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HEALTH SYSTEMS

Pharmaceutical pricing policies to improve the population's access to pharmaceuticals in Georgia

Dialogue Summary

December 2019

Acknowledgements

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The CIF team wish to thank participants for their valuable contributions. The views expressed in the dialogue summary are the views of the dialogue participants and should not be taken to represent the views of the Health and Social Issues Committee of the Parliament of Georgia or the authors of the dialogue summary.

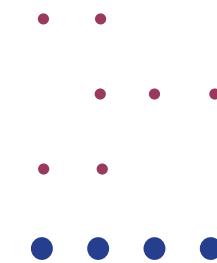


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Introduction

A national Policy Dialogue on pharmaceutical pricing policies to improve the population's access to pharmaceuticals in Georgia was conducted on November 20, 2019. The Policy Dialogue was attended by 33 representatives of various stakeholder institutions:

- The Parliament of Georgia
- Ministry of Internally Displaced Persons from the occupied territories, Labour, Health and Social Affairs of Georgia (MoILHSA)
- Ministry of Finance of Georgia
- State Audit agency of Georgia
- Competition Agency of Georgia
- Public Defender (Ombudsmen) of Georgia
- Association of Pharmaceutical Companies Representatives in Georgia
- Pharmaceutical Companies Association
- Medicines du Monde- MDM
- Union of Georgian Medical Associations
- Georgian Family Medicines Association
- Experts and academicians

The policy dialogue was informed by a rapid response document developed to answer a high priority question raised by health policy makers in Georgia formulated as follows: how to reduce the overall cost paid by the nation on pharmaceuticals and how to protect the public. The evidence synthesis product, encompassing local and international evidence about the problem, possible mechanisms (tools, elements) to deal with the problem and implementation considerations, was prepared by CIF in collaboration with the Parliament of Georgia. This document was shared with the policy dialogue participants prior to the actual face to face dialogue held on November 20, 2019.

The policy dialogue was facilitated by Dr. George Gotsadze, the President of Curatio International Foundation (CIF) and co-facilitated by Dr. Fadi El-Jardali, the Director of the K2P Center. Discussions about the size and depth of the problem for Georgian population was commenced by the representatives of the Government institutions – by Dr. Akaki Zoidze, the Chairmen of the Health and Social Issues Committee of the Parliament of Georgia and by Dr. Tamar Gabunia, Deputy Minister of the MoILHSA.

Deliberations about the Problem

Overview of problem

Policy Dialogue participants discussed the problem of access to outpatient pharmaceuticals for the population of Georgia and the underlying factors contributing to this problem. All agreed that access to pharmaceuticals is one of the most challenging issues for the Georgia health system preventing the whole system from achieving Universal Health Coverage (UHC) goals. This statement was proved by the recent statistical information presented at the beginning of the dialogue which examined the trends of total pharmaceutical spending and out of pocket (OOP) payments households pay to purchase pharmaceuticals:

- Georgia is a leading spender on pharmaceuticals with **35.7%** out of total health spending. Spending on pharmaceuticals as a percent of GDP is **twice higher** in Georgia than in OECD countries. Considering all of these figures one participant asked the following question during the dialogue: **are we the sickest nation in the world in need to spend more than 3rd part of the total health expenditure on purchasing pharmaceuticals?**
- The enormously high expenditure on outpatient pharmaceuticals is mostly made up by households OOP expenses: OOP expenditures on pharmaceuticals is **96%** of total pharmaceutical spending and government share in this spending equals only 2% (according to National Health Accounts, 2017). Up to **two-third of the population purchases medicines through OOP** and for almost the **third of the population, these payments are associated with catastrophic health care costs**. In 2017, Georgian population spent **983 million Georgian Lari** to purchase pharmaceuticals though OOP payments.

At the end of the problem discussion part of the dialogue, there was agreement among participants that **high OOP payments for pharmaceuticals places a heavy financial burden on households' disposable income and creates significant financial access barriers, especially for poor and for patients with chronic conditions.**

Underlying causes of problem

Deliberations stressed out several factors contributing to enormously high pharmaceutical expenditures in Georgia. **Lack of regulations** was mentioned as a leading cause of high prices on the pharmaceutical market. The wholesale and retail mark-ups are as high as can be borne by the market. Participants also acknowledged that low-cost generics are less available in pharmacies compared to the expensive brand name drugs which further contribute to the unnecessarily high expenditures on pharmaceuticals. As it was mentioned during the dialogue, **50% of households are unable to buy prescribed drugs because of their high costs**. Dialogue participants highlighted that the agenda for improving access to pharmaceuticals is broad. Affordability is the cornerstone of access, but many other factors also determine whether people get the medicines they need:

