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Rationalization of Pharmaceutical Expenditures in Georgia

Position Paper

Tamar Gotsadze, MD., PhD

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SCOPE OF THE PROBLEM

Health care is under reform in Georgia. Main cause of the need for changing of health system and policy has been the rapidly increasing difference between escalating health care cost and economic sustainability of health care services. The increase of pharmaceutical expenditures has outlined the growth of GDP and other health care spending. While the pace of growth of pharmaceutical expenditures was well balanced in most Western European countries it has increased in an exponential way in Georgia.

Expenditure on health for the 4.3 million inhabitants in Georgia comprised of 10% of Gross Domestic Product (GDP) in 2010. The household health expenditure increased by 59% in nominal terms over period of three years, which amounts to 16.7% annual growth per year.

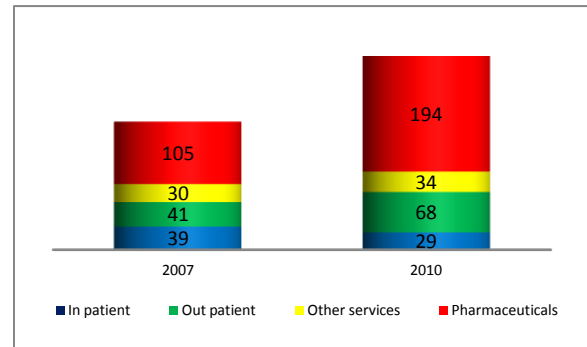
Health expenditures have increased at a different pace for various services. For inpatient care, the average expenditure per head of population grew by 31%, while for outpatient services the increase was 54%. The most significant increase is seen for pharmaceuticals and medical nondurables – 85%, which amounts to average annual 22.7% growth year on year¹. Per capita spending for pharmaceuticals increased from 105 Gel to 194 Gel in current terms (Figure 1).

It is notable that treatment costs of certain diseases as shown on the Figure 2, have increased mainly on the expense of the medicines.

By this time it became obvious the country's economic growth and the improvement of the wealth of the population does not allow for such an increase in medicines' expenditure.

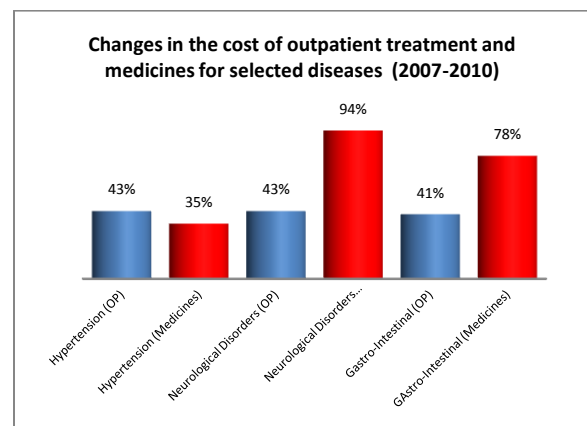
¹ Household Health expenditure and Utilization Survey, World Bank, Curatio International Foundation, 2011

Figure 1: Structure of the Per Capita Health expenditure (2007-2010)



Source: Health expenditure and Utilization Survey, 2010

Figure 2: Changes in the cost of outpatient treatment and medicines for selected diseases (2007-2010)



Source: Health expenditure and Utilization Survey, 2010

Although later fact was recognized by health government little has taken place to rationalize pharmaceutical expenditures and to create a tool, a long-term pharmaceutical policy, which helps the explicit decision making in this field.

The current paper attempts to understand what contributes towards increase of pharmaceutical expenditure in Georgia and how these expenditures can be rationalized. For this purpose Three possible contributing factors have been analyzed:

- Changes in Consumption Price Index

- Characteristics of the pharmaceutical market
- Characteristics of the prescription practices

This might be partly due to an unregulated and oligopolistic pharmaceutical market², which long has concerned policy makers.

