

2012

***National Centre for Legislative
Regulation Project Implementation Unit
at the Government Staff of the
Republic of Armenia***

Project Progress Report

*Project Progress Report Period
January, 2012-June, 2012*



Project Progress Report

Contract No. 8283-01/2011

As at June, 05 2012

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Project title:

PROMOTING GOOD GOVERNANCE IN THE REPUBLIC OF ARMENIA THROUGH SUPPORTING THE IMPLEMENTATION OF A RAPID REGULATORY SIMPLIFICATION (REGULATORY GUILLOTINE) EXERCISE

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Reporting period:

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1. SUMMARY OF THE PROJECT PROGRESS

The Letter of Intent on Promotion Good Economic Governance in the Republic of Armenia Through Supporting the Implementation of a Rapid Regulatory Simplification (Regulatory Guillotine) Exercise (hereinafter referred as “Letter of Intent”) was signed in Yerevan, RA, on 3 November, 2011 between the GoA and the Austrian Development Agency, the Office of the Organization for Security and Cooperation in Europe in Yerevan, the World Bank Country Office in the RA, the USAID in the Republic of Armenia, the UNDP office in the RA. It was aimed to support the Rapid Regulatory Simplification Reform to update Armenia’s regulatory policies and policy instruments through counting, reviewing and streamlining the national regulatory frameworks affecting business activity and the lives of citizens.

According to the point 4 of the Letter of Intent, the Head of the Reform Unit should present detailed monitoring system for the regulatory reform as well as submit to the donors the proposed quarterly progress reports.

The process of making the Reform Unit operational took about half a year and was consisted of the following:

1. The Reform Unit was established in October 2011 under the Staff of GoA as a body mandated to execute the decisions of the reforms of the Reform Council.
2. After the signing Grant Agreement between ADA and GoA dated 8 December, 2011, the funds were promptly disbursed in December, 2011.
3. The adequate premises to ensure the performance of the Reform Unit were provided by the Government in October 2011 at Saryan St. 22, 10th floor, Yerevan. The renovations started in October, 2011 and were completed in the end of January, 2012.
4. The purchase of the office supplies was financed by the GoA via the World Bank Public Sector Modernization Project and performed in accordance with the World Bank guidelines. It started in November, 2011 and the office was fully equipped and the operational facilities were set in the end of April, 2011.
5. The recruitment of the staff of the Reform Unit took place in January-May, 2012 and was consisted of four phases:
 - I. The Head of the Reform Unit was appointed by the Prime Minister in October, 2011. The Financial Officer and the Office manager were hired by the Head of the Reform Unit in January, 2012.
 - II. The vacancies for the Deputy Director, the Head of Policy and Legal Acts Drafting Department, the PR and IT specialists were publicly announced in February, 2012. The candidates were appointed in March, 2012 based on the selection process in accordance with the national legislation.

- III. The vacancies for four expert lawyers and two legal drafting specialists were publicly announced in April, 2012. The candidates were appointed in May, 2012 based on the selection process in accordance with the national legislation
- IV. The vacancies for the Business processes experts, Economic experts and Public Administration Agencies Support Officers were publicly announced in April, 2012. The candidates were appointed in May, 2012 based on the selection process in accordance with the national legislation
- V. The recruitments of the Administrative Assistant to the Director of the Reform Unit and the Administrative Assistant to the Deputy Director of the Reform Unit took place in April, 2012 and May, 2012 respectively.

The Selection Commission was formed of the representatives of the state agencies of GoA and the donors.

Due to the results of the transparent and effective competitions the Reform Unit was staffed with strong team of professionals.

6. In April, 2012 after the renovations and installation of the technical facilities were completed and the technicalities were set for launching the project the then already appointed staff moved to the office.
7. The first Session of the Reform Council was held on 6 April, 2012. On the Session the Head presented the tasks completed so far.
 1. Completed tasks.
 2. Actions to be employed. Timetable for the activities.
Recommendations on the first three priorities (to start with) at project appraisal stage.
 3. Approval of the Reform Unit Budget.
 4. Appointment of Aram Gharibyan, the chief adviser to the President of the Republic of Armenia, one of the members of Reform Council as a chairman of the Joint Dialogue Forum according to the point 3 of the Letter of Intent.

7.1. In the process of consultations and discussions during the Session of the Reform Council a new list of the starting priorities was approved.

Those priorities are:

1. Public Utility Sector Regulation.
2. Transport and Communication Sector Regulation.
3. Public Health Sector Regulation.

The decision to set a new list of priorities is to get prompt results at the appraisal stage of the project in anticipation of a positive response from the businesses and civil society.

At present there are discussions on the implementation of the reforms in the education and construction sectors (construction permits) during 2012. The Reform Unit will do its best to accomplish reforms in other sectors as well by the end of 2012 depending on the complexity and volume of the works. Meanwhile, the other priorities defined by the

Project Proposal and the President Decree will be implemented during the Project period.

8. The arrival of the international experts and the purchase of IT Software were expected in February, 2012. However, due to the negotiations with the international experts and donors and according to the procurement procedures the purchase of IT software (E-Guillotine) and the arrival of the international experts are expected in July, 2012.

2. BACKGROUND/ CONTEXT

The Government of the Republic of Armenia (hereinafter referred as “GoA”) has launched a program of systematic regulatory reform:

- 1) To improve national competitiveness by updating its regulatory policies and policy instruments in order to stipulate market-driven growth.
- 2) Drastically increase effectiveness and efficiency of services delivered to its citizens by removing administrative hurdles and thus consumption risks in the services mostly irritating population (e.g. health care, permits, licensing).

The particular goal of the reform is to boost foreign investment. Armenia is highly regulated, with over 25 000 legal norms on the books at the national level, and more added every week. Though many of these norms are sensible and well designed, there are inconsistencies and contradictions through the legal framework that are burdensome especially to businesses and citizens as well and therefore discourage business and investment in Armenia.

To implement the regulatory reform in Armenia, in September, 2011 by the President Decree NH-246-N dated 17 September 2011 (See Annex VII) the Council of Legal Acts Reforms Regulating the Economic Sphere of the Republic of Armenia (hereinafter referred as “Reform Council”) has been established. It is headed by the Prime Minister of the Republic of Armenia and is mandated to identify and address redundancies in government functions by means of institutional and legislative improvement and regulations, as well as changes to current practice. The Decree states the structure of Council for Reformation of Legal Acts regulating Economic Sector of the Republic of Armenia (See Annex V) and the list of Areas to be included in the Reforming Process (See Annex VI). The 17 priority areas subject to reform are defined. The Reform Council has set the first three priority sectors at project appraisal stage.

In October 2011, the “National Centre for Legislative “Regulation Project Implementation Unit” (hereinafter referred as “Reform Unit”) was established under the Staff of GoA as a body mandated to implement the decisions of the Reform Council.

The aim of the Reform Unit is to compile and review all the legal norms that affect businesses and citizens and eliminate or simplify most of those that are illegal, obsolete, unnecessary or business unfriendly.

3. TARGET GROUP, BENEFICIARIES AND PROJECT PARTNERS

A. Scope of the Reform.

The main goals of the project are:

- To reduce the costs and risks of regulations affecting businesses and citizens by simplifying or abolishing unnecessary and unneeded rules and regulations, hence reducing the corruption risks and business uncertainty.
- To build sustainable capacities in the GoA that will result in better regulatory development and improve the flow of new regulations.

B. Summary of decisions in the guillotine framework

a) Institutions: Broad application

The scope has been set as follows:

- 1) 16 ministries at national level.
- 2) 10 regulatory bodies at national level.
- 3) The city government of Yerevan.

The full list of institutions is provided in Annex III to this Report.

b) Legal instruments

The guillotine framework covers all legal norms which are broadly defined as any requirement placed on the businesses or on citizens. This will require the ministries and agencies to validate inventory of all legal norms enforced by them, plus any other normative documents including forms, official letters, notices, guidelines, instructions, etc.

c) Reference groups: Either businesses or citizens or both.

d) Project partners

The Reform Project is supported by five donors: The Austrian Development Agency (ADA), The Office of the Organization for Security and Cooperation in Europe in Yerevan (OSCE), the World Bank Country Office in the Republic of Armenia, the USAID in the Republic of Armenia (USAID), and the UNDP office in the Republic of Armenia (UNDP).

OSCE- Donor coordinator and provider of the short terms experts from the internal roster.

ADA-Salaries Financing

WB- Financing the short and long term experts' consultancy. (Capacity building of the Reform Unit).

USAID- Financing the short and long term experts and IT (E-Guillotine) Software.

UNDP- PR component financing and assistance. Support for gender equality.

e) Priority sectors: Set early priorities

The Presidential Decree on Launching Regulatory Reform defines 17 priority areas subject to reform. At project appraisal stage the starting priorities (to start with) were defined as follows:

- 1) Tax and Custom administration.
- 2) Inspection reforms.
- 3) Construction permits.

Later, the starting priorities were changed in the implementation stage of the project.

f) Legal Norms included in the guillotine framework

- a. Laws.
- b. Presidential Decrees.
- c. Decisions of National Assembly and the Chairman of the Assembly.
- d. Presidential Orders.
- e. Government Decisions.
- f. Regulatory Decisions of Prime Minister.
- g. Departmental acts registered with the Ministry of Justice.
- h. Departmental acts not registered with the Ministry of Justice.
- i. The city government of Yerevan Legal Acts.

4. INTERVENTION LOGIC

Table 1 (Project results/ project status) and Table 2 (Description of the activities completed/planned by the Reform Unit)

A. Description of the progress of the expected results and their visible effects and impacts.

Project results/ project status*

Table 1. Logframe Matrix

	Intervention logic	Indicators	Sources of Verification	Assumptions/ Risks
Overall Objective	To improve national competitiveness by updating Armenia’s regulatory policies and policy instruments to stimulate market-driven growth.	<ul style="list-style-type: none"> • Improved national macro-economic indicators; • Improved country ranking (WB Doing Business Report, WEF Country Competitiveness Report); • Increased confidence of foreign investors; Increased level of private business’s and citizen’s satisfaction from the services delivered by targeted 27 governmental agencies. 	<ul style="list-style-type: none"> • Reports of the National Statistical Survey; • Rankings of international organizations (WB, WEF, etc); Reports of country-wide surveys (private sector and citizens). 	
Project Purpose	Reviewed legal norms that affect businesses and citizens (perhaps around 15,000 of the	Number of legal norms that has been abolished and/or simplified. Their ratio against overall number of legal norms.	National legal database (“ARLIS”)	Political commitment might fade in the face of strong resistance. The broad application and organization of the