Dialogue participants emphasized that high price of pharmaceuticals and high prevalence of expensive medicines on the market are not the only problem of the pharmaceutical sector of Georgia, but **inappropriate prescribing** has also been greatly contributing to the persistent challenge of high pharmaceutical spending throughout the country. In Georgia the pharmaceutical sector utilizes a brilliant strategy to maximize its profits - raise prices and increase consumption of pharmaceuticals. Over-prescription not only adds to the cost of drugs but also harms thousands of Georgians lives each year. Meeting participants brought several examples of physicians and pharmaceutical companies' interaction which affect customer buying habits and result in high volumes of consumed medications for the population. Some participants asked about mechanisms affecting provider behavior to improve prescribing patterns and quality as this was considered important issue to effectively contain pharmaceutical expenditure in Georgia.

Another topic widely discussed during the dialogue was related to the state role in protecting its households from experiencing catastrophic payments for pharmaceuticals. **Participants agreed that with only 2% state contribution in total pharmaceutical expenditure, the country cannot achieve UHC goals of providing quality-assured affordable pharmaceuticals to everyone in need.**

This discussion was further elaborated among dialogue participants who raised concerns around current **challenges with state health program implementation**, under which the government subsidizes outpatient medicines for chronic patients for six most prevalent chronic conditions (hypertension, COPD, diabetes type 2, thyroid diseases, Parkinson's and Epilepsy diseases) for the poor and pensioners. Of note, is that under this program, socially vulnerable citizens have their medication almost fully funded (co-funding amounts to a maximum of GEL 1); pensioners and disabled people have partial funding for their medicine where beneficiaries co-pay 50% of the medicine's market value. As was discussed in the meeting, although the demand for outpatient pharmaceuticals is huge in terms of country enrollment in and utilization of publicly subsidized outpatient pharmaceuticals, state health program has not achieved its planned targets yet. Hence, the program budget which is very low compared to the need, expressed by the actual expenditures on pharmaceuticals, has not been fully executed (spent) during its implementation cycles since July 2017 when the program was launched in the country.

Meeting participants discussed the challenges hindering the program to achieve its goals and deliver medicines to thousands of targeted populations: the poor and the pensioners with chronic conditions. Some participants outlined the **problem related to procurement practices under the chronic medicines' subsidization program**, in particular, large part of medications are purchased and stored at contractor parties beforehand. Others emphasized the problems related to lead times for pharmaceutical companies according to public tenders' documentations that create challenges to deliver medicines to consumers on time. Some dialogue participants also raised **concerns around the list of medications subsidized under this program**, how the list was defined, whether bioequivalence was taken into the consideration as a criteria while selecting a particular medicine in the list of reimbursable medicines. Participants acknowledged that, to some point, there is **discrepancy between the list of reimbursable medicines and the essential medicines list (EML)** recently updated by the world health organization. Participants further elaborated on the urgent need to revise the

EML in Georgia as it was not updated since 2007 and ensure that the EML and the list of reimbursable medicines are compatible to each other.

Dialogue participants also discussed the issues related to nutritional supplements which are much more expensive than some pharmaceuticals, although their therapeutic effect could be lesser compared to the actual medicine. Many physicians prescribe supplements as pharmaceuticals and patients are not aware whether what the physician has prescribed. Participants agreed there is need to make changes in the legislation to distinguish medicines from supplements.

Deliberations

Deliberations about Elements of a Policy Approach for addressing the Problem

Dialogue participants discussed three elements that have been examined in the rapid response document: **Reference Pricing, Tiered Co-payments (Formularies) and Cost-sharing Strategies (Caps, Deductibles, Coinsurance)**. Each policy element was discussed with participants.

This section of the dialogue started with a small introduction that there is no **single gold standard** of pharmaceutical pricing policies that has the potential to improve the population's access to pharmaceuticals and to control public and private expenditures on medicines; Instead, countries are using a **mix of policy options** to achieve their expected goals by adapting tools to the country-specific context.

