

THE EFFECT OF PRICING POLICIES AND COST-CONTAINMENT MEASURES IN ALBANIAN HEALTH INSURANCE SCHEME

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Abstract

This paper presents and analyses the evolution of pharmaceutical expenditure, to see the effect of policy measures targeting pharmaceutical expenditure in Health Insurance Scheme in Albania. Quantitative analysis of time series data, comparing and controlled before-after measures are undertaken. In order to answer the research question concerning Albanian pharmaceutical expenditures on HIS are used official data from Health Insurance Institute and other institutions' statistics. Based on this analysis, the appropriate model of regulation in Albanian health scheme, may involve a combination of positive list, restriction on prescribing and reimbursement systems, price control, reference pricing, expenditures drugs control, mark-up scheme and generic substitution. The controlling of health care costs requires a more effective and efficient health care system. The high level of expenditures on pharmaceuticals is likely due to the lack of rules and regulations to control this sector and the lack of a significant policy for using generic drugs as substitutes for expensive products with the same active substances. In the economic and social conditions of Albania, it is important the continual expansion of the list of generic reimbursable drugs, as well as the strengthening the control and monitoring of the financial impact. Is necessary an increasing of accountability of policy makers at all levels of the management health scheme and to strengthen the role of the HII as the sole purchaser of health services in Albania.

Key words: expenditure, pharmaceuticles, reimbursement, reference pricing, quantitative analysis.

JEL Classification: I18, H51

1. Introduction

In Albanian social health insurance scheme (HIS), the costs of illnesses are considered as a public concern, and also as a protection against the social costs of illnesses. Health Insurance Institute (HII) is a semi-autonomous agency accountable to the Parliament, a third party payer that manages the HIS. HII is in charge of managing the reimbursement list, monitors prescribing behaviors, contracts with pharmacies, administers Primary Health Care service etc. HII has purchased a restricted package of health services and pharmaceuticals. Controlling health care expenditures has been years for several a political objective in Albania. Health scheme functions partly, an informal labor market, lack of incentives for participation in health scheme, weak administration capacity for contributions' collecting and poor

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structure, regulatory and supervisor and all in all it's funding challenges, are the main factors that accompany for years the health care system. Public health care expenditures have reached a threshold that, politically, seems difficult to cross.

A complex mix of factors and risks, both, supply and demand has contributed to the increasing in health care spending. Informal payments are partly a reaction to the health care system, particularly of the managers of health care, the lack of financial resources and patients' response to a system that is unable to provide adequate access to the basic services. HII enrolment varies among the different population groups. The whole population is included in this scheme but there is a categorization of the population such as pensioners, children under one year old, war veterans etc., who receive different level of reimbursement. The majority of the unemployed people, including children and women, who work at home, and the elderly, are automatically covered by the state budget. The state is responsible for covering the non-active population (such as pensioners, veterans and students). Increasing costs constantly for these categories constitutes the internal risk for health scheme. For example, expenses for drugs used to treat the category of "Pensioners" patient's, that comprises about 14% of the population, or about 230 thousand, benefited in 2012 more than 45% of the budget for reimbursement of drugs. Also in the new EU member states, from Central and Eastern Europe, a large share of total expenditures on pharmaceuticals is paid by public means. Different measures have been introduced in an attempt to contain costs, but at the same time these countries have maintained their inherited concern with protecting vulnerable groups and those who are suffering from serious diseases (Mossialos E. et al., 2004).

HII reimburses a defined list of out-patient drugs for the estimated 40-45% of the population that benefit from effective scheme coverage (World Bank, 2006). The Albanian reimbursement scheme is designed to cover a broad range of drugs that are reviewed annually. The current reimbursement scheme was first introduced in 1995. The reimbursed list has been continuously expanded with more innovative drugs and for a broader specter of diseases. A person with a newly diagnosed illness may register with HII and will receive immediate coverage without a waiting period or an exclusion of pre-existing conditions. There is a positive list (in 2013 has 426 generic drugs), which contains a restricted number of pharmaceuticals compared with the total number of drugs under circulation in the country (approximately 4000). Expenditures for drugs, both in the out-patient and in-patient care, are increasing on an annual basis. Decisions regarding inclusion on HII positive list are made by the Reimbursement Commission established by the Ministry of Health (MOH). The Reimbursement Departments at HII manages the list, while the 12 regional HII offices are responsible for issuing the serial coded, prescription forms and for the reimbursing of the contracting pharmacies. A controlling department analyzes prescriptions and investigates cases of alleged abuse or fraud.

Contracting with physicians, pharmacies and wholesalers allows HII to collect data for monitoring prescribing behavior and to catch those who try to play the

system for their own benefits. Reimbursed drugs are dispensed through a network of approximately 80 wholesalers 950 private pharmacies and pharmaceutical agencies across the country (HII, 2013), which have contracts with HII. All the drugs that have received permission from the National Centre of Drugs Control to enter the Albanian market can be included in the Reimbursement Drugs List. Previous to drafting of the list, other criteria are taken in consideration such as: the financial impact on the HII budget, requirements from the patients, lack of alternative therapies and reference price. The hospital services are covered by the special governmental budget. The reimbursement scheme is not applied for pharmaceuticals served at hospitals.