	<p>25,000 legal norms existing in Armenia), resulted elimination and/or simplification of those that are not legal, needed, or business friendly. The Project goals are to:</p> <ul style="list-style-type: none"> • Substantially reduce the costs and risks of regulations affecting businesses and citizens by simplifying or abolishing unneeded rules and regulations, hence also reducing corruption risks and business uncertainty resulting from complex and discretionary procedures; • Build sustainable capacities of the government and improve the flow of new regulations. 	<ul style="list-style-type: none"> • Reduced amount of risk and costs and risks of regulations affecting businesses; • Strengthened capacities of the Government and improved flow of new regulations. 	<p>Reports of country-wide surveys (private sector and citizens).</p> <ul style="list-style-type: none"> • Number of RIA reports developed by 27 agencies; • Number of RIA reports received positive assessment by Central RIA Unit. 	<p>guillotine is intended to reduce the conflict of reform by using a consistent and transparent process across the whole of the government, but resistance from powerful groups inside and outside the government is likely.</p>
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Project Proposal Number	Expected results/ Activities	Indicators	Sources of Verification	Assumptions and Risks
1.	<p>1. High level of performance, efficiency and effectiveness of Reform Unit is insured through securing a strong team of professionals, its political independence, building professional capabilities and collaborative participation of key stakeholders.</p> <p>1.1 Experienced and prominent local experts/ Consultants for the positions of Head of Guillotine Unit, deputies, long-term senior adviser and other staff selected. <u>Completed</u></p> <p>1.2. Instructing the bodies under the scope of the reform on the procedures needed to comply with the schedule. <u>Ongoing</u></p>	<ul style="list-style-type: none"> • A strong candidate is selected for the position of the Head of the Reform Unit; • Experienced and prominent local expert/consultant is selected as a long-term Senior Adviser to the Reform Unit; • Capable and experienced experts/consultants are selected and trained for the Reform Unit; • Reform Unit's performance is periodically assessed positively against approved benchmarks; • Proper justification is provided for each and every reform proposal 	<p>1.1. A Reform Unit of about 22 fulltime people initially has been created as follows:</p> <ul style="list-style-type: none"> • A strong candidate is selected for the position of the Head of the Reform Unit; The Head of the Unit was appointed by the Prime Minister; • Experienced and prominent local expert/consultant is selected as a long-term Senior Adviser to the Reform Unit; • Capable and experienced experts/consultants are selected for the Reform Unit. <p>The staff of the Reform Unit, is composed of the skilled mix of</p>	<p>Lack of leadership. The Head of the guillotine unit will be unable to carry out a credible reform, keeping both the integrity of the process and the trust of the political leadership that the guillotine is making the right decisions.</p> <p>Staff skills in law and business affairs will not be available to staff the central unit. If all other organizational issues are properly solved, e.g. sufficient funding and attractive salaries, capable and experienced Head of the Unit, political support, etc., then it will be rather possible to attract staff equipped with all necessary skills,</p>

		<p>and number of appeals is low.</p>	<p>business experts, economists, lawyers, with a few IT and PR support experts.</p> <ul style="list-style-type: none"> • The staff will be (it depends on the arrival of the international experts stated in the point 4 of the Table 1) trained in the methodology of the reform. • Expansion of the staff of the Reform Unit as needed and as resources become available. <p>Donor resources might be used to support temporary experts, and business associations might also supply some people. They will work according to defined processes and schedules, using a staff performance measurement system supported by the e-Guillotine software.</p> <p>1) The Reform Unit functions under the direct authority of the Prime Minister and the Reform Council, with day to day implementation by the Reform Unit Head</p>	<p>knowledge and experience. No country that has operated the guillotine has yet been unable to put together a capable staff for the central unit.</p> <p>It is important that even controversial issues go through the normal guillotine process, and that special pleas do not short-circuit the structure. The proposed structure of</p>
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	<p>1.3. Developing proper justification for each and every reform proposal and ensuring low number of appeals. <u>Ongoing</u></p> <p>1.4. Liaising with the President and the Prime Minister regularly and whenever such issues arise that threaten the successful completion of the reform.</p>		<p>2) Continued support of the Reform Unit by the Ministry of Justice and the Ministry of Economy.</p> <p>3) The staff works in a highly professional environment focused on performance.</p> <p>1.3. Within the period of preparing reform proposals. Each proposal should have a proper justification before the submission to the Reform Council to assure the low number of appeals. *See Annex I.</p> <p>1.4..Taking into account that the Reform has high support from the President of RA and the Prime Minister of RA the Reform Unit may apply for the assistance whenever such issues arise,</p>	<p>Prime Ministerial leadership with a mandate and active oversight from the President is intended to establish strong political credibility of the reform process.</p>
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	<i>Ongoing</i>			
<p>2.</p>	<p>2. Capacities of 27 ministries and government agencies are increased significantly to provide required outputs.</p> <p>2.1. Collect the full texts of each legal norm, templates and fee schedules, and keep these documents in a central location in paper or electronic copy or both. <u>Completed.</u></p> <p>2.2. Compile all currently valid legal norms issued and/or implemented by the ministries or agencies and all other documents containing procedures being enforced by them. <u>Completed.</u></p> <p>2.3 .Prepare inventory and review forms for each legal norm in a standard electronic format. <u>Completed</u></p>	<ul style="list-style-type: none"> • Well experienced local experts/consultants are selected for the inter-ministerial support unit; • The responsible civil servants from 27 ministries and other regulatory bodies are duly trained; • Required input by 27 ministries and other regulatory bodies is provided to the Reform Unit on a timely manner. 	<p>2. Completed for the first 3 priority sectors</p> <p>a. The Reform Unit issued the instructions and forms (checklist) to the Ministries and state Agencies. See Annex II.</p> <p>b. The inventory preparation and reviews for the institution.</p> <p>c. Compiling all currently valid legal norms issued or implemented by the ministry or agency.</p> <p>*Expert input of Ministerial support team (within Central guillotine Unit)</p> <ul style="list-style-type: none"> • Well experienced local experts/consultants are selected for the inter-ministerial support unit; • Required input by 27 ministries and other regulatory bodies is provided to the Reform Unit on a timely manner. <p>*Each ministry and agency involved in the reform should identify all legal norms that it</p>	<p>Ministry organization might be slow or poor quality.</p> <p>In the initial design, a help desk function of 5 people were added to the central unit with the primary task of assisting the ministries to carry out their reviews.</p>

	<p>2.4 .Submit the inventory and review forms to the central Reform Unit as they are completed <u>Completed</u></p> <p>2.5. Respond to any questions from the Reform Unit and supply any information that is requested. <u>Ongoing</u></p> <p>2.6. Consult as necessary with stakeholders to properly carry out these tasks. <u>Ongoing</u></p> <p>2.7. Promptly implement the recommendations of the Reform Unit once they are adopted. <u>To be implemented.</u></p>		<p>enforces on businesses and citizens, regardless of the document or its legal form, and shall provide each legal norm to the Reform Unit in the form and on the schedule requested by the Reform Unit, as well as all currently valid legal normative documents issued by the ministry or agency and all other documents containing procedures being enforced by the ministry or agency such as official letters, notices, instructions guidelines or other documents issued by the ministry or agency or any of its departments or sub-departments, as well as higher level legal normative documents that the ministry or agency is responsible to implement.</p> <p>Taking into account the professional capabilities in agencies quoted above, it has been decided to establish a ministerial support team, which will be responsible for provision of day-to-day consulting, coaching and methodological support for the implementation of activities mentioned above.</p>	
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<p>3.</p>	<p>3. Business Advisory Council is established, operational and ensures timely and adequate contribution of business associations and civil society organization to the review process.</p> <p>3.1. Inform and encourage input from organizations such as business associations and other stakeholders in the process of review of legal norms. Hold consultative seminars, workshops, meetings, or other forms of communication as needed to ensure transparency in the process of the reform. <u>Ongoing.</u></p>	<ul style="list-style-type: none"> • Number of review proposals submitted by Business Advisory Council; • Number and ratio of proposals accepted by Reform Unit; 	<p>3.1. List of NGOs, associations, etc. acting on the corresponding field needed regulation. <u>Completed.</u> Work with NGO-s on the corresponding field of regulation. <u>Ongoing</u> Preparation of letters for cooperation. <u>Ongoing</u> Preparation of Seminars/Discussions/ Meetings. <u>Ongoing</u></p> <p>*Work with the Reform Unit to carry out three tasks:</p> <p>1.Cooperate directly with the Reform Unit (such as by setting up working groups) to provide stakeholder comments on individual legal norms to identify problems and assist in a high</p>	
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			<p>quality review;</p> <p>2. Monitor the overall progress of the reform and report to the PM, the media, and the parliament;</p> <p>3. Review the final recommendations for action developed by the Reform Unit.</p> <p>*A small unit of dedicated expert group will also be created to support business organization and participation.</p> <p>Expert input of the Secretariat of Business Advisory Council</p> <p>The reforms cannot be done in isolation inside the state units, because only the affected stakeholders fully understand the impacts and problems created by administrative procedures in the business sector and day-to-day life. Participation of business and other relevant stakeholders such as media and academia is important for two reasons:</p> <p>1) Stakeholder groups are needed to mobilize the political system for continued change. That is, pro-reform elements of the business sector must act as a pressure</p>	
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			<p>group for change; 2) The business sector holds unique information about regulatory impacts that will greatly boost the impact of any reform.</p>	
4.	<p>4. High level mentorship of reformation efforts is secured through engagement of a world-class expert.</p> <p>4.1. Recruitment of internationally recognized expert/consultant. <u>To be implemented.</u></p> <p>4.2. Development of reform benchmarks, negotiations with the Government and partner donor agencies. <u>To be implemented.</u></p> <p>4.3. Development of quarterly progress reports, recommendations and implementation of political debates within the Reform Council. <u>To be implemented.</u></p>	<ul style="list-style-type: none"> • An internationally recognized expert/consultant is hired under SSA; • Reform benchmarks are developed, negotiated with the Government and partner donor agencies and correctly defined; • Progress reports of the expert/consultant are approved by the Reform Council and recommendations are implemented; 	<p>4.1. USAID and OSCE have already negotiated with the international experts and at this moment the procurement procedure of the services is in progress. The package includes the e-guillotine Software, proper trainings and consultations.</p> <p>*Professional input of the of the world class experts</p> <ul style="list-style-type: none"> • An internationally recognized expert/consultant is hired under SSA; • Reform benchmarks are developed, negotiated with the Government and partner donor 	

			<p>agencies and correctly defined;</p> <ul style="list-style-type: none"> • Progress reports of the expert/consultant are approved by the Reform Council and recommendations are implemented. 	
5.	<p>5. Custom made IT software is purchased, installed and respective staff members are trained.</p> <p>5.1. Procurement and installation of licensed e-guillotine software. <u>To be implemented.</u></p> <p>5.2. Implementation of trainings for Guillotine Unit staff on how to operate the e-guillotine software. <u>To be implemented.</u></p>	<ul style="list-style-type: none"> • Customized software is procured, installed and operational; • Adequate staff skills to use the software. 	<p>5. USAID and OSCE have already negotiated with the international experts and at this moment the procurement procedure of the services is in progress. The package includes the e-guillotine Software, proper trainings and consultations.</p> <p>*Adequate staff skills improvement to use the software to Improve the consistency, quality, transparency and speed of the reform.</p>	Risk of delay
6.	<p>6. Adequate communication strategy and branding resulted broader political support and pro-active participation of businesses, civil society and public in general.</p>	<p>Implemented surveys and opinion polls reveal increased support of citizens and businesses to the reforms.</p>		<p>Organization of business participation might be slow or ineffective.</p> <p>A small unit of dedicated staff is needed to support business organization and participation.</p>