CHANGE IN CONSUMPTION PRICE INDEX

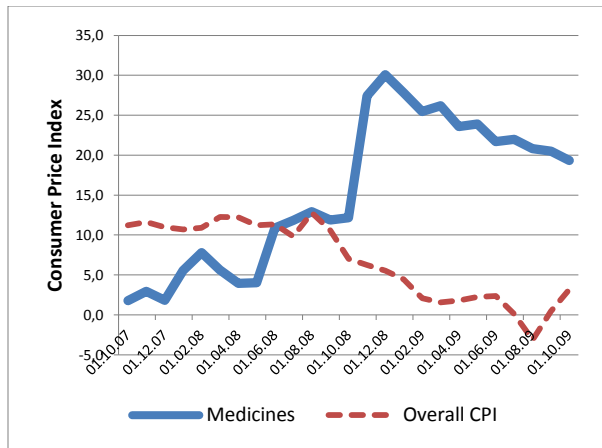
- The Health Expenditure and Utilisation Survey (HUES) 2010 revealed that household expenditure in current terms increased significantly over three years from 2007. The annualised growth rate of expenditure was higher compared to general inflation. Expenditure on pharmaceuticals grew at a pace of 23.7% year on year (in current terms).

CHARACTERISTICS OF PHARMACEUTICAL MARKET

As the main characteristics of the pharmaceutical market, researchers looked at:

- trends of the medicine costs
- market penetration with Original Brands (OB) and Equivalent Lowest Price Generics (LPG)
- Markups on pharmaceuticals

Figure 3: Consumer price indices and drug price inflation



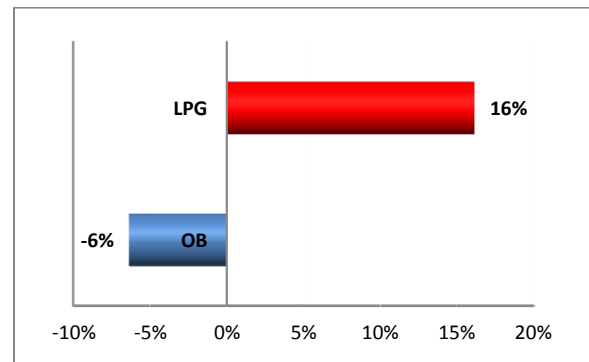
Source: State Statistics, 2009

Findings of the HUES are further confirmed with Consumer Price Index published by Geostat for general consumer goods and services and for medicines (Figure 3). Geostat data shows that price increases for pharmaceuticals far outpaced price increases for general goods and services in the Georgian economy between October 2007 – October 2009.

Trends in medicine costs

Over the course of one year (2009-2010) medicine price change has been observed³.

Figure 4: Unit Median Price change (GEL) 2009-2010



Source: Price, Availability and Affordability of Medicines in Georgia, 2010, WB, Curatio International Foundation

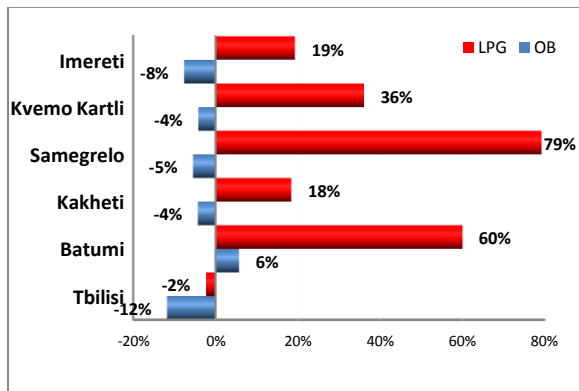
² Chanturidze T, Ugulava T, Durán A, Ensor T and Richardson E. Georgia: Health system review. Health Systems in Transition, 2009; 11(8):1-116.p.60

³ Price, Availability and Affordability of Pharmaceuticals in Georgia, 2010, WB, Curatio International Foundation

Alongside with OB unit median price decrease by 6%, LPG median unit price increase by 16% was noted. The price decrease has not affected the studied basket of medicines equally. In OB basket price decrease was observed in only 27% medicines, while prices increased for the remaining. A same trend has been observed for the LPG basket, where prices decreased for only 21% of medicines within the basket.

Price change appears to be disproportionate for both, OB and LPG across different regions of Georgia which in its term results in unequal financial access options available to the population.

Figure 5: Unit Median Price Change (GEL) by Region 2009-2010



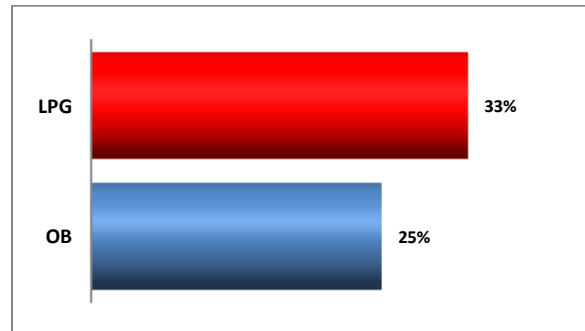
Source: Price, Availability and Affordability of Medicines in Georgia, 2010, WB, Curatio International Foundation

Availability of the Original Brands (OB) and Equivalent lowest price Generics (LPG)

Apart from unequal affordability wide range differences were observed in the physical availability of medicines. According to the same research availability has significantly improved for both OB and LPG (Figure 5), but again with different degrees. 33% increase in availability of LPGs ensures LPG market penetration by 36.8% only still being lower than the OBs, while OB availability country wide accounts for 57%.