New policies and political decisions in health and pharmaceutical sector are introduced with no corresponding financial impact considered or accounted for the in budget. Increasing effectiveness and efficiency of health care and long-term care are getting more value for money out of the resources allocated to the sector are likely to become one of the most important challenges in the coming years for all actors of health insurance scheme in Albania.

The aim of this paper is to review the existing pharmaceuticals cost-containment policies in Albania in order to illustrate the complexity of the drug policy decision making and to assess the effectiveness of the cost-containment measures introduced so far. The paper will be focused on measures that aim the reducing of the public expenditures on pharmaceutical products. To discuss the possible policy options for better achievement of health policy goals within the context of strained health budgets and to evidence the main risks related to HIS costs; obstacles and factors underlying present and future spending pressures and main challenges in health spending and administer in Albania. The paper will focus and will include a review of pricing related major changes in reimbursement lists, margins, co-payment rates, reference prices system, ceiling or mixed mechanism used by health insurance scheme and highlights the need for policies and interventions for further ill costs reduction in Albania health insurance scheme.

2. Research design and methodology

After a general overview of the evolution of the reimbursement scheme from its beginning in 1995 until now, I have described the policies and measures taken over the years, by analyzing two perspectives supply-side and demand-side cost-containment measures. According to the official data of Health Insurance Institute and other Albanian institutions, I analyzed different data of Health Insurance Scheme, from 1995-2012 and mainly pharmaceutical expenditures data. Via the different methods and quantitative analysis of time series data, comparing and controlled before-after measures and descriptive analysis, drew conclusions and made concrete analysis. I referred to groups of drugs with higher weight in the costs of the scheme (expensive drugs), analysis of new drug, comparison of categories with higher value in drug's expenditures, etc. For a detailed analysis, I was precisely

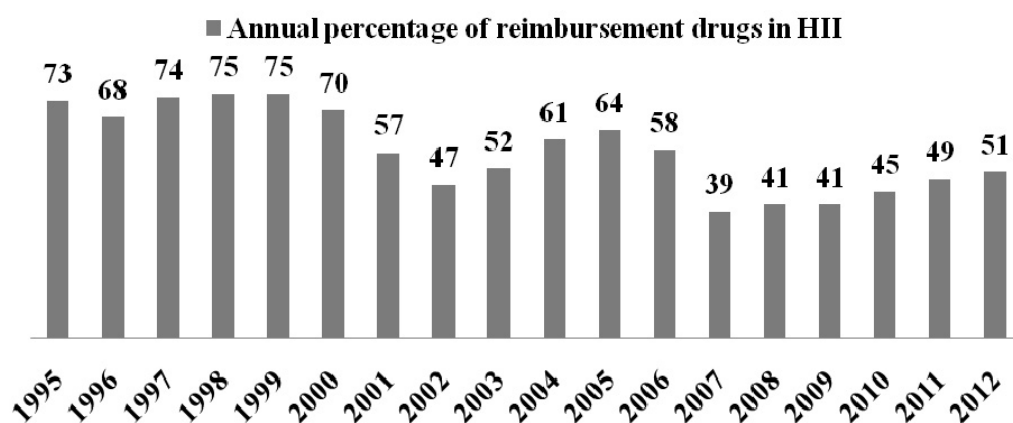
focused in HII data between 2005 and 2012 in Albania. I have chosen to analyze these years, because in the recent years result the major effects of the policies and measures related to pricing and reimbursement.

2.1 Reimbursement scheme, funds and drugs reimbursement list

Albanian health services are funded through a mix of taxation and statutory insurance. The State budget revenues remain the main sources, not only for all public health sectors, but also for the HIS. The health scheme revenues in 2011 and 2012 came approximately 23% from health contributions and approximately 77% from State budget.

HII manages a total annual budget of approximately € 200 million. This budget in 2013 is planned approximately 2% of GDP, while for three years, 2010-2012 the rate of 2.1% has not changed (MOF, 2011). Expenditures of reimbursement drugs in 2012 occupy 23% of total health expenditure in Albania (MOH, 2012). The main part of HII expenditures in 2012 (without the hospital's budget) was for pharmaceutical reimbursement 51% (or € 57 million) and primary health care financing 40% (Currency in Albania; 1 € exchange with 140 ALL), (HII, 2013). During the operation of the HIS, the value of the reimbursement costs in the total cost of the scheme has been different, but significant (figure no.1).

Figure no.1 - Trend of expenditure's drugs as percentage in total HIS's expenditures



Source: HII, the author's calculation

HII receives annually a certain budget from the Ministry of Finance for the reimbursement of drugs on the positive list. Expenditures for the coverage of the drugs reimbursement have been continuously increased due to different reasons, such as expansion of the health insurance scheme, reimbursement of innovative drugs, the tendency of the physicians to prescribe expensive therapies, etc.

MOH and HII are responsible for pharmaceuticals reimbursement for all the drugs included in the positive list, for some categories of patients and the information concerns pharmaceuticals prices and reimbursement policy. The reimbursement scheme is designed in such manner that covers the most essential drugs and a broad scope of diseases.