	<p>6.1. Communication mechanisms should be used such as written reports, training seminars, workshops, videos, e-mails, newsletters, TV ads, etc. <u>Ongoing</u></p> <p>6.2. Key elements of information to be distributed by the different mechanisms will be identified, including frequency and information collection and collation. <u>Ongoing</u></p> <p>6.3. Roles and responsibilities of the key individuals responsible for ensuring that communication are adequate / appropriate and timely. <u>Ongoing</u></p> <p>6.4. Identification of how unexpected information from other parties (including stakeholders) will be handled</p>		<p>6.1. Preparation works on holding consultative seminars, workshops, meetings and other form of communication as needed with organizations, business groups and other stakeholders. Development of webpage Hotmail; Hotline; Social networks, TV and Video materials</p> <p>6.2. In the course of consultations with the donors the slogan is identified. "Let's cut together": Unique information regarding to the particular priority sector will be identified later.</p> <p>6.3. Deputy Director of the Head of the Reform Unit , PR assistant of the Reform Unit, UNDP PR Team, other donors, PR experts.</p> <p>6.4. This part of the process is handled by the PR responsible in the Reform Unit itself and the Head of Policy and Legal Acts Drafting Department .</p>	
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	<p>within the scope of the activity. <u>Ongoing</u></p>			
7.	<p>7. Reform Unit is provided with fully equipped office premises and monthly office running costs are taken care.</p> <p>7.1. Identification and provision of suitable office premises to the Reform Unit by Government of Armenia. <u>Completed</u></p> <p>7.2. Procurement and installation of office furniture, equipment and other necessary technical facilities. <u>Completed</u></p> <p>7.3 Implementation of monthly payments for utility and other miscellaneous costs. <u>Ongoing</u></p>	<ul style="list-style-type: none"> • Office premises are provided; • Equipment and furniture is provided; • Running costs are taken care. 		<p>7.3. Office premises are provided; Equipment and furniture is provided; Running costs are taken care.</p>
8.	<p>8. Reform Council decides to accept or reject appeals.</p> <p>8.1. Guillotine Unit prepares justifications for controversial simplifications based on the input from respective</p>	<ul style="list-style-type: none"> • Number of appeals; • Proportion of positive decisions vs. negative ones. 	8.	<ul style="list-style-type: none"> • Number of appeals; • Proportion of positive decisions vs. negative ones. • Project monitoring and evaluation reports; • Reports of Reform Council.

	<p>government agencies, Business Advisory Council and its own assessments. <u>To be implemented.</u></p> <p>8.2. Reform Council organizes hearings (if necessary public) and provides all parties with the opportunity to properly present the case and justifications, followed by taking decision on approval or rejection of the appeal. <u>To be implemented.</u></p>			
<p>9.</p>	<p>9. Reform Unit drafts legal text to implement the recommendations and assembles the final package.</p> <p>9.1: Reform Unit (if necessary in close collaboration with concerned government agency and other stakeholders) develops the texts of necessary amendments aimed at implementing recommendation, as well as assembles final package.</p>	<p>Recommendations are presented and final package is assembled.</p>		

	<u>To be implemented.</u>			
10.	<p>10. Packages are sent by Prime Minister to the Government for action as a single unit (one vote up or down).</p> <p>10.1: After implementation of all necessary procedures, the final package is being submitted for Government's consideration and final decision.</p> <p><u>To be implemented.</u></p>	Number of packages sent by the Prime Minister to the Government.		
11.	<p>11. Government adopts package of reforms.</p> <p>11.1: Government adopts package of reform.</p> <p><u>To be implemented.</u></p>	Number of adopted reform packages.		
12.	<p>12. Procedures begin to legal adopt revised legal text.</p> <p>12.1: The recommendations are adopted by the appropriate legal authority (the Government, the President, the Prime Minister, the ministries and agencies, or the parliament).</p> <p><u>To be implemented.</u></p>	Number of recommendations adopted by appropriate legal entity.		
13.	Reform Unit monitors	Number of monitored		

	<p>adoption and reports to Prime Minister and President.</p> <p>13.1: Reform Unit creates and maintains an online electronic registry of all legal norms, with positive legal security, so that businesses can rely on a central information source for all legal obligations.</p> <p><u>To be implemented.</u></p>	<p>adoption processes; Number of revealed non-compliances.</p>		
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The term "completed" in the Table 1 under the 3rd column "Activities (Indicators)" refers to the activities (Activity 2.1; Activity 2.3; Activity 2.4.) that are completed for the first three priority sectors at the project appraisal stage; Public Utility Sector Regulation, Transport and Communication Sector Regulation, Public Health Sector Regulation. Activity 1.1; Activity 7.1; Activity 7.2 .are competed for the Project implementation period. The next Logframe will be prepared and submitted to the Donors as soon as the Reform Council Session approves the other priority sectors.

B. Description of the activities completed/planned by the Reform Unit

Table 2*

N.	Activities	Current Status	Deviations/ comments
1.	<p>Preparation of the Methodology of the Reform Unit *Attached Annex IV</p>	<p>Inventory of legal acts needed to regulation.</p> <ul style="list-style-type: none"> • Classification of legal acts needed regulation. <u>Ongoing</u> • The list of the legal acts needed regulation as a result of the inventory of legal acts. <u>Ongoing</u> 	<p>Inventory of Normative Legal Acts</p> <p>*The sources for the inventory of legal acts</p> <p>-States bodies of the Republic of Armenia responsible for the corresponding sphere</p> <p>www.arlis.am www.e-gov.am www.parliament.am</p> <p>-Other sources not restricted by laws of the Republic of Armenia</p>
2.	<p>Preparation of the Work plan Of the Reform Unit *Attached Annex I</p>	<p>The Work plan Of the State Agency “National Centre for Legislative Regulation project implementation unit” at the Staff of Government of the Republic of Armenia is proved for the 3 priority sectors: Public utility services. Transport.</p>	

		Health care/Drug licensing. <u>Completed. April-May</u>	
3.	Drafting the Form for Review of a business procedure *Attached Annex II	Form for review of a business procedure <u>Completed. April-May</u>	<p>A standard review methodology created in the form of simple checklist that can be filled out by every regulator and stakeholder for each regulation under review. The draft checklist thoroughly reviewed and discussed by experts before being finalized, and will be market tested to ensure that it is clear and practical.</p> <p>In the Form, the review criteria are organized into three basic questions:</p> <ul style="list-style-type: none"> • <i>Is the legal norm legal?</i> • <i>Is the legal norm business friendly?</i> • <i>Is the legal norm needed?</i>
4.	Seminar for the staff of the Reformation Unit to focus on the main strategies of the Reform Project.	Before the seminar, participants were contacted by e-mail and asked to respond to a set of questions regarding issues at their priority sectors and their expectations for the seminar as well as to submit their comments and recommendations. The	<p>The Seminar introduced the experts to valuable strategies and key decisions for the Reform Project and institutional awareness that will enhance the effectiveness of their work.</p> <p>Discussions were combined with small, interactive sessions</p>

		<p>answers were sent to the seminar chairs and speakers to assist them with final agenda planning.</p> <p><u>Completed. May</u></p>	<p>to create ample opportunities for working, learning and relationship building.</p>
5.	<ul style="list-style-type: none"> • Meeting with the experts of the Reform Unit. • Setting a schedule and goals for the project. • Establishing the procedures and requirements of the work and issuing instructions to the staff of the Reform Unit. • Instructing the staff of the Reform Unit on the procedures needed to comply on schedule and guidelines. 	<p>A. Planning and dividing into 3 major groups for the three priority sectors 3, 3 and 5 experts respectively:</p> <ol style="list-style-type: none"> 1. Public utility services sector. 2. Transport sector. 3. Health care sector/Drug Licensing. <p>B. Instructions issued to the staff of the Reform Unit through the established procedures and requirements of the work.</p> <p>C. The staff is instructed on the procedures needed to comply on schedule and guidelines.</p> <p><u>Completed. May</u></p>	
6.	<p>Launching the Reform Project.</p>	<p>A. Inventory of legal acts.</p> <p>B. Review of legal acts</p> <p>C. Description of the business processes.</p> <p>D. Study and Research of best</p>	

		<p>practices in transitional and developed economies.</p> <p><u>Mechanisms</u></p> <ol style="list-style-type: none"> 1. Carrying out independent reviews of the legal norms by the experts of the Reform Unit. 2. Generating the legal and analytical information needed for the Reform Unit reviews. 3. Monitoring and evaluating the present and proposed business processes and their expected results. <p><u>Ongoing</u></p>	
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Table 1 is a description of the progress of the expected results and their visible effects and impacts. In contrast to the Table 1, the Table 2 describes the activities that are completed or in progress or already planned by the Reform Unit. The activities of the Table 2 are not mentioned in the Table 1 as they are specific only for the Reform Unit Project performance and are intended for the implementation of the Reform Unit Staff activities. Thus, the activities indicated in the Table 2 (Preparation of the Methodology of the Reform Unit, Work Plan, Checklist, etc) are directed to the organization and management of the effective works of the Reform Unit Staff for the accomplishment of the Project.

5. MONITORING, PROJECT MANAGEMENT (DIFFICULTIES ENCOUNTERED, MANAMEGEMENT MEASURES)

The Reform Unit has not encountered difficulties and obstacles yet during the project implementation: no changed project environment, target group, local partner organization and other local parties involved and/ or other difficulties encountered that have led to a change in project planning

6. SUSTAINABILITY

The reform is aimed at inventorising and reviewing at least 15.000 legal norms that affect businesses and citizens in priority sectors defined by Presidential Decree and eliminate or simplify those that are not legal, needed, or business friendly. It is supposed to be a one time ad-hoc task, with the following goals:

- Substantially reduce the costs and risks of regulations affecting businesses and citizens by simplifying or abolishing rules such as procedures, and produce concrete and visible results in 2011 and 2012;
- Reduce corruption and business uncertainty resulting from complex and discretionary procedures;
- Build sustainable capacities for better future regulation development;
- Prepare for trade agreements, particularly the EU-Armenia Free and Comprehensive Trade Association Agreement.

Sustainability of the project results will be achieved mainly by simultaneous or subsequent implementation of Regulatory Impact Assessment (RIA) as a main tool to ensure the quality of the future legislation and regulatory flow.

7. ANNEXES OF THE PROGRESS REPORT

1. ANNEX I

Work plan Of the State Agency “National Centre for Legislative Regulation project implementation unit “at the Staff of Government of the Republic of Armenia

2. ANNEX II FORM FOR REVIEW OF A BUSINESS PROCEDURE

3. ANNEX III INSTITUTIONS IN THE SCOPE OF THE GUILLOTINE

4. ANNEX IV Methodology of the Reform Unit performs the following tasks

5. ANNEX V

to the RA President Decree NH-246-N dated 17 September 2011

STRUCTURE OF COUNCIL FOR REFORMATION OF LEGAL ACTS REGULATING ECONOMIC SECTOR OF THE REPUBLIC OF ARMENIA

6. ANNEX VI

to the RA President Decree NH-246-N dated 17 September 2011

LIST OF AREAS TO BE INCLUDED IN THE REFORMS PROCESS

7. ANNEX VII

PRESIDENT OF THE REPUBLIC OF ARMENIA DECREE ON ESTABLISHING A COUNCIL FOR COORDINATION OF MEASURES TO IMPROVE GOVERNANCE OF ECONOMIC ACTIVITIES AND REFORMATION OF LEGAL ACTS REGULATING ECONOMIC SECTOR OF THE REPUBLIC OF ARMENIA

8. ANNEX VIII

Gender Considerations

Environment Considerations

9. Annex IX. Monitoring Plan.

Table 1. Public Utility Sector Regulation

Table 2 Transport and Communication Sector Regulation

Table 3. Public Health Sector Regulation

10. ANNEX X Time plan

11. ANNEX XI 23 May, 2012 Roundtable with the representatives of pharmacy NGOs and associations

12. ANNEX XII Meeting with representatives of non-governmental organisations and associations

13. ANNEX XIII. List of NGO's

14. ANNEX XIV Draft Memorandum of Understanding on Establishing a Business Advisory Council

Work plan*
Of the State Agency “National Centre for Legislative Regulation project implementation unit”
at the Staff of Government of the Republic of Armenia
Time period from 02.05.2012 to 01.11.2012