Availability of LPGs and OBs differ across

Figure 6: Percentage Change in Availability of Medicines 2009-2010

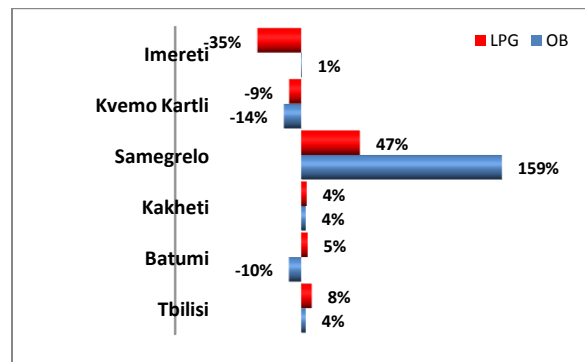


Source: Price, Availability and Affordability of Medicines in Georgia, 2010, WB, Curatio International Foundation

surveyed regions (Figure 6). Samegrelo region being the most underserved has been supplied by both LPGs and OBs but at different degrees in 2010, however availability of both medicines remains lower of national average.

Thus the market penetration with OB and LPGs remains uneven and is mainly flooded with OB medicines.

Figure 7: Percentage Change in Availability of Medicines by regions 2009-2010



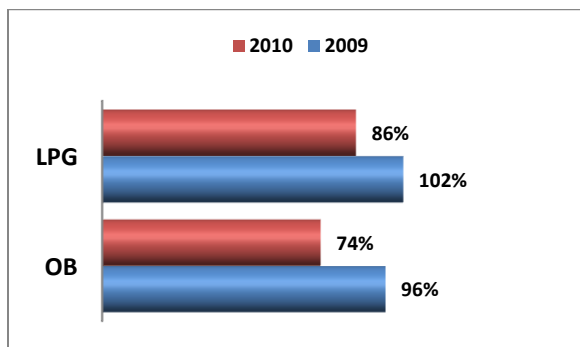
Source: Price, Availability and Affordability of Medicines in Georgia, 2010, WB, Curatio International Foundation

Markups

As described above, during past year Georgia experienced drug unit median price changes.

The same study reports that the markups do not follow the price trend.

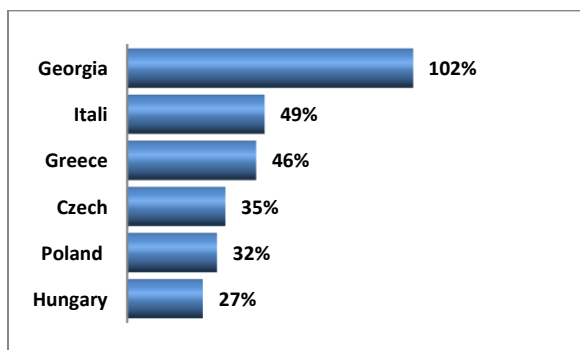
Figure 8: Drug Price Markup Change (2009-2010)



Source: Price, Availability and Affordability of Medicines in Georgia, 2010, WB, Curatio International Foundation

Although the markup decreasing trend is revealed by the study for both, OB and LPGs, it is noteworthy to mention that the markup for LPGs prevails of OB by about 12% in Georgian pharmaceutical market (Figure 8).

Figure 9: Comparison of Markups in Georgia to other European Countries (2009)



Source: Price, Availability and Affordability of Medicines in Georgia, 2010, WB, Curatio International Foundation

The same research compares markups in Georgia to other European countries. The findings show that on average markups account to 102% in Georgia, while the lowest markup been reported is 27% in Hungary (Figure 9).

High prices of medicines ultimately raise a risk of affordability in the population. This has been confirmed by the “Health Expenditure and Utilizations Survey (HUES)” carried out in

Georgia. The study results report that percentage of consultations where medicine was prescribed but not purchased because it was too expensive in 2010 increased to 21.7% from 16.4% in 2007.

