;1:23–7.
- [6] De Marchi M, Rocchi M. Basic research in the Italian industry. *Research and Development Management* 2002;30(1):79–88.
- [7] Garattini L, Tediosi F. A comparative analysis of generics markets in five European countries. *Health Policy* 2000;51(3):149–62.
- [8] Danzon P, Chao L. Does regulation drive out competition in pharmaceutical markets? *Journal of Law and Economics* 2000;43:311–57.
- [9] Lopez-Casnovas G, Puig-Junoy J. Review of the literature on reference pricing. *Health Policy* 2000;54:87–123.
- [10] Martina S, Cornago D, Garattini L. Gruppo di studio I.H.A.G.O. Incentivi ai farmaci generici a livello di ASL: l'osservatorio I.H.A.G.O. *Farmacoeconomia e percorsi terapeutici* 2002;3(2):71–80.
- [11] Pavcnik N. Do pharmaceutical prices respond to potential out-of-pocket expenses? *RAND Journal of Economics* 2002;33(3):469–87.
- [12] Ghislandi S. Generic drugs: regulation and competition in the Italian pharmaceutical industry. MPhil thesis, University of Oxford; 2003.
- [13] Varian HR. *Microeconomic analysis*. 3rd ed. New York: WW Norton & Company, 1992.
- [14] Giuliani G, Selke G, Garattini L. The German experience in reference pricing. *Health Policy* 1998;44:73–85.
- [15] Grootendorst PV, Dolovich LR, O'Brien BJ, Holbrook AM, Levy AR. Impact of reference-based pricing of nitrates on the use and costs of anti-anginal drugs. *Canadian Medical Association Journal* 2001;165(8):1011–9.