N	Scope of area	Public Services				Transport		Health Care/Licensing of Drugs		
		Energy	Water	Gas	Telecommuni- cations	Urban Transport	Intercity Transport	Ambulatory Medical Care	Clinics	Quality Control on Drugs
1	Collect the full texts of each legal norm, templates and fee schedule, and keep these documents in a central location in paper or electronic copy or both.	Up to 01.06.2012		Up to 01.06.2012		Up to 08.06.2012		Up to 15.06.2012		
2	Research of the best practice in the international legislation (reference country)	Up to 01.06.2012		Up to 01.06.2012		Up to 15.06.2012		Up to 22.06.2012		
3	Description of business processes	Up to 15.06.2012		Up to 15.06.2012		Up to 06.07.2012		Up to 13.07.2012		
3	Description of the best regulation practices	Up to 15.06.2012		Up to 15.06.2012		Up to 13.07.2012		Up to 20.07.2012		
4	Comparison of the acting and the best regulation practices through the inventory and review forms for each legal norm in a standard electronic format. Drafting proposals and	Up to 22.06.2012		Up to 22.06.2012		Up to 27.07.2012		Up to 03.08.2012		

	recommendations. Development of reform benchmarks. Discussion of at least for 3 types of processing, including: 1) Reduction 2) Modification (Amendments) 3) Introduction of new regulation				
5	Drafting of the proposed type of the regulation. Description of the proposed amendment.	Up to 06.07.2012	Up to 06.07.2012	Up to 10.08.2012	Up to 24.08.2012
6	Public discussions	Up to 20.07.2012	Up to 20.07.2012	Up to 24.08.2012	Up to 14.09.2012
7	Drafting of legal acts. Statement(Justification) Inter-agency discussions.	Up to 17.08.2012	Up to 17.08.2012	Up to 07.09.2012	Up to 12.10.2012
8	Revision of the drafts of laws as a result upon the discussions	Up to 24.08.2012	Up to 24.08.2012	Up to 21.09.2012	Up to 26.10.2012
9	Submission to the Reformation Council	03.09.2012		01.10.2012	01.11.2012
	Technical Staff	1 Legal expert 1 Business expert 1 legal drafter 1 ministerial staff support specialist 1 business processing expert	1 Legal expert 1 Business expert	1 Legal expert 1 Business expert 1 legal drafter	1 Legal expert 1 business processing expert 1 ministerial staff support specialist

The Work Plan (ANNEX I) differs from the Table 2 so that the Work Plan presents the methods and tools for the implementation of the Project (Inventory of legal norms, Description of the business process, Drafting of the proposed type of the regulation, Drafting of legal acts, etc). Table 2 describes the activities of the Reform Unit for the implementation of the project. The Work Plan is directed for the implementation of the activities for the first three priority sectors and is a component part of the Table 2 point 2.

FORM FOR REVIEW OF A BUSINESS PROCEDURE

REVIEW CRITERIA	
BRIEFLY RESPOND TO THE QUESTIONS AS PRECISELY AS POSSIBLE	
Is the procedure legal? If not, eliminate.	
Has the Business Procedure been published in the Gazette?	Yes No If yes, cite the date of publication and the name of the legal instrument published:
Do all aspects of the Business Procedure have express authority in an identified law?	Yes No If yes, identify the provisions of the law:
Are any fees connected to the Business Procedure?	Yes No
	If yes, are such fees and fee schedule defined in published bylaws or laws? Yes No
	If yes, identify the legal provisions:
Are all documents and information required and sought for issuing the Business Procedure expressly and exhaustively identified in a bylaw or law?	Yes No
	If yes, Identify the bylaw or law:
Is the procedure needed? If not, eliminate	
Are the objectives of the Business Procedure defined so that the desired results are clear to all?	Yes No

What is the objective?			
Are those objectives health, safety, or environmental protection?	Yes No		
	If Yes, is there clear evidence that the Business Procedure is in fact effective in protecting health, safety or the environment? Yes No		
	<table border="1"> <tr> <td style="background-color: #cccccc;"></td> <td>If Yes, define the nature of that evidence: Evaluation studies Scientific research International experience Other _____</td> </tr> </table>		If Yes, define the nature of that evidence: Evaluation studies Scientific research International experience Other _____
		If Yes, define the nature of that evidence: Evaluation studies Scientific research International experience Other _____	
	If No, is the Business Procedure still needed to implement public policy goals within a context of free markets, open borders, European integration, and consumer choice? Yes No		
<table border="1"> <tr> <td style="background-color: #cccccc;"></td> <td>If Yes, explain briefly:</td> </tr> </table>		If Yes, explain briefly:	
	If Yes, explain briefly:		
Is the procedure business-friendly? If not, simplify or eliminate			
Does the Business Procedure impose high costs on businesses that are not justified by the policy goals? For example, is the procedure or information similar or identical to the content of another procedure?	Yes No		
	If Yes, explain:		
Are the Business Procedure and its forms practical, clear and simple for businesses and implementing officials?	Yes No		
Are deadlines for response by the implementing body explicitly established?	Yes No		
Does the Business	Yes No		

Procedure create barriers to entry for SMEs?	Does the procedure require actions before a business starts commercial activities? Yes No
Does the Business Procedure reduce as far as possible costs to consumers and businesses, particularly SMEs?	Yes No
Are there ways to simplify the Business Procedure to reduce burdens on businesses?	Yes No
Is the Business Procedures and requirements consistent international regulations?	Yes No
	If yes, indicate the grounds of the international commitment
Have concerns been voiced by stakeholders about inconsistency with European regulations?	Yes No
What is the budget effect?	
Are fees collected in connection with the application or implementation of the Business Procedure?	Yes No
	If yes, what is the value of the fees collected, per year?
Recommendation	

ANNEX III

INSTITUTIONS IN THE SCOPE OF THE GUILLOTINE

Included in the scope of the guillotine

1. [Ministry of Territorial Administration](#)
2. [Ministry of Agriculture](#)
3. [Ministry of Culture](#)
4. [Ministry of Economy](#)
5. [Ministry of Education and Science](#)
6. [Ministry of Emergency Situations](#)
7. [Ministry of Energy and Natural Resources](#)
8. [Ministry of Finance](#)
9. [Ministry of Foreign Affairs](#)
10. [Ministry of Healthcare](#)
11. [Ministry of Justice](#)
12. [Ministry of Labor and Social Affairs](#)
13. [Ministry of Nature Protection](#)
14. [Ministry of Sport and Youth Affairs](#)
15. [Ministry of Transport and Communication](#)
16. [Ministry of Urban Development](#)
17. [General Department of Civil Aviation](#)
18. [National Security Service](#)
19. [Republic of Armenia Police](#)
20. [State Committee of the Real Estate Cadastre](#)
21. [State Property Management Department](#)
22. [State Revenue Committee](#)
23. Central bank of Armenia
24. Public services regulatory commission
25. State commission for the protection of economic competition
26. State committee of water system
27. City government of Yerevan

Methodology

The following steps are needed to complete the Regulatory Reform:

Step 1. The Reform Unit issues the instructions and forms for the inventory phase to the Ministries and State agencies, and trains them:

- Work with the Ministries and State agencies
- Collecting the legal acts from the Ministries and State agencies.
- Submitting the names of the candidates of the Ministries and State agencies for every day work with the Reform Unit.

Ministries, regulatory bodies and the City of Yerevan. Each ministry, agency, and the City of Yerevan should identify each legal norm that it enforces on businesses and citizens, regardless of the document or legal form, and shall provide each legal norm to the Reform Unit in the form and on the schedule requested by the Reform Unit, as well as all currently valid legal normative documents issued by the ministry or agency and all other documents containing procedures being enforced by the ministry or agency such as official letters, notices, instructions guidelines or other documents issued by the ministry or agency or any of its departments or sub-departments, as well as higher level legal normative documents that the ministry or agency is responsible to implement.

Each ministry and agency shall conduct a review of each legal norm procedure to determine if it is legal, necessary, and business friendly, and shall submit the results of the review to the Reform Unit in the manner and on the schedule requested by the Reform Unit.

To prepare its inventory and to carry out its reviews, each ministry and state agency should:

- Identify a contact person or persons responsible for overseeing the inventory preparation and reviews for the institution
- Create a small group reporting to the head of the agency to oversee the development of the inventory and reviews
- Prepare a comprehensive list of all legal norms enforced by the institution on citizens and businesses, using the “Arlis” database of the Ministry of Justice, and the inventory form required by the Reform Unit;
- Collect the full text of each legal norm, form, and fee schedule, and keep these documents in a central location in paper or electronic copy or both;
- Compile all currently valid legal norms issued or implemented by the ministry or agency and all other documents containing procedures being enforced by the ministry or agency such as official letters, notices, instructions guidelines or other documents issued by the ministry or agency or any of its departments or

sub-departments, as well as higher level legal normative documents that the ministry or agency is responsible to implement and keep these documents in a central location in paper or electronic copy or both, as well as submit paper or electronic copies thereof to the Reform Unit no later than the deadline provided in the schedule;

- Prepare an inventory form for each legal norm in the standard electronic format, and a review form;
- Submit the inventory and review forms to the central Reform Unit as forms are completed;
- Respond to any questions from the Reform Unit and supply any information that is requested;
- Consult as necessary with stakeholders to carry out these task at a high level of quality;
- Promptly implement the recommendations of the Reform Unit once they are adopted.

Step 2. The inventory will rely to the maximum extent possible on the “Arlis” www.arlis.am database being developed by the Ministry of Justice, other legal sources such as; www.parliament.am, www.datalex.am. www.e-gov.am.

- Each legal norm must be precisely identified as to the enforcing institution and the instrument itself. This is because the titles of many norms are similar and other procedures overlap or duplicate. There must be precision in order to manage each dossier properly.
- Each norm must have some basic descriptive information about the nature of the procedure, such as whether it affects businesses or citizens, or involves a license, or has forms attached, or requires fees. This is to allow the Review Unit to establish priorities in the review phase by identifying these kinds of high cost norms.
- There should be a contact point for each norm in order to facilitate quality control and the collection of further information if necessary.

Step 3: Ministries and state agencies submit inventory forms.

Step 4: Reform Unit completes the electronic inventory. This allows, for the first time, a clear estimation of the legal norms needed for the Regulation Reform.

Step 5. Study and Research of International practices in transitional and developed economies using all possible sources by the Reform Unit.

Step 6. Description of business processes by the Reform Unit. Monitoring and evaluating the present and proposed business processes and their expected results.

Step 7. Carry out independent reviews of the legal norms, considering information provided by the ministries, other state bodies, and civil society such as businesses and the public.

Step 8. Public hearings and discussions. Inform and encourage input from organizations such as the business group, and other stakeholders in the review of legal norms, and hold consultative seminars, workshops, meetings, or other forms of communication as needed to ensure transparency in the process of the reform;

- To understand the stakeholders' needs and problems in business process.
- To discuss the Reform Unit's recommendations and proposals with the stakeholders.

Step 9. Business groups carry out their reviews. This is staggered as well to accelerate priority areas.