Based on these findings it is obvious that there is a room for rationing pharmaceutical expenditures by introduction of policies that promotes cost-containment through price control mechanisms, as has been experienced by most of European countries, as well as improves access and affordability to medicines.

CHARACTERISTICS DRUG UTILIZATION

In order to describe characteristics of drug utilization in Georgia and assess its potential impact on the pharmaceutical expenditures, the paper explores the following areas:

- Levels of self treatment
- Prescription behaviors
- Behavior of the pharmaceutical market
- Management of pharmaceutical benefits by private insurance industry.

Self Treatment

The number of cases of self-treatment⁴ captured by the HUES was significantly lower in 2010 (59.3% per 1000 population) compared with 2007 (80.3 per 1000 population) and represent only small portion (6%) of population. The mean amount spent by a self-treating individual was 20.4 Gel in 2010, which is significantly higher than the amount observed in 2007 – 13.4 Gel (Table 1).

⁴ All individuals reporting, “Yes” on the question “Did you take any medicine or treatment for this problem based only on your own knowledge and not based on consulting a health care provider in the last 30 days?” were included as self-treating.

Table 1: Mean expenditure per case of self-treatment (current Gel)

Population Groups	2007 HUES Mean Per Patient	2010 HUES Mean Per Patient
Urban	14.9	21.6
Rural	11.5	19.4
Total population	13.4	20.4

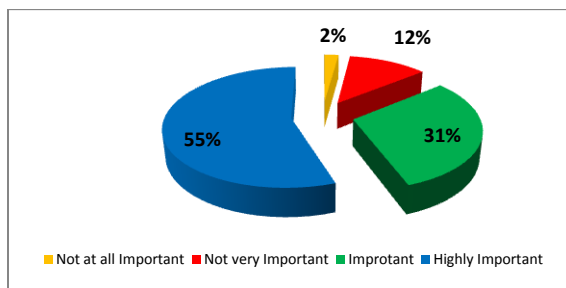
Source: Health expenditure and Utilization Survey, 2010

The largest portion (95%) of the amount spent on self-treatment is spent on drugs and herbal remedies and the rest (5%) on medical supplies and on diagnostic tests when performed.

Prescription behaviors

Inappropriate prescribing reduces the quality of medical care and leads to a waste of resources. Considering the magnitude of resources that are wasted on inappropriately used drugs, many promising interventions are relatively inexpensive. This paper looked at available evidence in Georgia to uncover level of inappropriate prescription practices.

Figure 10: Price of Medicine as a factor of Drug Choice

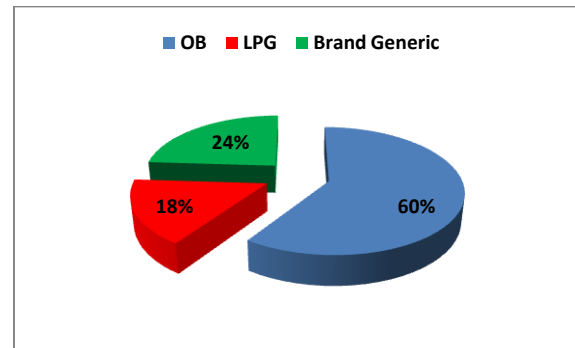


Source: Factors Influencing Prescription Practices in Georgia, 2011, Georgian Insurers Association

Absolute majority (86%) of Georgian physicians consider drug cost to be highly important and important factor to be well thought-out for prescription purposes (Figure 10), but only few

(7%) physicians take it less or more seriously into consideration when prescribing⁵.

Figure 11: Drug Prescription Patterns



Source: Factors Influencing Prescription Practices in Georgia, 2011, Georgian Insurers Association

It is also noteworthy that more than half of surveyed doctors in Georgia find generic drugs excellent or satisfactory in terms of efficacy, safety and effectiveness and cheaper to their branded ones. Moreover, majority (86%) of them consider cost of medicines as an important factor for prescribing decision, but in a reality generic drugs are rarely prescribed, physicians do not prescribe generic drugs as a means to curtail expenditure (Figure 11).

Obviously, such behavior is not influenced by the lack of knowledge and/or information and/or negative attitude towards generic prescribing, rather by the incentives present in the market. Low generic drug prescription can be explained by the combination of several factors such as: poorly defined government stewardship and regulatory role, namely absence of well formulated pharmaceutical policy, loosely regulated pharmaceutical sector, no restrictions for Pharmaceutical marketing, few treatment guidelines and no enforcement for utilization, diminishing role of the state in health human resource management and development, including post diploma and continuous medical education and pharmaceutical market becoming major

⁵ Factors Influencing Prescription Practices in Georgia, 2011, Georgian Insurers Association

financier of human resource development activities. Furthermore, in Georgia there are no financial incentives to motivate physicians to prescribe generics.