The HII reimbursement scheme involves the whole country and the whole population and it covers all the medical services. Medical examinations and pharmaceutical service for out-patient care are reimbursed by HII through contracts with general and specialist practitioners, and pharmacies.

Table no.1 Trend of Drugs Reimbursement List in Albanian HIS, 1995-2013

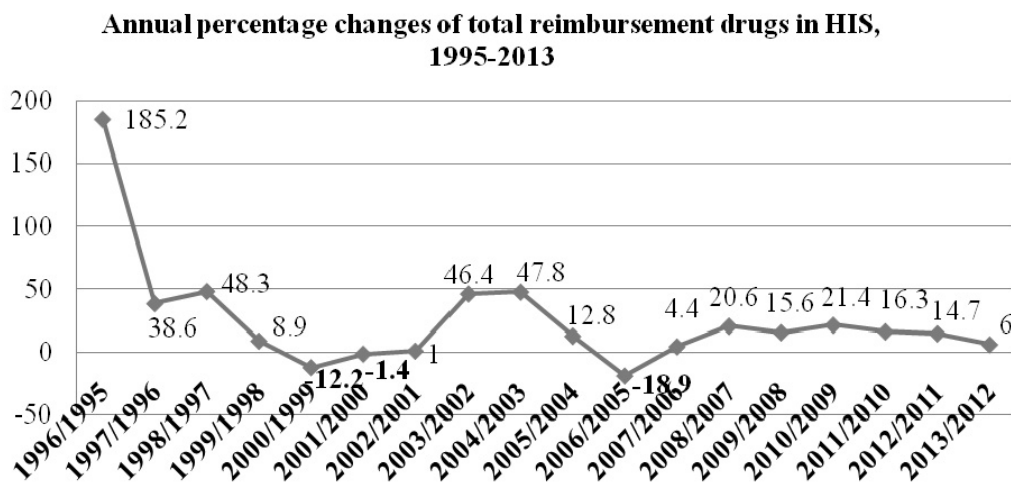
Years	Annual Expenditures of Reimbursement Drugs (in millions ALL)	Annual Percentage Changes of Total Reimbursement Drugs	Number of the First Alternative Drugs	Number of the Active Substances	Number of the Total Alternative Drugs
1995	304		174	174	174
1996	867	185.2	278	174	278
1997	1,202	38.6	278	184	278
1998	1,783	48.3	278	184	278
1999	1,941	8.9	278	197	596
2000	1,705	-12.2	308	175	611
2001	1,681	-1.4	308	181	625
2002	1,697	1	341	213	650
2003	2,484	46.4	346	209	791
2004	3,672	47.8	346	209	724
2005	4,143	12.8	402	238	722
2006	3,361	-18.9	355	207	748
2007	3,510	4.4	362	220	824
2008	4,233	20.6	377	222	865
2009	4,892	15.6	405	233	944
2010	5,941	21.4	409	236	991
2011	6,909	16.3	420	236	1061
2012	7,922	14.7	413	233	1102
2013	8,400	6	426	239	1135

Source: HII

During the years 2005-2013 list of reimbursable drugs has totally increased with 206 new drugs reaching the number of 426 drugs in 2013, 239 current active principles, always keeping within budgets allocated provision for reimbursement of drugs (table no. 1). At the same period the drugs' number in 2013 is increased only with 24 drugs, compared to 2005 (from 402 to 426 drugs or 6%) and active substances are increased only with 1 drug, (in 2005 are 238 and 2013 are 239 active substances). Basing on HII data, a continuous increase of expenditures for reimbursed drugs is evident. If I refer to 1995, the average growth of expenditures of pharmaceutical in drugs' scheme is 25.3%, including the expected value for 2013. The main changes in reimbursement scheme are made by 2005.

From 2005 to 2012, the growth of drug reimbursement expenditures was average 10.9% (figure no. 2). The expenditures for reimbursed drugs from 2005 to 2013 are doubled (€ 29 million in 2005 to € 60 million planned to 2013). One main reason is the expansion of the reimbursement scheme. For example, if referring increase spending by therapeutic groups, expenses for drugs used to treat patients suffering from cardiovascular and hypertension diseases are increased by about 936 million ALL/ € 7 million or about 43% (for the period 2007-2012). This group (C Group) makes up nearly 32% of total drug reimbursement expenditures. The chronic diseases are growing because of different reasons and the risk is greater. For example, diabetes's cost increased by 159% more in 2012, compared to 2007. Policies may also aim directly the controlling expenditures.

Figure no. 2 – The trend of changing reimbursement of expenditures of reimbursed drugs, from the introduction of health insurance schemes in Albania, 1995-2013



Pricing and reimbursement policies are always interlinked. Pharmaceutical policies are related to pricing, reimbursement, market entry and expenditure control. A positive list contains the drugs that will receive different levels of reimbursement (Nuijten M. et al., 2001). In 2005 the reimbursable scheme was extended to 72 drugs or 44 active substances, reimbursement, whose has occupied about 14.5-22.2% of total reimbursement of expenditures each year, between 2005 and 2012 (table no. 2).