Step 10. Reform Unit carries out its own reviews, which are also timed to complete early packages on schedule. For each recommendation, the Reform Unit estimates the impacts on tax revenues and business/citizen cost savings (economic and financial justification).

Step 11. Inter-agency discussions. Reform Unit submits the packages to the Ministries and State agencies.

Step 12: Ministries, State agencies, and the City of Yerevan submit reviews to the Reform Unit. This is staggered, so early priority areas are reviewed first, followed by other reviews through the entire reform process.

Step 13. The Reform Unit carries out reviews based on the results of received discussions and recommendations.

Step 14. The Reform Unit develops the final recommendations and prepares the necessary draft legal normative documents to implement those recommendations, assembles the final package and transmits those recommendations and draft legal norms to the Reform Council.

Step 15. Reform Council decides to accept or reject appeals.

Step 16. Reform Unit makes amendments in the package based on the recommendations of the Reform Council and assembles the final package.

Step 17. After implementation of all necessary procedures, the final package is being submitted for Government's consideration and final decision.

Step 18: Government adopts package of reforms.

**ANNEX V
to the RA President
Decree NH-246-N
dated 17 September 2011**

**STRUCTURE
OF COUNCIL FOR REFORMATION OF LEGAL ACTS REGULATING ECONOMIC
SECTOR OF THE REPUBLIC OF ARMENIA**

Prime Minister of the Republic of Armenia (Chairman of the Council)

Chief Advisor to President of the Republic of Armenia

Minister of Economy of the Republic of Armenia

Minister of Finance of the Republic of Armenia

Minister of Justice of the Republic of Armenia

V. SARGSYAN

ACTING HEAD OF ADMINISTRATION

OF PRESIDENT OF ARMENIA

**ANNEX VI
to the RA President
Decree NH-246-N
dated 17 September 2011**

**LIST
OF AREAS TO BE INCLUDED IN THE REFORMS PROCESS**

1. Local government and local self-governance sector
2. Sector of agriculture and water economy management
3. Sector of culture, health, social issues, education and science
4. Entrepreneurial, financial, tax and customs sector
5. Sector of emergency situations
6. Sector of energy, natural resources, nature protection
7. Sector of external affairs and international relations
8. Law enforcement and justice sector
9. Sector of sport and youth issues
10. Sector of transport and communication
11. Sector of urban development
12. Sector of civil aviation
13. Sector of land relations and cadastre of immovable property
14. Sector of state property management
15. Sector of financial markets
16. Public services regulation sector
17. Economic competition protection

V. SARGSYAN

ACTING HEAD OF ADMINISTRATION

OF PRESIDENT OF ARMENIA

PRESIDENT OF THE REPUBLIC OF ARMENIA

DECREE

ON ESTABLISHING A COUNCIL FOR COORDINATION OF MEASURES TO IMPROVE GOVERNANCE OF ECONOMIC ACTIVITIES AND REFORMATION OF LEGAL ACTS REGULATING ECONOMIC SECTOR OF THE REPUBLIC OF ARMENIA

Given the need of bringing economic competitiveness of the country to a new qualitative level for countering socio-economic challenges faced by the Republic of Armenia as well as improving effectiveness of state regulation in economic activities and guided with Article 55.6 of the Constitution of the Republic of Armenia, I decree:

1. Establish Council for Reformation of Legal Acts Regulating Economic Sector of the Republic of Armenia (hereinafter referred to as Reformation Council) to develop recommendations on removing provisions hampering the development of business environment and market relations, improving and simplifying services rendered to citizens by the state, improving normative legal acts effective in this area as well as cutting economically non-effective, costly and improper mechanisms set out by them and improve the structure of the council in accordance with Annex 1;
2. Approve list of areas to be covered by the reforms process stipulated under clause 1 of this Decree in accordance with Annex 2;
3. To the Government of the Republic of Armenia – on making this Decree effective:
 - 1) Approve Charter of the Reformation Council within a one-month period;
 - 2) Approve Concept on Improvement of Regulatory Impact Assessment System of Legal Acts Regulating Economic Sector of the Republic of Armenia (Better Regulation Agenda) by 1 January 2012.
4. Define:
 - 1) Everyday activities of the Reformation Council shall be ensured by state organization;
 - 2) Reformation Council shall at least on quarterly basis report to the President of the Republic of Armenia on activities implemented in the frames of the process stipulated under Clause 1 of this Decree;

- 3) Reformation Council shall discuss recommendations on reformation, simplification of legislation of the Republic of Armenia regulating the economic sector and where appropriate proceed in an established procedure. In case of disagreement by relevant entities about the presented recommendations Reformation Council shall, in compliance with its regulation, take a decision on appropriateness on proceeding with their implementation.
5. Propose to the Yerevan Mayor, Chairman of the Central Bank of Armenia, Chairman of Committee on Public Services Regulation of Armenia and Chairman of State Committee for the Protection of Economic Competition of Armenia to cooperate with Reformation Council and state organization ensuring its operation in the frames of the process stipulated under Clause 1 of this Decree.
6. This Decree shall become effective on the day following its official promulgation.

S. Sargsyan

President of the Republic of Armenia

17 September 2011

Yerevan

NH-246-N

ANNEX VIII

3. GENDER CONSIDERATIONS

Since the Reform Unit's strategy is to regulate all areas of socio-economic activities in Armenia, it will also address such issues as gender equality (gender relations, involvement of women) and environmental sustainability.

A. B. Gender analysis (to the Gender considerations)

With regard to gender analysis and gender experts it is worth indicating that the UNDP has expressed interest in providing documents, reports, studies and analyses on gender equality, which can be taken into account during the project implementation period.

The UN Gender Team has expressed readiness to cooperate with the Reform Unit staff, and the experts from the Reform Unit will participate in a UN meeting (training) on gender issues on 1st of June, 2012.

Meanwhile, the Reform Unit invited a number of women associations to participate in public consultations, namely the Women in Business Investment Association (WiBIF) headed by Nune Eghiazaryan, the Social-Economic Analysis Center headed by Nairuhi Jrbashyan, the Consumer Protection Organization headed by Lusine Yakubyan, the Women's Resource Center Armenia (WRCA Yerevan), and the Public Information and Need of Knowledge (PINK) NGO.

In order to ensure proper consideration of gender issues and to conduct a transparent survey the Reform Unit will amend the Business Procedure Review Form (Checklist) (see Annex II to the Project Progress Report) by adding a new point on gender issues (whether a particular regulation impacts gender issues/gender relations/equality/women involvement). This amendment will be made after the meetings with the UN representatives.

C.2. Elimination of barriers.

In order to ensure gender equality in all spheres in Armenia (political life, decision-making, labour market, elimination of violence against women, health, education, construction, customs, etc.) the Reform Unit staff is highly encouraged to take gender issues into account when creating or amending regulations during the regulatory reform process.

For this reason it is important:

- a. To amend the Business Procedure Review Checklist to ensure the elimination of all discriminatory barriers set for women.
- b. To consider the 2004-2010 Republic of Armenia National Action Plan.
- c. To take into account the Donors' considerations on gender issues.

C.3. Participation and control.

The implementation of the gender aspect of the project will be pursued in close cooperation with women's international and local NGOs, business organizations, female entrepreneur associations. As mentioned above, women associations such as the WiBIF, the Social-Economic Analysis Center, the Consumer Protection Organization, the WRCA Yerevan, the PINK, etc. are invited to actively participate in public discussions and hearings during the regulatory reform process and be involved in the Business Advisory Council.

C.4. Indicators

To promote the equality of rights and opportunities for men and women the Reform Unit considered gender equality issues also during the staffing process.

In fact, the number of female employees recruited in the Reform Unit staff exceeds the number of male employees. Currently, the Reform Unit is staffed by 14 female and 10 male employees.

The Reform Unit staff understands the importance of surveys and opinion polls with a strong participation of women in addressing social and economic problems of women.

C5. Qualified personnel

Given that equal rights of women and men should be ensured in all sectors of Armenian economic and social life, the RIA will be an integral part of the regulatory project and will be included in the methodology of the Reform Unit. Thus, the RIA, the 2004-2010 Republic of Armenia National Action Plan and other legal documents and analyses will be taken into consideration during the implementation of the project to ensure gender equality in future legislation.

C6. Consultations

As stated above, the Reform Unit encourages the participation of women's organizations and associations in all stages of the regulatory process.

The Reform Unit has adopted a strategy aimed at addressing gender issues and formulating recommendations by strongly cooperating with women's NGOs and associations. Therefore, the role of the gender equality team is significant, and it is expected that during the first meeting with the UN gender team on 1st of June, 2012, it will be introduced to useful mechanisms and tools for detecting and resolving gender issues during the legislative process. The UN team will hopefully cooperate with the Reform Unit during the whole period of the project implementation with regard to women's issues.

4. ENVIRONMENTAL CONSIDERATIONS

Social development programs, economic projects and plans, operating businesses, etc. can affect the environment by causing, for instance, land degradation, extinction of many species of flora and fauna, pollution, and negative impact on global climate. Thus, human economic activities will be subject to an Environmental Impact Assessment.

It is important to mention that the areas specified in Presidential Decree No. 246-N of 17 September 2011, which are to be included in the reform process (agriculture and water economy management, energy, natural resources, nature protection, public utility services regulation, urban development, culture, health, social issues, education and science etc.) are related to environment issues in some way or another, and further developments and regulations in these areas, especially the construction sector, can affect the environment. Other sectors might relate to environmental issues as well, and they will be taken into account during the regulation process.

At this point it is worth mentioning that all newly developed legal acts are subject to mandatory Regulatory Impact Assessment, and the Environmental Impact Assessment is one of the key components of the RIA.

For this reason the Reform Unit will change the Business Procedure Review Form (Checklist) to add a new point on EIA and make sure that any particular regulation is in compliance with Armenia's international commitments with regard to environmental issues.

New regulations within the Project framework will be brought in line with international agreements, such as the Convention on Biological Diversity, the UN-Framework Convention on Climate Change, the UNECE Convention on Access to Information, Public Participation in Decision Making and Access to Justice in Environmental Matters etc. Defining the scope of the EIA is a fundamental component of the RIA, which addresses environmental topics and methods to be used

The Government of Armenia aims to improve the RIA, of which EIA is a key component. Further development of the EIA system is first of all connected to harmonization of the newly developed legislation with the European standards and international agreements signed and/or ratified by the Republic of Armenia.

It is expected that public involvement will help to promote the necessary level of reliability, transparency and democracy needed to ensure gender equality and environmental protection.

MONITORING PLAN

For the Implementation by the Reform Unit of Reforms in First Three Priority Sectors during 2012¹

PUBLIC UTILITY SECTOR REGULATION TEAM	TRANSPORT AND COMMUNICATION SECTOR REGULATION Team	PUBLIC HEALTH SECTOR REGULATION Team
<ul style="list-style-type: none">• Expert Lawyer• Public Administration Agencies Support Officer• Economic Expert• Business Expert• Legal Drafting Specialist	<ul style="list-style-type: none">• Expert Lawyer• Public Administration Agencies Support Officer• Legal Drafting Specialist	<ul style="list-style-type: none">• Two Expert Lawyers• Two Economic Experts• Business Expert

¹The Reform Unit will initiate reforms in other 2-3 sectors by the end of 2012 depending on the complexity and volume of the works. Other priority sectors will be approved at the Reform Council Session approximately in August, 2012. The next Monitoring Plan will be prepared and submitted to the Donors as soon as the Reform Council Session approves the other priority sectors.