According to the present analysis, the largest proportion of participants has more than 20 years of practical experience, thus representing more experienced sample. More than half of Physicians upgrade their professional education by attending local or international conferences and short-term course. It is notable that the Georgian Government stopped financing of CME activities for last couple of years. The state funding is no longer available neither for participation in local or international conferences, or for short-term courses in support of physicians' continuous medical education. The professional associations also fall short to meet members' requirements; therefore these types of educational events at a lesser degree are financed privately by doctors and more frequently by Pharmaceutical companies. Thus the pharmaceutical market using their financial leverage in support of CME may have potential influence on physician's prescription practices.

The study also found that the majority of physicians in Georgia believe that a higher price of medicine imply better patient outcomes. The perceptions of physicians are that new drugs are more effective. In case of new drugs, pharmaceutical market appears to be the most powerful source of information. About half of physicians receive information about new drugs from pharmaceutical sector financed conferences, sales representatives and drug marketing materials. These data are consistent with those from other international studies, where it has been also shown that pharmaceutical sales representatives are highly influential on decisions to prescribe new drugs⁶⁷.

⁶ Prosser H, Almond S, Walley T: Influences of GP's decision to prescribe new drugs – the importance of who says what. *Fam Pract* 2003, 20:61-68

Even though adverse drug reactions may not appear very often, they do have a profound effect on a physician prescribing patterns, so doctors seek information in order to be protected and prepared. It is notable, however, that when they encounter such problems physicians rarely inform the authorities accordingly, perhaps because they either do not know who responsible authority is or do not want to acknowledge the fact that their patients had side effects. According to the finding of the study Georgian physicians mostly inform pharmaceutical companies (37%) and share information with colleagues (44%).

On a positive note, the results of the same study show that one third of physicians use national and international guidelines to justify their drug selection decision. The policy makers can build on this finding and foster wider use of guidelines in order to improve treatment clinical and cost effectiveness.

Behavior of Pharmaceutical Market

Estimation of pharmaceutical market behavior patterns that influences drug utilization appears to be difficult due to the limited available information and research. However, the anecdotal evidence suggests that pharmacists are not restricted to change physician's prescription by substituting prescribed medicine with alternative, thus promoting particular brand and/or locally produced medicines. Such behavior is not regulated by the legislation, however as it appears to be well established practice in the market accepted by the customers, the policymaker's can capitalize on this approach and apply for the institutionalization of the generic substitution policy.

⁷ Jones M, Greenfield S, Bradley C: Prescribing new drugs: qualitative study of influences on consultants and general practitioners. *BMJ* 2001, 323:1-7.

Management of pharmaceutical benefits by private insurance industry

There has been a striking increase in the proportion of the population that is covered by health insurance since 2007. Overall, some 30% of individuals are covered by health insurance, with the state financed Medical Insurance Program (MIP), representing the majority of coverage, covering some 21% of the population as a whole and remaining 9% representing mainly group insurance in 2010⁸. The MIP did not provide pharmaceutical benefit (PB) until summer 2010, though the government may consider expansion of PB coverage in future.

This paper purposefully avoids analysis of the PB management results for MIP, as the design and administration of the latter differs from the private insurance PB management and the data available for analysis at present is not sufficient to arrive to sound conclusions. Thus this paper mainly focuses on analyzing data for private group and individual insurance.

Table 2: Average pharmaceutical expenditure per member per year in GEL for group insurance

	2007	2008	2009	2010
Reimbursed	31,2	29,6	36,2	39,2
Co-insurance	10,05	11,42	14,4	15,95
Total	41,25	41,02	50,6	55,15

Source: Georgian Insurers Association

The given analysis revealed that total average expenditure per member per year increases alongside with increased co-insurance expenditures (Table 2). However, Insurance industry manages to maintain lower annualized growth rate (11%) of pharmaceutical spending in comparison to overall pharmaceutical expenditure growth rate (26%).

The mechanism applied by insurance industry for PB management is limited to co-insurance

⁸ Health Expenditure and Utilization Survey, 2010, WB, Curatio International Foundation

and negotiated discounts with pharmaceutical providers only. Indeed later are some of many other mechanisms that can manage utilization of medicines, but insufficient to ensure quality outcomes with lowest cost possible.