Expenditures on HII financed prescription drugs are doubled over the past three years, during 2005 have been increased 25% more than in 2004 and 94% more than in 2003. This comes in a HII deficit for the following year. The rapidly increasing spending on prescription drugs over the past these years was largely the result of an imprudent expansion of the positive list of drugs, and of the cancellation of co-payments for most beneficiaries. Pensioners, the main beneficiaries of these new reimbursement rules, from 2005 are now responsible for close from 50% in 2005 to 70% of total HII drug's expenditures in 2010. These policy changes led to a substantial deficit of HII in 2005 and a situation in which HII was no longer in a position to pay suppliers (HII hasn't respected contracts with pharmacies, for payment of refunds for many months. This led to increased interest payment and therefore delay further aggravated the situation in the budget of the health scheme). The Government adopted an amendment to the Budget Law in December of 2005, allowing for an additional transfer from the state budget to HII of 1 billion ALL. In the spring of 2006 the Government reintroduced a flat co-payment per prescription to help stem the rapidly rising drugs expenditure. Additional policy measures, such as the tightening of the positive list of drugs, changes to the reimbursement policy and further revision of the margins to drugs were necessary to curb further cost increases and ensure the sustainability of HII's drugs reimbursement scheme (Avdi. E. 2011).

In order to reduce the costs of reimbursement due to the financial situation of HII, in 2006 were removed 37 drugs with recommendation of the World Bank and WHO, as well as unregistered drugs' entire. Between 2005 and 2013, the policy related to the inclusion or not of new drugs in the list of reimbursable drugs, has been variable depending on the budget allocated to the health insurance scheme. Table no. 2 reflects the performance of all new drugs in the reimbursement scheme in Albania, from the year of their entry in the list of reimbursement up 2012. In 2012 for the first time after 2004, the list was not increased because of budget constraints. I made analysis of 2005, because in this year was increased not only the largest number of drugs (72 drugs), but also with continuing financial effect of expenditures in the health scheme.

Table no.2 Annual trend in percentage of the reimbursement of new drugs, in relation to the total cost of reimbursement, from the moment of inclusion in the health scheme, from 2005 up to 2012.

	2005	2006	2007	2008	2009	2010	2011
2005	14.50						
2006	19.19	0.04					
2007	22.23	0.19	4.84				
2008	20.08	0.18	8.44	0.23			
2009	17.99	0.15	8.00	2.38	2.05		
2010	15.99	0.11	7.67	4.44	9.78	0.37	
2011	14.76	0.10	7.08	6.21	12.87	1.64	0.31
2012	15.92	0.07	5.84	6.89	11.08	3.20	1.20
MIN	14.5	0.04	4.84	0.23	2.05	0.37	0.31
MAX	22.23	0.19	8.44	6.89	12.87	3.20	1.20
MEDIAN	16.99	0.11	7.38	4.44	10.43	1.64	0.76
AVERAGE	17.58	0.12	6.98	4.03	8.95	1.74	0.76

Source: HII, the author's calculation

Expressed in value, 13 new drugs included in 2007 and 31 new drugs involved in 2009, continue to have the larger weight of the costs of the HIS until 2012, respectively € 16 million and € 17 million, for each group of new drugs. Studies about benefits and costs of newer drugs in EU countries came to the conclusion that allowing people to use only generic drugs would increase total treatment costs, instead of reducing them, and would lead to worse outcomes (Lichtenberg FR. 2001).

2.2 Need to force cost-containment measures in Albanian health insurance scheme

Being that cost containment provides a support for the review, development and implementation of policies which define the funding and overall allocation of resources to health services, HII is trying to improve the insurance mechanisms in order to contain cost. The cost containment policies show that in many countries, pharmaceuticals markets are heavily regulated, governments are trying to protect population health and to guarantee access to safe and effective medicines, while constraining pharmaceuticals expenditures (Mossialos E. at al., 2005). The price controls certainly can have an impact on either slowing price increases or lowering drug prices. To what extent pharmaceuticals prices can be regulated or what is the reasonable price is still an ongoing debate, as shown by the various methods used in the EU countries.

Supply-side cost-containment measures are primarily targeted either directly or indirectly at regulating the prices of pharmaceuticals. Prices of reimbursed drugs are negotiable at the manufacturer level whereas prices of pharmaceuticals not included in the positive list are not negotiable. Prices of non-reimbursed drugs are set on free

bases and are subject to statutory mark-ups. Drugs included in the positive list are selected according to the following criteria: product specific criterion, disease criterion and economic criterion. Pharmacies are supplied by wholesalers with all the types of drugs circulating at the Albanian market.

Reference prices in Albanian pharmaceutical scheme are established basing on the cheapest drug with the same active substance and dosage within a group, i.e. on ATC 5 level (application for the first time in 2001). They are changed on annual basis just like the reimbursement drugs list depending on the drugs and the relevant prices offered by pharmaceutical companies. If a more expensive drug is prescribed, the patient has to pay the difference out-of-pocket. There is no mandatory generic substitution in place but the pharmacist is allowed to substitute a drug with its generic of the same substance, strength and form on a voluntary basis.