1. Public Utility Sector Regulation

Table 1. Time period from 02.05.2012 to 03.09.2012

N	Scope of area	Agencies/ Stakeholders	Public Utility Sector			
			Energy	Water	Gas	Tele-communication s
1	Law mapping/ Inventory phase in accordance with the Methodology	Public Services Regulatory Commission of RA -Ministry of Justice of RA -Ministry of Energy and Natural Sources of RA	01.06.2012 <u>Completed</u>		01.06.2012 <u>Completed</u>	
2	Study of international legislation/practices	Foreign State Agencies, Ministries and Government Bodies, Internet sources	01.06.2012 <u>Completed</u>		01.06.2012 <u>Completed</u>	
3	Description of business processes	NGO's, Foundations, Associations	15.06.2012 <u>In progress</u>		15.06.2012 <u>In progress</u>	
3.1	Description of best regulation practices		15.06.2012 <u>In progress</u>		15.06.2012 <u>In progress</u>	
4	I. Comparison of regulations in force with the best regulation practices through the inventory and review of each legal requirement according to a standard electronic format. II. Drafting proposals and recommendations.	-Public Services Regulatory Commission of RA -Ministry of Justice of RA -Ministry of Energy and Natural Resources of RA -Ministry of Nature Protection of RA -Ministry of Urban Development of RA -Ministry of Economy of RA	22.06.2012 <u>In progress</u>		22.06.2012 <u>In progress</u>	

	<p>Development of reform benchmarks.</p> <p>III. Discussion of at least 3 types of processing, including:</p> <p>4) Reduction</p> <p>5) Modification (Amendments)</p> <p>6) Introduction of new regulation</p>	-Ministry of Emergency Situations		
5	<p>I. Drafting of the proposed regulation.</p> <p>II. Description of the proposed regulation.</p>		06.07.2012	06.07.2012
6	Public discussions/hearings	<p>NGO's, associations, foundations</p> <p>-Women in Business Investment Future (WiBIF)</p> <p>-Social-Economic Analysis Center</p> <p>-Protection of Taxpayers</p> <p>-Protection of Consumer Rights</p> <p>-Public Defenders' Association</p> <p>-Consumers' Association</p> <p>-SME DNC Foundation</p> <p>-Condominium Presidents' Association</p> <p>-Armenian Merchants' Organization</p> <p>-Chamber of Commerce and Industry of RA</p> <p>-Foundation of Small and</p>	20.07.2012 <u>Ongoing</u>	20.07.2012

		<p>Medium Businesses -Union of Manufacturers and Businessmen (Employers) of Armenia (UMB(E)A) -Media</p>		
7	<p>I. Drafting of legal acts II. Economic Justification III. Inter-agency discussions</p>	<p>-Ministry of Justice of RA -Public Services Regulatory Commission of RA -Ministry of Agriculture of RA -Ministry of Energy and Natural Resources of RA -Ministry of Nature Protection of RA -Ministry of Urban Development of RA -Ministry of Economy of RA -Ministry of Emergency Situations</p>	17.08.2012	17.08.2012
8	Revision of draft legal acts following the discussions		24.08.2012	24.08.2012
9	Submission of draft legal acts to the Reform Council		03.09.2012	

2. Transport and Communication Sector Regulation

Table 2. Time period from 02.05.2012 to 01.10.2012

N	Scope of area	Agencies/ Stakeholders	Transport	
			Urban Transport ²	Intercity Transport
1	Law mapping/ Inventory phase in accordance with the Methodology	-Ministry of Transport and Communication of RA -Ministry of Justice of RA		08.06.2012 <u>Completed</u>
2	Study of international legislation/practices	Foreign State Agencies, Ministries and Government Bodies, Internet sources		15.06.2012 <u>Completed</u>
3	Description of business processes	NGO's, Foundations, Associations		06.07.2012 <u>Completed</u>
3. 1	Description of best regulation practices			13.07.2012
4	I. Comparison of regulations in force with the best regulation practices through the inventory and review of each legal requirement according to a standard electronic format. II. Drafting proposals and recommendations. Development of reform	-Ministry of Transport and Communication of RA -Ministry of Justice of RA -Ministry of Economy of RA -Ministry of Labor and Social Affairs of RA -Ministry of Territorial Administration of RA		27.07.2012 <u>Completed</u>

² Taxis/ Mini buses/Shuttles/Trolleybuses/Carriage of passengers and goods

	<p>benchmarks.</p> <p>III. Discussion of at least 3 types of processing, including:</p> <p>1) Reduction</p> <p>2) Modification (Amendments)</p> <p>3) Introduction of new regulation</p>		
5	<p>I. Drafting of the proposed regulation.</p> <p>II. Description of the proposed regulation.</p>		<p>10.08.2012</p> <p><i><u>In progress</u></i></p>
6	<p>Public discussions/hearings</p>	<p>NGO's, associations, foundations</p> <p>Women in Business Investment Future (WiBIF)</p> <p>-Social-Economic Analysis Center</p> <p>-Planeta Travelers Club</p> <p>-Achilles Drivers' Rights Protection Center</p> <p>-Armenian Auto Importing Corporation</p> <p>-Taxi Services Association IAM</p> <p>-Media</p>	<p>24.08.2012</p> <p><i><u>ongoing</u></i></p>
7	<p>I. Drafting of legal acts</p> <p>II. Economic Justification</p> <p>III. Inter-agency discussions</p>	<p>Ministry of Justice of RA</p> <p>-Ministry of Transport and Communication of RA</p> <p>-Ministry of Justice of RA</p> <p>-Ministry of Economy of RA</p> <p>-Ministry of Labor and Social Affairs of RA</p> <p>-Ministry of Territorial Administration of RA</p>	<p>07.09.2012</p>
8	<p>Revision of draft legal acts following the discussions</p>		<p>21.09.2012</p>

9	Submission of draft legal acts to the Reform Council		01.10.2012
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3. Public Health Sector Regulation

Table 3. Time period from 02.05.2012 to 01.11.2012

N	Scope of area	Agencies/ Stakeholders	Health Care/Licensing of Drugs ³		
			Ambulatory Medical Care	Clinics	Quality Control on Drugs
1	Law mapping/ Inventory phase in accordance with the Methodology	-Ministry of Healthcare of RA -Ministry of Justice of RA			15.06.2012 <u>Completed</u>
2	Study of international legislation/practices	Foreign State Agencies, Ministries and Government Bodies, Internet sources			22.06.2012 <u>Completed</u>
3	Description of business processes	NGO's, Foundations, Associations			13.07.2012 <u>Completed</u>
3.1	Description of best regulation practices				20.07.2012 <u>In progress</u>
4	I. Comparison of regulations in force with the best	-Ministry of Healthcare of RA -Ministry of Justice of RA - -Ministry of Economy of RA			03.08.2012 <u>In progress</u>

³ Drugs, drug production, export, import/ Pharmacy, drugstores/ Public medical care/ Public sanitary and epidemiological security/ Psychiatric care/ Psychotropic substances/Licensees/Blood giving and transfusion/Reproductive health care.

	<p>regulation practices through the inventory and review of each legal requirement according to a standard electronic format.</p> <p>II. Drafting proposals and recommendations. Development of reform benchmarks.</p> <p>III. Discussion of at least 3 types of processing, including:</p> <p>1) Reduction</p> <p>2) Modification (Amendments)</p> <p>3) Introduction of new regulation</p>	<ul style="list-style-type: none"> -Ministry of Finance of RA -Ministry of Nature Protection of RA -Ministry of Agriculture of RA - Ministry of Emergency Situations of RA -Police Department -State Revenue Committee of RA 	
5	<p>I. Drafting of the proposed regulation.</p> <p>II. Description of the proposed regulation.</p>		<p>24.08.2012</p> <p><u>In progress</u></p>
6	<p>Public discussions/hearings</p>	<p>NGO's, associations, foundations</p> <ul style="list-style-type: none"> -Women in Business Investment Future (WiBIF) -Social-Economic Analysis Center -Armenian Association of Public Health -Armenian Medical Association - Pharmaceutical Association - Armenian Stomatology Association -Armenian Drug Production and Import Association -Media 	<p>14.09.2012</p> <p><u>Ongoing</u></p>
7	<p>I. Drafting of legal acts.</p>		<p>12.10.2012</p>

	II. Economic Justification III. Inter-agency discussions.	Ministry of Healthcare of RA -Ministry of Justice of RA -Ministry of Economy of RA -Ministry of Finance of RA -Ministry of Nature Protection of RA -Ministry of Agriculture of RA - Ministry of Emergency Situations of RA -Police Department -State Revenue Committee of RA	
8	Revision of drafts legal acts following the discussions		26.10.2012
9	Submission of draft legal acts to the Reform Council		01.11.2012

Time plan*

Activities	Quarter							
	1	2	3	4	5	6	7	8
Expected Result 1: <i>High level of performance, efficiency and effectiveness of Reform Unit is insured through securing a strong team of professionals, its political independence, building professional capabilities and collaborative participation of key stakeholders.</i>								
1.1 Selecting experienced and prominent local experts/consultants for the positions of Head of Guillotine Unit, deputies, long-term senior adviser and other staff.	<u>Completed</u>							
1.2 Instructing the bodies under the scope of the reform on the procedures needed to comply with the schedule.	<u>Ongoing</u>							
1.3 Developing proper justification for each and every reform proposal and ensuring low number of appeals.		<u>Ongoing</u>	<u>Ongoing</u>	<u>Ongoing</u>	<u>Ongoing</u>	<u>Ongoing</u>	<u>Ongoing</u>	<u>Ongoing</u>
1.4 Liaising with the President and the Prime Minister regularly and whenever such issues arise that threaten the successful completion of the reform.		<u>Ongoing</u>	<u>Ongoing</u>	<u>Ongoing</u>	<u>Ongoing</u>	<u>Ongoing</u>	<u>Ongoing</u>	<u>Ongoing</u>
Expected Result 2: <i>Capacities of 27 ministries and government agencies are increased significantly to provide required outputs.</i>								

2.1 Collect the full texts of each legal norm, templates and fee schedules, and keep these documents in a central location in paper or electronic copy or both.	<u>Completed</u>							
2.2 Compile all currently valid legal norms issued and/or implemented by the ministries or agencies and all other documents containing procedures being enforced by them.	<u>Completed for the 1st 3 priority sectors</u>							
2.3 Prepare inventory and review forms for each legal norm in a standard electronic format.	<u>Completed for the 1st 3 priority sectors</u>							
2.4 Submit the inventory and review forms to the central Reform Unit as they are completed.	<u>Completed for the 1st 3 priority sectors</u>	<u>Ongoing</u>	<u>Ongoing</u>					
2.5 Respond to any questions from the Reform Unit and supply any information that is requested.		<u>Ongoing</u>	<u>Ongoing</u>	<u>Ongoing</u>	<u>Ongoing</u>			
2.6 Consult as necessary with stakeholders to properly carry out these tasks.			<u>Ongoing</u>	<u>Ongoing</u>	<u>Ongoing</u>	<u>Ongoing</u>	<u>Ongoing</u>	<u>Ongoing</u>
2.7 Promptly implement the recommendations of the Reform Unit once they are adopted.			<u>To be implemented</u>	<u>To be implemented</u>	<u>To be implemented</u>	<u>To be implemented</u>	<u>To be implemented</u>	<u>To be implemented</u>
Expected Result 3: <i>Business Advisory Council is established, operational and ensure timely and adequate contribution of business associations and civil society organization to the review process.</i>								