The study on pharmaceutical prescription practices revealed that patient's "insured" status does not influence prescription decisions. Forty two percent of surveyed physicians never take into account the patient's "insured" status and are free in their drug selection.

Furthermore, medicines are reimbursed on fee for service basis (FFS) across the board⁹ and the market lacks the risk sharing with physicians, the latter sets perverse incentives for prescribers to apply cost consciousness in drug selection.

However, when required, physicians do consider and base their decisions on the insurance company's formulary or national essential drug list (EDL). The industry should build on this positive experience and use widely the formularies in the design and management of the PB.

In summary, though insurance industry manages pharmaceutical expenditures better, still has potential for further cost containment.

SUMMARY OF ANALYSIS

This chapter attempts to summarize main factors influencing the rapid growth of pharmaceutical expenditures in Georgia.

Absence of price control policy influences levels of pharmaceutical expenditure. Although overall price decrease is observed, it effected mainly OBs, while price increase is detected for LPGs. Nevertheless, medicine prices in Georgia

⁹ Georgian Insurers Association , 2011

are still higher compared to other European countries. The declining trend is reported for medicine mark-ups as well, but it still remains significantly higher than in European countries. In the absence of state regulations, market exercises free price setting behavior.

After all, the price is not the whole story. Efficiency of pharmaceutical spending also depends on appropriate prescription and use of pharmaceuticals. Inappropriate prescribing practices are widely spread affecting quality and cost of treatment. Georgian physicians give preference to low generic prescribing and rarely take into account medicine prices in their prescribing decisions. Given behavior is not influenced by the lack of knowledge and/or information and/or negative attitude towards generic prescribing, rather by incentives introduced in the market.

Environment appears to be conducive for brand prescribing as the market is flooded by OBs, when their generic equivalents are less available. Furthermore, the country failed to promote utilization of treatment guidelines and ensure compliance, as well as felt short to institutionalize national EDL and continue funding of the health human resource development strategy. In the state absence this niche has been preoccupied by pharmaceutical market and used for their marketing base, thus influencing utilization and prescribing patterns in the country.

Furthermore, there is a lack of financial Incentives to promote cost efficient and effective treatment. Medicines are reimbursed on fee for service basis across the board. Furthermore, there are no incentives to motivate physicians to prescribe generics.

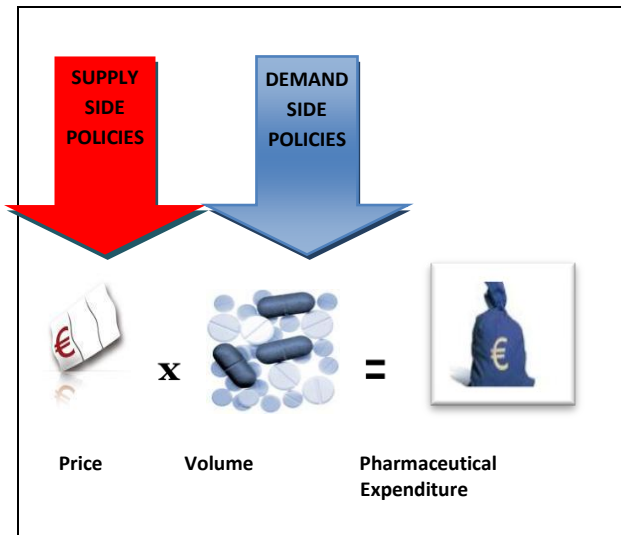
Insurance industry succeeded in lower pharmaceutical expenditure growth rates by introduction of co-insurance and negotiated price discounts from the pharmaceutical market, though underutilizes other possible cost containment strategies that could further

decrease pharmaceutical spending or contain its growth.

RECOMMENDATIONS

In this paper we have recommended approaches that we feel would establish a sound, broad-based program for quality drug use leading to better quality of care and improved cost effectiveness.

Figure 12: Cost-containment to control pharmaceutical expenditures



Georgia has to implement drastic policies to cut pharmaceutical spending, or at least contain its growth. The introduction of coherent generic medicine policy for health service payers in their attempt to increase value for money in pharmaceutical spending proved to be effective in some OECD countries. They have implemented policies to promote generic uptake through substitution of brand name products with its generic equivalents as well as introduced generic pricing strategies. However in some OECD countries generic markets remained underdeveloped suggesting that appropriate economic incentives for prescribers, patients and pharmacists are lacking.