The patient pays the difference between the reference price and the pharmacy price. Thus, the goal of this measure is to limit the third party expenditure on prescription drugs, not the overall expenditure on medicines.

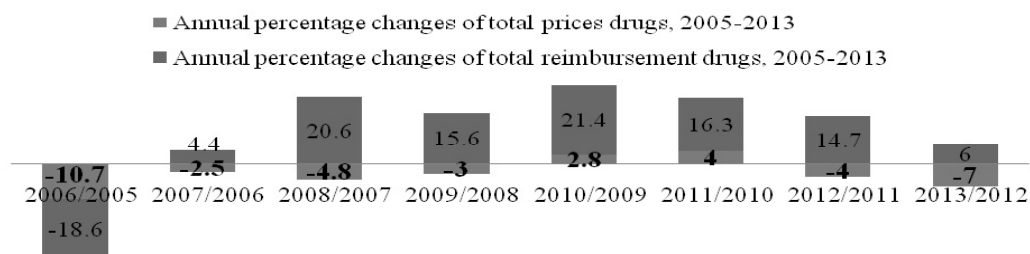
Different versions of internal reference pricing schemes are applied across EU. With the exception of Netherlands and Hungary, who apply therapeutic reference pricing schemes, the other EU countries apply an active substance reference pricing. The use of reference pricing does not always achieve the cost-containment aim and does not result in important long-term savings. (Lopez-Casasnovas G. at. al., 2000).

Various systems of price control can be found across the EU. In most countries, the maximum price of medicines is determined in comparison with the neighboring countries. In Bulgaria, the prices cannot be higher than the retail prices found in nine countries. In Romania, prices have been set as the lowest price from a basket of 12 countries (Ministry of Health, Romania, 2009).

However, not always these types of policies have the expected effect. This policy often fails to have a cost containment effect because the pharmaceutical companies lower their prices to coincide with the reference price (Mossialos E. at. al., 2005).

In Albania the introduction of therapeutic reference pricing between 2005 and 2013 had limited impact on reduction of the pharmaceutical expenditures (figure no.3).

Figure no. 3 - Reference prices and pharmaceutical expenditures correlation, 2005-2013



The reduce of the reference prices, not always reflected in the reduction of costs reimbursement. Although between 2006 and 2009 reference prices were reduced, the reimbursement costs continued to increase in 20.6% in 2008 compared to 2007. According to the prevision of the financial effect for the 2013, by lowering of the reference prices in 2013 compared with 2012, benefited a value of 693 million ALL / approximately € 5 million. Half of this amount was benefited by the application of external reference prices.

From 2012, in Albania exist as an official procedure *External Reference Price*, which is a price comparison that was made with a group of other countries. Each state selects which countries will formally compare prices according to his criteria. Countries with low income countries should refer to the same standard. Albania, as all European countries, use external reference price compared with other countries, at least 3 others, Greece, Macedonia and Italia.

In order to reduce expenditures in HIS, other significant politics and cost-containment measures are as follows:

Different levels of margins are applied for reimbursable pharmaceuticals in the reimbursement scheme. Pharmaceuticals are divided in six groups according to the percentage of the reimbursement coverage. According to percentages they are divided into groups as follows: 100% drugs that treat cancer, etc., 85-95% insulin for diabetics, etc., 75-85% drugs for chronic conditions, such as coronary heart disease, etc., 65-75% drugs for urinary infections, etc., 55%-65% drugs treating mycosis, rheumatisms, etc. and 50% antibiotics, etc.

It's a regressive margin system for medicines in Albania. The purpose of such a regressive margin is to reduce the incentive for pharmacists to recommend expensive, branded drugs over cheaper generics.

Margin cuts or the design of mark-ups for distributors of pharmaceuticals may affect dispensing behavior. Retail mark-ups (wholesale and retail margins) in Albania are annually regulated by the Council of Ministers. Decisions and according to the proposal put forth by the Prices Commission after negotiations with local and foreign producers or their representatives and holders of the registration certificate.

The first mark-up scheme on pharmaceuticals in Albania was introduced in 1995 and was 15% for wholesalers over the CIF prices and, 35% for pharmacies over wholesale prices. In May 1998 a new mark-up percentage of 12% for the wholesalers and 27% for the pharmacies were introduced by the Albanian authorities. In 2005 mark-ups were changed to 18% for the wholesalers and 33% for the pharmacies. For some reimbursable and expensive drugs lower mark-ups were applied (8%, 15%; 10%, 20%; 12%, 24%; and 15%, 30%). This application has inceased annual expenditures for drugs approximately € 1.5 million. In 2006 mark-up scheme were changed to 12% for the wholesalers and 29% for the pharmacies for all reimbursable

drugs (lower mark-ups for expensive drugs; 8%, 0%; 8%, 15%; 10%, 20%; and 12%, 24%), affected up to half of 2011 (table no. 3).

The pharmany mark-up scheme was last modified in 2011 by the Council of Ministers, affected in the drug list of 2012 and is still applying (10% for wholesalers and 26% for pharmacies for all reimbursable drugs).