Before jumping to the policy elements, there was a discussion on prescription-drug insurance plans as one of the most powerful policy alternatives available for both controlling expenditures in a health system and effective compliance and management among patients. Public drug insurance schemes are a critical precondition for countries to move on to the other policy elements. Dialogue participants acknowledged potential positive role of a public drug scheme for Georgia that would realize economies of scale and introduce a 4th player in the market with significant purchasing power.

Reference pricing policy

After discussing the reference pricing policy's overarching mechanism, most dialogue participants agreed that External Reference Pricing better suits the Georgia context and could achieve its ultimate goal - reduce prices of pharmaceuticals and total use and thus decrease expenditures related to purchasing medicines for the population compared to the internal reference pricing. Main reason of giving priority to external reference pricing over internal reference pricing was the oligopolistic market structure of Georgia's pharma market that may entail significant risks while setting the reference price. In the oligopolistic market structure, it is less prognosticated to ensure diversity in the pharmaceuticals prices that is essential implementation consideration suggested by the evidence.

The second important agreement was achieved between participants while discussing which price should be taken for reference price calculation under external reference pricing policy. Dialogue participants concluded that Georgia should not use ex-factory prices to set reference prices like many European countries do to avoid price differences caused by differences in distribution mark-ups. However, since Georgia is largely import dependent (90% of pharmaceuticals are imported in the country), Cost, Insurance and Freight (CIF) prices should be used if the reference pricing mechanism is applied, in order to minimize the increase in wholesale mark-up and decrease medicines prices.

Deliberations also pointed to the need to carefully select pharmaceuticals for external reference pricing. Pharmaceuticals with the same active ingredient can differ with respect to several aspects: a. strength, indicating the content and the concentration of an active ingredient expressed per dosage unit, b. pharmaceutical form, which is the physical characteristic of the combination of active substances and non-active ingredients forming a medicinal product, c. pack size and d. packaging. The ultimate goal for pharmaceuticals selection for external reference pricing is to support rational use of pharmaceuticals with demonstrated bioequivalence.

Tiered Formularies' and Cost sharing strategies

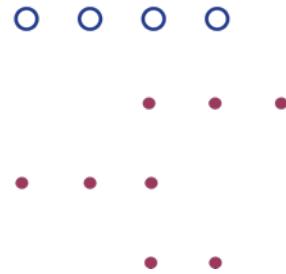
Dialogue participants acknowledged that, in principle, Tiered Formularies' and Cost sharing strategies have the potential to encourage use of generic drugs and thus lower OOP expenditure on pharmaceuticals for the households in Georgia as both mechanisms require increased investments in purchasing the pharmaceutical by the government. That will boost government's contribution to total pharmaceutical spending (considering the fact that public expenditure on pharmaceuticals does not exceed 2%) and will increase access to medicines for the population. Although possible positive impact of these policies was acknowledged in the meeting, dialogue, participants raised concerns around other factors that may impede positive relationship between policies and desirable outcomes. According to dialogue participants, unethical marketing and current prescribing patterns of physicians need further work in parallel with the abovementioned pricing policies to increase generics use among the population. As indicated by dialogue participants, currently prescribing patterns and utilization of pharmaceuticals are greatly affected by unethical marketing which is widely prevalent in the market.

Participants discussed anticipated challenges in changing the customer's behavior to use less expensive generics unless relationship between pharmaceutical companies and physicians is regulated. Dialogue participants agreed that interactions like kick-backs and gifts for prescribing certain pharmaceuticals should be abolished in the market. However, they stated that other kind of interactions between pharmaceutical companies and physicians like promoting continuous medical education should be supported.

During the dialogue, participants discussed the following additional issue that should be taken into the consideration in order to overcome the multifaceted problems existing in the pharmaceutical sector in Georgia and support new policies implementation to achieve desired outcomes:

Quality control of pharmaceuticals before and after their introduction on the market should be in place. Meeting participants agreed that a new state agency should be established that will oversee the quality control of pharmaceuticals in the market. In particular, this agency should ensure that the medicines in the market are safe. So, a system for pharmacovigilance needs to be in place. Likewise, participants indicated that supply chain management is needed to protect populations from substandard or falsified medical products. As it was discussed during the dialogue, quality assurance system of pharmaceuticals is extremely important to diminish perceived negative attitudes of population towards the generic medicines quality and support them in utilizing low cost but effective generics.

Moreover, deliberations pointed to the need to establish functional **e-prescriptions system** to monitor controlled substance prescriptions, prevent prescription drug errors, easily track prescription history, improve medication adherence and increase patient safety. E-prescribing makes it easier for the policy implementation agency to monitor prescriptions by physicians and control overprescribing.