Considering the OECD experience Georgia is recommended to embark on “coherent generic medicine policy”, the policy, which contains supply and demand policy measures (Figure 12).

The following sections presents summary of policy measures recommended.

SUPPLY SIDE POLICY RECOMMENDATIONS

In order to keep drug price reasonable and ensure that pharmaceutical expenditures are either decreased or maintained, different countries have used direct and indirect price regulation measures. Price control mechanisms are various, though this paper recommends only selected direct and indirect price control measures for policy maker’s consideration.

Reference pricing - the purpose of the reference pricing is to limit the raise in pharmaceutical expenditure by introduction of a limit on pharmaceuticals that the payers will fully reimburse. The reference price is set by reference to the price of other drugs in a given category. Different mechanisms are used to calculate drug reference price: it may be based on average price of drugs in a given category, on the price of the cheapest drug, on a price of the cheapest generic drug. The patient has to pay the difference between prescribed drug price and reference price if the former is priced higher. As the public financing for the pharmaceuticals is close to minimum in Georgia, recommended reference pricing can be effectively used by the insurance industry as their cost-containment measure for pharmaceutical expenditures.

Profit control is an indirect means of controlling drug prices and aims at ensuring that the firm does not make excessive profits on the pharmaceutical products.

Regulation of the distribution channel through introduction of **fixed mark-ups/ margins of wholesalers and pharmacies** is another indirect

Table 3: Summary of Supply Policy Recommendations

Policy Option	Considerations
Direct price control	Reference pricing/controls for reimbursement prices
Distribution controls along supply chain	Fixed mark-ups / margins (%) wholesale/distributor, retail pharmacy Regressive mark-ups / margins (motivation to dispense lower cost generics)

measure for price control and affects the retail price of the medicines. Mark-ups that include a regressive component with or without fixed fees probably lead to better outcomes than fixed percentage mark-ups through their influence on financial incentives. However, fixed fee mark-ups can dramatically increase the price of otherwise low-cost medicines.

Indirect price control measures are mostly those that should be endorsed by the state. Regulation of mark-ups as part of a comprehensive price regulation strategy probably will lead to reduced medicine prices. However, regulation of mark-ups without regulation of either the manufacturer’s selling price or the retail selling price is unlikely to lead to reduced medicine prices.

DEMAND SIDE POLICY RECOMMENDATIONS

Essential drug lists and formularies - Access to clinically relevant up to date, user specific, objective and unbiased information is essential for appropriate medicine use and basic requirement for rational prescription practice. Furthermore, formularies may be used to drive choice to lower cost drugs by structuring a sliding scale of co-payments favoring cheaper products or those for which there is a preferential agreement with the manufacturer. Some financiers may also categorize drugs

according to their 'essentialness' and determine the level of reimbursement the plan will provide and the portion that the patient is expected to pay.

Formularies may also segment drugs into categories for which a prior authorization is needed. This is usually done to limit the use of a high cost drug or one that has potential for inappropriate use (sometimes called 'off-label' as it involves using a product to treat conditions other than those for which its license was granted). In this circumstance a health care provider would have to seek permission to prescribe the product or the pharmacist would have to obtain permission prior to dispensing it.

Generic Substitution - Generic medicines play a key role in ensuring the affordability and sustainability of healthcare systems. Encouraging competition in the pharmaceutical market through increasing the use of generic medicines both promotes cost containment and stimulates the innovation needed to provide added value products.

The generic medicines industry's major contribution to healthcare involves the provision of high quality, cost-effective treatment for many of today's most common chronic illnesses and conditions, such as cancer, diabetes, depression and high blood pressure. Providing sustainable treatment for these illnesses, which are particularly prevalent in older patients, will become increasingly difficult as Georgia's population ages. In fact, the rapidly ageing population, the increase in the prevalence of certain diseases and the rise in prices for original brands are creating a critical need for higher volumes of more affordable generic medicines.

Introduction of generic substitution will enable pharmacists to fulfill a prescription for a branded medicine by dispensing an equivalent generic medicine. Provision will be made to allow the prescriber to opt out of substitution where, in his clinical judgment, it is appropriate

for the patient to receive a specific branded medicine. In these circumstances, the named brand must be dispensed. Provision may also be made to exclude certain categories of medicines for clinical reasons in the interests of patient safety'.