3.1 Inform and encourage input from organizations such as business associations and other stakeholders in the process of review of legal norms. Hold consultative seminars, workshops, meetings, or other forms of communication as needed to ensure transparency in the process of the reform.		Ongoing	Ongoing	Ongoing	Ongoing	Ongoing	Ongoing	Ongoing
Expected Result 4: <i>High level mentorship of reformation efforts is secured through engagement of a world-class expert.</i>								
4.1 Recruitment of internationally recognized expert/consultant.	<u>To be implemented</u>							
4.2 Development of reform benchmarks, negotiations with the Government and partner donor agencies.	<u>To be implemented</u>							
4.3 Development of quarterly progress reports, recommendations and implementation of political debates within the Reform Council.		<u>To be implemented</u>	<u>To be implemented</u>	<u>To be implemented</u>	<u>To be implemented</u>	<u>To be implemented</u>	<u>To be implemented</u>	<u>To be implemented</u>
Expected Result 5: <i>Custom made IT software is purchased, installed and respective staff members are trained.</i>								
5.1 Procurement and installation of licensed e-guillotine software.	<u>To be implemented</u>							
5.2 Implementation of trainings for Guillotine Unit staff on how to operate the e-guillotine software.	<u>To be implemented</u>							

Expected Result 6: Adequate communication strategy and branding resulted broader political support and pro-active participation of businesses, civil society and public in general.								
6.1 Communication mechanisms should be used such as written reports, training seminars, workshops, videos, e-mails, newsletters, TV ads, etc.	<u>Ongoing</u>	<u>Ongoing</u>	<u>Ongoing</u>	<u>Ongoing</u>	<u>Ongoing</u>	<u>Ongoing</u>	<u>Ongoing</u>	<u>Ongoing</u>
6.2 Key elements of information to be distributed by the different mechanisms will be identified, including frequency and information collection and collation.	<u>Ongoing</u>							
6.3 Roles and responsibilities of the key individuals responsible for ensuring that communication are adequate / appropriate and timely.	<u>Ongoing</u>							
6.4 Identification of how unexpected information from other parties (including stakeholders) will be handled within the scope of the activity.	<u>Ongoing</u>							
Expected Result 7: Reform Unit is provided with fully equipped office premises and monthly office running costs are taken care.								
7.1 Identification and provision of suitable office premises to the Reform Unit by Government of Armenia.	<u>Completed</u>							
7.2 Procurement and installation of office furniture, equipment and other necessary technical facilities.	<u>Completed</u>							
7.3 Implementation of monthly payments for utility and other miscellaneous costs.	<u>Ongoing</u>							
Expected Result 8: Reform Council decides to accept or reject appeals								

8.1 Guillotine Unit prepares justifications for controversial simplifications based on the input from respective government agencies, Business Advisory Council and its own assessments.			<u>To be implemented</u>	<u>To be implemented</u>	<u>To be implemented</u>	<u>To be implemented</u>		
8.2 Reform Council organizes hearings (if necessary public) and provides all parties with the opportunity to properly present the case and justifications, followed by taking decision on approval or rejection of the appeal.			<u>To be implemented</u>	<u>To be implemented</u>	<u>To be implemented</u>	<u>To be implemented</u>		
Expected Result 9: <i>Reform Unit drafts legal text to implement the recommendations and assembles the final package</i>								
9.1 Reform Unit (if necessary in close collaboration with concerned government agency and other stakeholders) develops the texts of necessary amendments aimed at implementing recommendation, as well as assembles final package.				<u>To be implemented</u>	<u>To be implemented</u>	<u>To be implemented</u>	<u>To be implemented</u>	
Expected Result 10: <i>Packages are sent by Prime Minister to the Government for action as a single unit (one vote up or down)</i>								
10.1 After implementation of all necessary procedures, the final package is being submitted for Government's consideration and final decision.							<u>To be implemented</u>	<u>To be implemented</u>

Expected Result 11: Government adopts package of reforms								
11.1 Government adopts package of reform.							To be implemented	To be implemented
Expected Result 12: Procedures begin to legal adopt revised legal text								
12.1 The recommendations are adopted by the appropriate legal authority (the Government, the President, the Prime Minister, the ministries and agencies, or the parliament).								To be implemented
Expected Result 13: Procedures begin to legal adopt revised legal text								
13.1 Reform Unit monitors adoption and reports to Prime Minister and President.								To be implemented

Starting period of the activities in the Time plan is 02 May 2012

ANNEX XI

23 May, 2012

Venue: National Centre for Legislative Regulation PIU¹,
22 Saryan str, Yerevan 0002, Armenia

Roundtable with the representatives of pharmacy NGOs and associations

In attendance:

1. Vardan Mkrtchyan – “Liqvor”
2. Ashot Gasparyan – “Esco Pharm”
3. Siraz Matevosyan - “Yerevan Chemical-Pharmaceutical Firm”
4. Seyran Hovsepyan – “Yerevan Chemical-Pharmaceutical Firm”
5. Shahe Qasis – “Medical Horizon”
6. Samvel Zaqaryan – “DAN Union”
7. Ruben Sarukhanyan – “DAN Union”
8. Ina Arzumanyan – “Abbott Laboratories”
9. Georgiy Serlanov – “Pharm Trust”
10. Gagik Grigoryan – “Esculap”
11. Eduard Dilanyan - "Vitamax-E"
12. Vahan Karganyan - “Lambron-Pharmimpex”

Main areas of discussion with the participants of the meeting were as follows:

- On marketing authorisation¹ of medicines
- On licensing (marketing authorisation) and expertise of imported medicines in context of customs (clearance)
- On timeline of licensing (marketing authorisation)

- On issue of the certificate
- On the efficiency/inefficiency of the Scientific Center of Drug and Medical Technologies Expertise (SCDMTE)¹
- Complaint on re-registration procedures (new marketing authorisation after the expiry date)
- New law on medicines ¹ (upcoming amendments to the existing law)

A brief record of the opinions, complaints and suggestions of the participants of the meeting

- On marketing authorisation¹ of medicines
 - Complaints on the timeline: no particular timeline. Participants felt unhappy with a 10-30 days issue → demand for a concrete timeline;
 - Usually referring to Article 87 of the Customs Code that was amended;
- On licensing and expertise of imported medicines in context of customs (clearance)
 - Participants agreed on a huge obstacle to be the clearance process (customs), particularly a process of decision on the clearance charges→ notwithstanding the Centre told this was not on its agenda at this time of the year;
 - Another area of discontent was the VAT→ they went on complaining that many states have got a VAT-free policy in regard to medical products and that this is an obstacle for businesses' development and additional factor fostering monopolies in this sector;

- The clearance they say is conducted according to fixed prices → they say before there was Art. 87 of the Customs Code in progress, according to which one went to state committee (պէս. կոմիտե) → got the documentation;
- New procedure operates as aforementioned according to fixed prices if one does not possess a contract or any other official document with fixed prices in it – invoice → say someone brought a Vaseline with a price of 3 USD which actually becomes a fixed price as such;

- *On timeline* → complaint → oncological medicines as well as other expensive and inevitably significant for human health medicines simultaneously valuable in terms of the businesses (manufacturing/import/export) when taken for an expertise become a big deal for the businesses as the samples are rarely returned after the expert analysis is over → besides such medications can be a cost of a human health;

→ Furthermore it is harsh and costly to distribute the new product on market, while in addition to this issue they have to cover clearance related costs and lose a sample;
- An order is as follows: a product gets into customs for check-in → a sample then is taken to expertise for licensing (marketing authorisation) → dissatisfaction of participants on the timeline → claiming 30 days isn't enough time period to do an in depth analysis → question → what do they actually do then and why does it take that long → demand → to give a detailed written explanation of the procedures they undertake for these purposes → if they study documentation or if they do chemical/biological analysis → the Scientific Center of Drug and Medical Technologies Expertise (SCDMTE) says the reason for delays is a big quantity of applications they receive;
- *On expertise* → for importation → those doing an expertise have got many reasons to justify the delay. However the participants claimed their justifications were not convincing whatsoever;

- Participants made a reference to the cases of Japan or EU in terms of registration procedures (marketing authorisation=licence);
- Participant gave the following suggestion → let the customs give a free quota on the period while the Scientific Center of Drug and Medical Technologies Expertise is conducting the expertise → or at least give them 10 days gratis → either permit to shorten the timeline for conducting the expertise → either to give them 10 extra days in the customs (grace period);

To sum up, the main discontent of the participants was regarding the settings of the customs value for imported medicines. Such practice of customs administration does not satisfy WTO requirements and is subjective as such.

- A complaint came on the fee for marketing authorisation → 500 000 AMD to register a medicine in Armenia (for each title);

Suggestion from the participants → if the product has a marketing authorisation and licence, i.e. it is registered in the EU/US/RF then wouldn't it be possible to simply make an examination of the sample¹ and give the authorisation based on the result of examination only;

- If there is a requirement to conduct a microbiological analysis than well it takes up to 30 days → in the meantime in Georgia in case the importers have doubts on whether a medicine requires the analysis, then they submit it for such an analysis by their own will told one of the participants¹.

➤ Yet no specific complaint came on the expertise centre (*Scientific Center of Drug and Medical Technologies Expertise (SCDMTE)*)

Overall opinion was that the centre works consistent with international standards and in general everyone was satisfied with their work as such.

- Then discussion passed onto the registration fees → claiming medicine produced under the GMP standards (Good Manufacturing Practice¹) can't be less costly elsewhere;
 - *Complaint on re-registration procedures (new marketing authorisation)*
- Participants told they did not comprehend how actually the re-registration scheme was operating → say the medicine was registered once and got a marketing authorisation → why would the medication pass through the same long procedure once again, they wondered, if the medication was all the same with identical ingredients → wouldn't it be possible to leave aside the same routine and shorten the procedure up to checking the certificates and check-in documentation they had already got once from the *SCDMTE* → if while doing the inspection they find inconsistency in documentation then let them conduct the analysis once again and punish the fake dealer, rather than applying to the same procedures with regard to everyone → suggestion;
 - *On future amendments to the law on medicines*
- A general opinion was pretty much positive. The expressions of discontent came regarding some particular provisions (see below);
- A complaint though came on the fee for expertise → as there is to be an increase in fees;
- The new provision on importing and distributing medicines → aiming to fight the monopolies → before one had to possess a specific certificate being a representative or a distributor of a particular company importing the medicine → how it is going to work now → one can purchase the medicine from a third person elsewhere who has got such a certificate in advance and import the medical product → participants complained on a side effects of such changes claiming these could be a threat to national security as one can't be sure if a certificate of

a third person is a fake one or an original one as such and who is a third person
→ issue of a bioterrorism;

→ besides, they complained on the unfairness of the new changes of procedures
→ representative spends money, get the registration done and then someone else brings the same medicine from say Belorussia without undertaking those procedures;

Sources

Medicine Producers and Importers Union (MPI Union) of Armenia – available at
<<http://www.pharmunion.am/en/members> >

Scientific Centre of Drug and Medical Technology Expertise - available at <
www.pharm.am >

GMP Question and Answers - available at
<http://www.who.int/medicines/areas/quality_safety/quality_assurance/gmp/en/index.html >

EudraGMP -
<<http://eudragmp.ema.europa.eu/inspections/displayWelcome.do;jsessionid=ac10292ad326ad2a623e0074191b570a1052042b238.rImNb38InIjqA4IpR9BcxaNbNu> >

ANNEX XII

29 May, 2012

Venue: National Centre for Legislative Regulation PIU¹,

22 Saryan str, Yerevan 0002, Armenia

Meeting with representatives of non-governmental organisations and associations.