Table no.3 Economic effect of appliance of tow last mark-up schemes

Prescription Average Values (in ALL)	Mark-up scheme 2010-2011			Mark-up scheme 2011-2012		
	Wholesalers	Pharmacies	Profits (in million ALL)	Wholesalers	Pharmacies	Profits (in million ALL)
180.000- 400.000	8%	0%	450	6%	0%	482
40.000- 180.000	8%	15%	17	6%	12%	18
10.000- 40.000	10%	20%	72	6%	15%	123
3.000- 10.000	12%	24%	63	8%	20%	123
Total Profits			602	Total Profits		746

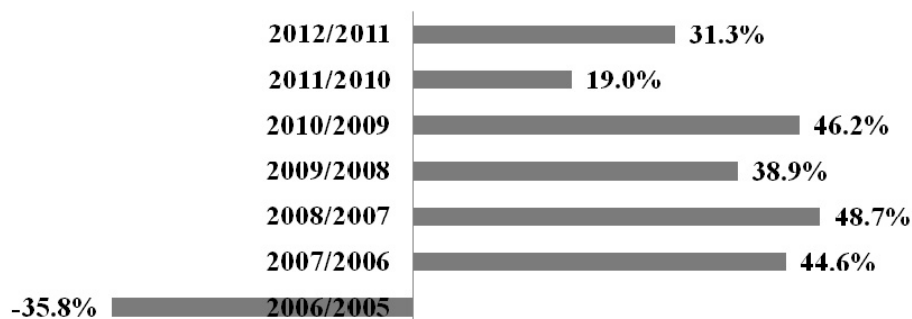
Source: HII, the author's calculation

Different levels of margins applied for more expensive reimbursable drugs, had an added average effect in health scheme expenditures. Because of the mark-up scheme for expensive drugs, in 2012 were spared 144 million ALL / approximately € 1 million or 24% more than in 2011.

The 24 expensive drugs in 2012 had taken 22% of reimbursable drugs, or 14% more compared to 2005. Their values obviously at figure no. 4 reflect the latest politics and measures to reduce expenditures in HIS from 2005.

There is a reduction of expenditures of the expensive drugs, only in 2006 approximately 35.8% compared to 2005, and a deceleration of the increasing of expenditures in 2011, approximately 19% compared to 2011.

With expensive drugs in 2012 were treated about 1054 patients, with an average prescription value of about 120.500 ALL per month.

Figure no. 4 – Trend of expensive drugs from 2005 to 2012**■ Annual percentage changes of reimbursement of expensive drugs, 2005-2012**

The introduction of reduced mark-ups for selected expensive reimbursed pharmaceuticals (covering about 20% of the products on the positive list) was a first step to overcome this situation.

The system for *the pricing generic drugs* is basically the same as the pricing for all drugs. Higher priced, innovative products may be reimbursed as long as there is no generic on the market. The HII makes use of the reimbursement ceiling and internal reference pricing to control costs. The reimbursement system stimulates price competition for generic drugs. All generics circulating into the Albanian market have to be registered at the National Center of Drug Control.

In Albania is introduced a *prescribing policies* for monitoring the prescribing budgets and preventing abuse. A list with the name of pharmacies with the highest prescription spending it's published. Prescribing policies are introduced in various countries, especially as an adjuvant tool for monitoring the prescribing budgets. In some countries, the prescribing pattern is monitored more as a way of preventing abuse: Portugal published a list of doctors with the highest prescription spending (Guillén AM. at. al., 2003), while in Romania a list with the name of over-prescribing physicians is published on the Romanian National Health Insurance Fund (NHIF) website.

Demand side policies can be seen as a four tiered structure of demand where the physician prescribes, the pharmacist dispenses, the patient consumes and a third party pays. The physicians are the key decision makers on the demand-side and many interventions are targeted at assuring best prescribing patterns. The importance of their role is reflected in the fact that, although within the demand side policies the most efficient in containing costs was proved to be generic prescribing or substitution (Simoens S. at. al., 2006), in order to change prescribing of drugs so that it becomes consistent with medical and cost-effectiveness evidence.

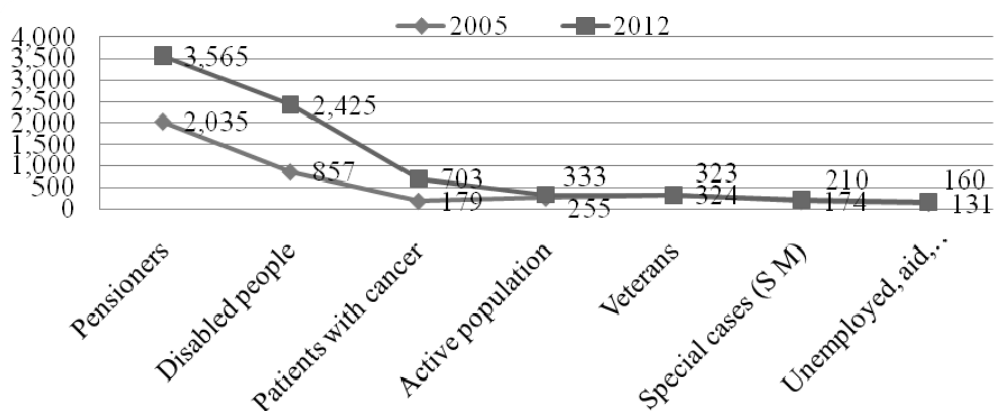
Even if physicians are periodically monitored by HII auditors and since 2004, every general practitioner (GP) has a limited annual budget for the reimbursed drugs

they have to prescribe, continue the cases of wasteful over-prescribing or fraud (collusion with patients and pharmaceuticals) will lead to fines and claims for compensation. Physicians who deviate from the expected prescribing track are being audited by the controllers. If the deviation is based on real medical need, the budget is increased. If the volume of the damage exceeds a certain amount, the contract with the physician is expected to be terminated. But, GP and specialist doctors are prescribing more expensive drugs rather than cheaper generic equivalents. There are not strong mechanisms of control.