Influencing Prescription Decisions –

Prescription decisions can be influenced through introduction, training and monitoring of adherence with the clinical guidelines, application of different incentive methodologies designed specifically for prescribers and patients.

Guidelines are consensus statements developed to assist clinicians in making decisions about treatment for specific conditions. They are systematically developed on the basis of evidence and aim to promote effectiveness and efficiency of healthcare delivery. To promote the development and use of guidelines, a designated body should exist in the country and be charged with the function of monitoring the implementation of such guidelines.

Incentive structures relate primarily to targeting the prescribing behavior of physicians, the dispensing patterns of pharmacists and consumer behavior. Physicians responsible for generating demand for medicines through prescribing may respond positively to the entry of generic drugs, but they are not always sensitive to price. As a result, influencing the way they prescribe can significantly influence overall generic prescribing, and can be achieved by providing them with financial or/and non-financial incentives.

Physicians have been provided financial incentives to prescribe cheaper alternatives in different ways: they may receive per capita funding for their patients and be allowed to keep savings achieved through economic prescribing, as it was a case for some physician groups in United States or GP fund holders in UK. They may be financially rewarded by extra

payments if they reach targets of generic prescribing, as defined by Pay for Performance (P4P) schemes.

Financial incentives include prescribing budgets and provide an explicit incentive to contain costs, which, in turn, encourages generic prescribing. The incentives in this case may be structured to reward physicians who under spend, or penalize those who overspend, or both. The international experience suggests that unless budgets are fixed and linked to clear and enforceable rules, they are unlikely to work.

Non-financial incentives affecting physician prescribing include promotion of generic prescribing, prescription monitoring, audit, and the use of clinical guidance and IT to influence prescribing decisions. It is unclear what effect nonfinancial incentives and measures have in practice, but it is thought that unless they are vigorously implemented and monitored, their effectiveness is likely to be poor¹⁰.

In order to influence the demand from patients effective incentives should be introduced. Incentives for patients depend on out of pocket payments. The way user charges are designed is likely to influence the generic take-up when patients have a choice. Patients have a financial interest to choose cheaper drugs when the co-payment is a co-insurance rate (expressed as a percentage of price), when fixed co-payments are lower for generic drugs (“tired” co-payments). Some countries have supplemented existing incentives with higher co-insurance rate for brand named medicines for which cheaper generic substitutions are available¹¹.

Strict Control - Policymakers can improve health care quality and reduce its costs by

restricting inappropriate drug industry marketing tactics that undermine the objectivity of doctors, hospitals and other health care providers.

Evidence suggests that direct-to-consumer advertising of prescription drugs increases pharmaceutical sales and both helps to avert underuse of medicines and leads to potential overuse¹².

Table 4: Summary of Demand Side Policy Recommendations

Policy Option	Considerations
Defining the market: listing systems and formularies	Positive lists for reimbursements, essential drug lists Generic prescribing and substitution policies
Influencing the prescribing behavior	Guidelines, protocols Financial and non-financial Incentives Auditing and benchmarking
Influencing the demand of patients e.g. cost-sharing, co-payment levels can be defined	Proportionality to the final price Fixed charge per prescription Annual deductible amount
Strict Control	Drug promotion, marketing, education, sponsorship gifts to doctors.

Intense marketing increases costs because new and expensive drugs are promoted more heavily than lower cost drugs that are equally or more effective. The enduring increase in prices of prescription drugs is directly related to marketing by pharmaceutical companies in the world. The international evidence suggests that calls for a moratorium on such advertising for new drugs would represent a dramatic departure from current practices.

¹⁰ Choutet P, Crochet B, et al. The effect of RMO/medical guidelines based on a critical assessment of antibiotic drug prescription. *Médecine et maladies infectieuses* 2000;30(3)Supplément:185s–192s

¹¹ Value for money in health spending, OECD Health Policy Studies, 2010.

¹² Julie M. Donohue, Ph.D., Marisa Cevalco, B.A., and Meredith B. Rosenthal, Ph.D. A Decade of Direct-to-Consumer Advertising of Prescription Drugs, *N Engl J Med* 2007;357:673-81.

The Policy makers can provide leadership in several ways: as large-scale purchasers of drugs, as providers of medical education in medical schools, as industry regulators, and as influential leaders in health care policy.

It is now up to government to face the generics challenge head on. They can do this by implementing pro-generics policy measures particularly in the area of pricing and reimbursement, while better informing doctors, pharmacists and patients about the benefits of generic medicines.