Next Steps

Next Steps

Policy dialogue participants emphasized that the meeting was fruitful for them as it enabled them to discuss a high priority issues for the country's health system and collectively think about potential solutions to overcome the existing problem of access to pharmaceuticals for the Georgian population.

Based on the dialogue discussions and the evidence from the rapid response document, the below set of action plan is recommended, encompassing different options of the pharmaceutical pricing policies:

Recommended Action Plan

Recommended action	Stakeholders involved
→ Further discussion around external reference pricing is needed among stakeholders in order to reach consensus on whether this is one of the policy options that the country is going to implement. The discussion should address several components that are important to take into consideration while planning and/or implementing this policy: <ul style="list-style-type: none">○ Criteria and process for selection of:<ul style="list-style-type: none">○ A sample of medicines that should be included under the reference group;○ Reference countries;○ Access to prices from reference countries and date of the available price;○ Determination of method of reference price calculation (minimum price of set of reference countries, or average price of reference countries, etc.);<ul style="list-style-type: none">▪ Given that Georgia is largely import dependent, participants	 MoILSHA  Health and Social Issues Committee of the Parliament of Georgia  State Regulation Agency for Pharmaceutical and Medical Activities  Experts and academicians  Pharmaceutical field experts  Association of Pharmaceutical Companies Representatives in Georgia  Pharma Companies Association  Union of Georgian Medical Associations  Georgian Family Medicines Association

Recommended action	Stakeholders involved
<p>indicated a preference for Cost, Insurance and Freight (CIF) prices (as opposed to ex-factory prices), if the reference pricing mechanism is applied, in order to minimize the increase in wholesale mark-up and decrease medicines prices;</p> <ul style="list-style-type: none"> ● Assessment of the adequacy of medicine regulatory system and development of regulatory framework allowing generic substitution or prescribing using international non-proprietary names (INN). 	
<p>→ Further the discussions on policies to support successful implementation of Cost Sharing strategies and increase generics use under the existing state health program subsidizing outpatient medicines for chronic patients for six of the most prevalent chronic conditions by discussing and agreeing on:</p> <ul style="list-style-type: none"> ● Policies to regulate healthcare providers' interactions with pharmaceutical industry; ● A communication strategy to promote generic drugs and demystify misconceptions and perceptions about inferiority of generics relative to branded drugs; ● Alternative options for purchasing medicines to overcome existing procurement challenges. 	 MoILSHA  Health and Social Issues Committee of the Parliament of Georgia  Experts and academicians  State Regulation Agency for Pharmaceutical and Medical Activities  Association of Pharmaceutical Companies Representatives in Georgia  Pharma Companies Association  Union of Georgian Medical Associations  Georgian Family Medicines Association 
<p>→ Additional action points developed based on complementary issues discussed during the dialogue:</p>	 Pharmaceutical field experts

Recommended action	Stakeholders involved
<ul style="list-style-type: none"> ○ Consider revising the Essential Medication List (EML) in Georgia and ensure it is compatible with the list of reimbursable medicines. Considerations could also be given to establish a transparent process with explicit criteria (e.g. bioequivalence; generic alternative) for including a drug in the list of reimbursable medicines; ○ Consider establishing a new state agency to oversee quality control of pharmaceutical in the market. The agency could put in place a system for pharmacovigilance as part of efforts to promote safety of medicines in the market. 	<ul style="list-style-type: none"> ○ MoILSHA ○ State Regulation Agency for Pharmaceutical and Medical Activities ○ World Health Organization (with regard to EML update)

Way Forward

Several commitments have been made that will be further tracked by Curatio International Foundation:

- Health and Social Issues Committee of the Parliament of Georgia will invite the committee members for further discussion of these policy elements including the recommended action plan emerging from the dialogue, and may also invite plenary session on this issue to make changes in the legislation;
- Ministry of Internally Displaced Persons from the occupied territories, Labour, Health and Social Affairs (MoILHSA) of Georgia will work further to make changes in the design of the State Health Program for Medicines Subsidization for Chronic Patients to overcome existing challenges in program implementation and achieve efficiency in usage of public resources;
- Curatio International Foundation will conduct additional meetings with different stakeholders if needed to further disseminate the knowledge synthesized in the rapid response document and the subsequent dialogue summary as part of efforts to improve population access to pharmaceuticals and support evidence use in policy making process in the country.