Out-of-pocket payments and percentage co-payments. While HII reimburses those drugs that are included in its positive list with varying co-payments, an estimated 60% of the population pays for their medicines out-of-pocket (INSTAT, 2008). The whole population, based on their age, health status, income and other criteria, is divided into 20 categories, where 10 of these categories are reimbursed at a 100% rate and 10 others are partially reimbursed. There are two categories of co-payment in Albania. Have two categories of population, where a part of the population receives 100% reimbursement and the rest pays for a part of drugs according to the percentage of their coverage for each separate drug. 0% co-payment is applying to: drugs, that treat cancer, multiply sclerosis, growth hormone, deficiency and to all pensioners, war veterans and disabled people. Partial co-payment is applying to specific patients according to specific pharmaceuticals.

7 by 20 categories had taken 7.720 million ALL / approximately € 55 million in 2012, or approximately 97% of all expenditures of the drug's health scheme (figure no. 5). Expenditure for these 7 categories are approximately 95% increased, compared to 2005.

Figure no. 5 – Comparison of categories with higher values in annual reimbursement expenditures, 2005-2012 (in million ALL)



Co-payments are effective when price elasticity is higher - as in the pharmaceutical field - and less effective for other health services like hospital care

(Zweifel P. at. al., 2000). Co-payments are the most used cost-control measures on the demand side but their level differs across EU. The majority of EU countries have in place a 100% reimbursement scheme for highly vulnerable groups or for those suffering from very serious diseases. However, there are situations where the concern for vulnerable groups costs more than the public system can afford to pay for.

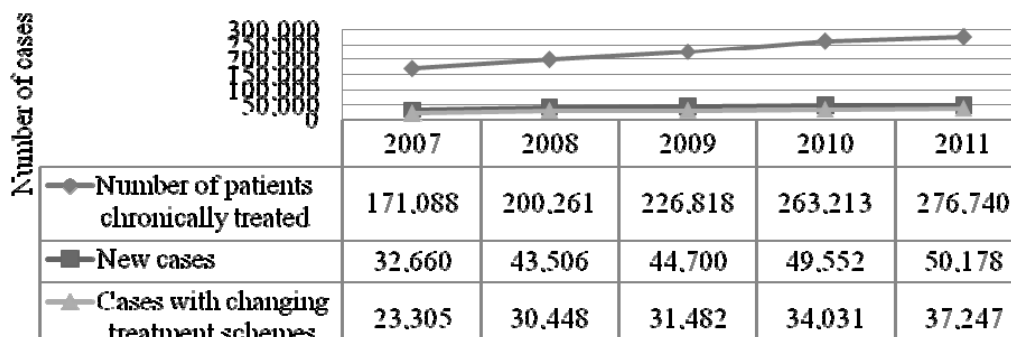
To conclude the analysis of the main facts in the matter of paper, I am giving some figures of the policy health scheme in relation to out-patients (table no. 4).

Table no. 4 Trend of out-patients data on HIS, from 2005-2012

Years	The total number of prescriptions	Annual percentage changes of prescriptions	Value reimbursement For prescription (in ALL)	Value reimbursement for inhabitant (in ALL)
2005	2,898,297		1,430	84
2006	2,415,048	-17	1,396	69
2007	2,333,150	-3	1,507	71
2008	2,630,967	13	1,609	87
2009	2,920,648	11	1,675	99
2010	3,245,103	11	1,831	123
2011	3,411,671	5	2,025	139
2012	3,733,744	9	2,122	159

Factors that have contributed to increase the expenditures of reimbursement are related to: 1) Increasing chronic disease, 2) New cases of the patients and 3) Cases with medication changes. The number of patients with prescriptions beneficiary reimbursement, increased from 2007 to 2011 in 76.000 patients or 24.5% more. These patients with highly handle, carrying 218.000 new cases and 153.280 cases of schemes change treatment, depending on the diagnosis of which they suffer. New cases and the total changes in therapy constitute about 3.2% of the total expenditure reimbursement morbidity. The following data (figure no. 6), are the number of chronic patients, new cases and cases with medication changes in five years, 2007-2011.

Figure no. 6 – Trend in the number of cases that have led to increased costs in the reimbursement scheme in HII



Number of patients chronically treated with reimbursement from family physicians in 2011 was 62% more compared to 2007, or 105,652 more cases. New cases in 2007 were 35,531 cases total, in 2011 their number reached a total of 50,178 new cases, or 41% more new cases. Cases with changing treatment schemes in 2011 were 37,247 total cases, or 35% more compared to 2007.

3. Final results

Despite the constant ups and downs, expenditures of reimbursement drugs have always had an important weight in the total cost of the health insurance scheme in Albania. The rapidly increasing spending on prescription drugs between 2003-2005 was largely the result of an imprudent expansion of the positive list of drugs, and of the cancellation of co-payments for most beneficiaries. Because of the policy followed and the cost-containment measures taken by the Albanian government in advising foreign factors, in 2006 reimbursement costs were reduced approximately 19% compared to 2005. Also were swept aside 37 drugs with the highest economic effect from the list, included in 2005 and the marketing margins were reduced to wholesalers and pharmacists.

The policy related to inclusion or not of new drugs in the list of reimbursable drugs between 2005 and 2013 is variable depended on the budget allocated to the health insurance scheme. The generic substitution can be considered one of the solutions for cost-containment. From the descriptive analysis of new drugs costs in the HII shows that their use would increase total treatment costs, instead of reducing them, especially in out-patient expenditures. The new drugs involved it in the years 2009 and 2010, still continue to have more weight in reimbursement costs. Only in the case of generic alternatives involvement, in 2011, have a slight decrease in spending of some drugs.

Other factors, influencing total pharmaceutical expenditures, have often occurred simultaneously and make it difficult to isolate specific effects of reference pricing. In Albania the introduction of therapeutic reference pricing between 2005

and 2013 had limited impact on reduction of the pharmaceutical expenditures. The price controls certainly had an impact on slowing price increases, but the results of reference pricing do not show any clear pattern in relationship to the immediate effects. The reduce of the reference prices, not always reflected in the reduction of costs reimbursement.

By the application of external reference price in 2012 was benefited approximately € 2.5 million. Reference drug pricing and external reference price can reduce third party drug expenditures by inducing a shift in drug use towards less expensive drugs.

A regressive margin system for medicines in Albania or the mark-ups schemes for distributors and pharmacists have influenced HIS expenditures. Different levels of margins applied for more expensive reimbursable drugs, had an added average effect in health scheme expenditures. Because of the mark-up scheme for expensive drugs, only in 2012 was spared approximately 24% more than in 2011. The introduction of reduced mark-ups for selected expensive reimbursed pharmaceuticals was a good step in order to reduce costs for drugs.

To decrease the financial risks for the target population, lower cost sharing policy will usually be followed by over consumption of health services. One of the strategies that should be considered by the policy makers is to analyze the risk level or health status of the target population: lower cost sharing level to those with the higher risk of diseases; higher cost sharing policy for those with lower risk of diseases.

4. Conclusions and further directions

Based on this analysis, the appropriate model of regulation in Albanian HIS, may involve a combination of positive list, restriction on prescribing and reimbursement systems, price control, reference pricing, expenditures drugs control, mark-up scheme and generic substitution. The majority of the effective measures in containing costs are on the supply-side from the demand-side especially co-payments are used in a systematic way at health insurance scheme in Albania.

Pharmaceutical expenditures is a major area of the health sector in Albania, that needs to be better managed and regulated, if health care expenditure growth shall stay in the budgetary limits. The high level of expenditures on pharmaceuticals is likely due to the lack of rules and regulations controlling this sector and lack of a significant policy for using generic drugs as substitutes for expensive products with the same active substances.

Various problems in Albania, associated with the process of introducing new drugs to the list of drugs and influence of interest groups, such as the service chiefs' intervention, representatives of companies, are increasing. The physician's prescriptions consist in more drugs and of drugs with higher cost. Public health care expenditures have reached a threshold that, economically and politically, seems difficult to overcome. The reimbursed drugs and the cost of reimbursement are not well managed by HII.

In the economic and social conditions of Albania, it is important the continual expansion of the list of generic reimbursable drugs, as well as the strengthening the control and monitoring of the financial impact. Based on different experience CEE countries, in terms of incentives for doctors and pharmacists for the generic description, incentive policies should be strengthened.

It is required a closer collaboration with clinics, HII and MOH for determining the cost-effectiveness of drugs. The accountability of policy makers at all levels of the management scheme should be increased and also the role of the HII as the sole purchaser of health services in Albania should be strengthened.

Health financing reforms aimed at improving the insurance coverage of a wider population group, together with stricter registration requirements for generic drugs, are likely to put additional pressure on drug expenditures. The structure and level of margins for distributors and pharmacists should be further reviewed. There are many small importers and wholesalers in Albania. Drug price negotiations with importers of new drugs could be further strengthened by adopting a more standardized approach to the use of reference prices. A price volume agreement should be taken into consideration for reimbursed drugs. Another element, the delay of price approval after granting of marketing authorization or for obtaining the reimbursement status, can be considered an important impediment in patient access to medicines (Cohen J. at. al., 2007), but in the same time a potential measure for cost-containment.

Controlling health care costs requires a more effective and efficient health care system. The most important challenge for the HII is the inclusion of the hospital care in the health insurance scheme. The effects of pharmaceutical policies on patient health associated health care costs and administrative costs which remain to be investigated.

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