Topic: presentation of the concept and programme of activities of the National Centre for Legislative Regulation.

In attendance:

1. Paylak Tadevosyan – “Protection of Taxpayers”
2. Karen Chilingaryan – “Consumers’ Rights Protection” NGO
3. Aram Grigoryan – “Union of Social Protection” NGO
4. Gagik Tsutsulyan – “National Centre for Development of Small and Medium Enterprise”
5. Aram Grigoryan – “Association of Heads of Condominiums” NGO
6. Tsolvard Gevorgyan – “Armenian Union of Traders” NGO
7. Eduard Kirakosyan – “Union of Armenian Industrialists and Entrepreneurs”
8. Nune Yeghiazaryan – “Women in Business” Invest for the Future”
9. Nairuhi Jrbashyan – Social and Economic Analysis Centre

Main areas of discussion with the participants of the meeting were as follows:

- Reform Council of the National Centre for Legislative Regulation
- Focus areas of the reforms
- Memorandum of Understanding

Below are the comments of the participants upon the project presentation:

➤ Reform Council of the National Centre for Legislative Regulation

As the Reform Council of the National Centre for Legislative Regulation did not formally include representatives of public (NGOs, grass-roots, ordinary citizens) the participant expressed a concern on the fact that the Council might ignore a proper public participation in its decision-making process → some suggested to have a public council attached to the project with 50% of representatives of businesses, and 50% - of the representatives of state agencies → this way they would feel more secure as decision-makers was the claim of participants → otherwise they feared the good ideas might reach the government and get postponed after all;

➤ Focus areas of the reforms

- After the three areas subject to regulatory guillotine were presented (healthcare, transportation, public utilities) → some expressed a query of why the areas of taxation and customs were not on the agenda as those were the areas of strong concern and dissatisfaction of the businesses → the answer was that those fields were to be covered in 2013 according to the programme of activities;
- Some participants suggested to share contact information of those individuals, NGOs and organisations active in and having a sufficient expertise in the fields subject to regulatory guillotine;
- Some enquiries were on whether they could bring a prepared legal drafts for the Centre's consideration as for instance they have already got one on public utilities;
- Another question raised during the discussion touched upon the issue of inefficient institutions or administrative units → if one does not justify itself, whether it was in the scope of the Centre's competence to dissolve it → such institutions exist on the account of tax payers → thus the participants were wondering if the Centre could at least conduct an impact assessment of those institutions;
- Last questions came on the upcoming legal amendments, laws and legal drafts → i.e., the Centre might be cutting down the already existing regulations while in the meantime the new unnecessary procedures might be coming into forth later on → contradicting the previous ones or contradicting

the changes passed under the regulatory guillotine → participants asked if they could send their advisory opinion on upcoming changes in regulations and legal amendments to the Centre;

- Finally, one of the participants suggested to conduct a general public opinion poll to find how ordinary citizens engaged in businesses or anywise related to this or that sphere subject to regulatory guillotine feel about upcoming changes (their positions and opinions on that matter) → the reason is that NGOs sometimes are too busy/too lazy/too slow to show an adequate feedback to public → thus information might simply not reach the public as a consequence;

- As a conclusion and response to complaints of the participants on the Reform Council the Centre called on the members of non-governmental organisations and associations to sign a Memorandum of Understanding → the document calls on the members of non-governmental bodies, agencies and organisations to co-operate with the Centre on every single step it takes when conducting a regulatory guillotine, give their suggestions and opinions on the procedures the Centre takes → meet consistently on seminars, workshops and conferences organised by the Centre → as well as receive a prompt feedback from the Centre on the ideas and initiatives given by the non-governmental organisations/associations signatory to the MoU;

29 May, 2012

Venue: National Centre for Legislative Regulation PIU,

22 Saryan str, Yerevan 0002, Armenia

Meeting with the Healthcare NGOs

Topic: presentation of the concept and programme of activities of the National Centre for Legislative Regulation

In attendance:

1. Lala Margaryan – “Armenian Union of Public Health” NGO
2. Ashot Gevorgyan – “Armenian Dental Association” NGO

Main areas of discussion with the participants of the meeting are as follows:

- Amendments to the law on medicines
- Licences for dental clinics (X-ray equipments, X-ray specialists)
- Degrees of competence for dental specialists
- Marketing authorisation (licensing) of medicines

Below are the comments of the participants upon the project presentation:

- A brief talk of the participants was on the upcoming amendments to the law on medicines → a law will give a new definition of the medicines and this was a matter of interest to them;
- Licences for dental clinics
- The process of licensing the equipments was a matter of concerns as it requires additional licence apart from the general one → e.g. X-ray equipment → each licence required an additional fee → a separate fee even exists for the same company-owner of the general dental clinic to open a children dental clinic → even though the fee was not that high (50 000 AMD) it was a matter of discontent;
- The other issue of misunderstanding concerned the Atom-Inspection (Atomnadzor) → they did not understand why X-ray services were to be

licensed by a department of the Atom- Inspection if X-ray services are part of the healthcare → a comment came for it to be an unnecessary institution for that purpose;

- Another suggestion for an X-ray equipment was to leave the formal part entirely to the customs → for clearance procedures only → a participant proposed the customs to have a check-list for X-ray equipments to inspect how are they consistent with international safety standards right at the place to make the process faster;
- Passing onto the discussion on the certificates and trainings for an X-ray specialist → an opinion was raised that the doctor himself as well as the nurse and other clinical staff were not necessarily be X-ray specialists → instead they shall pass a course of trainings to save the time and money;
 - Degrees of competence → the participant suggested to employ the old scheme of degrees of competence to dental practitioners → 2nd, 1st, 3rd degree of competence → claiming this would raise the level of competency and expertise amongst the dentists → as an example the participant brought a case of Germany where such degrees are issued by dental associations (giving out licenses/certificates);
 - Marketing authorisation (licence) → in the end the discussion passed onto the licensing procedure for medicines (marketing authorisation) → the participants told 30 days of the expertise at the SCDMTE was justified as it takes time to investigate the documentation thoroughly → nevertheless that is a big issue with regard to the clearance (customs) as it is too costly in terms of losses the businesses are experiencing as a consequence;
- To sum up → participants found the expertise scheme to be fine in general and told the problem was with the customs not the SCDMTE as such.

LIST

Of Non-governmental organisations and associations. (Future signatories to the Memorandum of Understanding on the Establishment of the Business Advisory Council)

- 10. Paylak Tadevosyan – “Protection of Taxpayers” NGO**
- 11. Karen Chilingaryan – “Consumers’ Rights Protection” NGO**
- 12. Aram Grigoryan – “Union of Social Protection” NGO**
- 13. Gagik Tsutsulyan – “National Centre for Development of Small and Medium Enterprise”**
- 14. Aram Grigoryan – “Association of Heads of Condominiums” NGO**
- 15. Tsolvard Gevorgyan – “Armenian Union of Traders” NGO**
- 16. Eduard Kirakosyan – “Union of Armenian Industrialists and Entrepreneurs”**
- 17. Nune Yeghiazaryan – “Women in Business” Invest for the Future”**
- 18. Nairuhi Jrbashyan – Social and Economic Analysis Centre**

List of NGO’s to cooperate with for the Project Implementation period

1. “Consumers Association” NGO
2. “Towards the Market” Public Assistance to Reforms” NGO
3. “Yerevan Chamber of Commerce and Industry”
4. Foundation for Small and Medium Enterprise
5. “Enterprise Incubator Foundation”
6. “Union of Information Technology Enterprises (UITE)”

Pharmacy NGOs and associations

13. Vardan Mkrtchyan – “Liqvor”
14. Ashot Gasparyan – “Esco Pharm”
15. Siraz Matevosyan - “Yerevan Chemical-Pharmaceutical Firm”
16. Seyran Hovsepyan – “Yerevan Chemical-Pharmaceutical Firm”
17. Shahe Qasis – “Medical Horizon”

18. Samvel Zaqaryan – “DAN Union”
19. Ruben Sarukhanyan – “DAN Union”
20. Ina Arzumanyan – “Abbott Laboratories”
21. Georgiy Serlanov – “Pharm Trust”
22. Gagik Grigoryan – “Esculap”
23. Eduard Dilanyan - "Vitamax-E"
24. Vahan Karganyan - “Lambron-Pharmimpex”

Healthcare NGOs

1. Lala Margaryan – “Armenian Union of Public Health” NGO
2. Ashot Gevorgyan – “Armenian Dental Association” NGO
3. “Armenian Medical Association” NGO
4. “Pharmaceutical Association” NGO
5. “Medicine Producers and Importers Union (MPI Union)”

Transportation NGOs

1. “Achilles” Centre for Protection of Drivers’ Rights” NGO
2. “Armenian Union of Car Importers”
3. “Taxi Services Association”
4. “Legara LTD Cargo Transporting Company”

Public Utility NGOs

1. “Enterprise Incubator Foundation”
2. “Union of Information Technology Enterprises (UITE)”

Memorandum of Understanding
on Establishing a Business Advisory Council

Yerevan

June ... 2012

The present Memorandum of Understanding (hereinafter MOU) is entered into between the State Agency “National Centre for Legislative Regulation project implementation unit” at the Staff of the Government of the Republic of Armenia (hereinafter Agency) and A, B, C, D, E (hereinafter NGOs, and together with the Agency collectively referred to as the Parties).

Whereas, in order to reduce and simplify regulations provided by current legislation and involving individuals and businesses, the Agency is willing to cooperate with interested persons possessing relevant professional knowledge and experience, and acknowledges the importance of cooperation of the state and the civil society in this area as well as the effectiveness and expedience of participation of the civil society in law-making processes,

Whereas, the NGOs are interested in close cooperation with the Agency in the area of law-making and are willing to use their potential to implement joint projects and improve the legal framework,

Whereas, the Parties have assumed the said missions and are willing to cooperate for their effective implementation,

The Parties have come to the following agreement.

Article I

Purpose

The purpose of the present MOU is to ensure the effective cooperation of the Agency and the NGOs, which will enable the Agency to benefit from the assistance of the civil society and will enable the NGOs to be involved in law-making processes.

Article II

Areas of Cooperation

The Agency shall make available for the NGOs packages of legislative initiatives prepared at the Agency to enable the NGOs to examine them and issue professional conclusions. The Agency shall address in detail the professional conclusions submitted by the NGOs, discuss all reasonable proposals, and if a proposal is rejected, provide grounds for such rejection. The NGOs agree to provide to the Agency professional conclusions on packages of legislative initiatives.

The Parties also express willingness to cooperate in matters of organizing discussions, seminars and other events and use their best efforts to reach the goals specified in the present MOU.

Article III

Advice and Information Exchange

The Parties express willingness to periodically exchange information of mutual interest and discuss opportunities for cooperation.

The exchange of information shall not lead to disclosure of information protected by law.

The NGOs agree not to disclose any information, which has been provided or made known to them under the present MOU, unless such information is publicly available or the Agency has consented to such disclosure.

Employees of the Agency and the NGOs meet when the need arises to evaluate the work completed and to plan for further tasks under the present MOU.

The Agency and each of the NGOs appoint persons responsible for effective implementation of the present MOU.

Article IV

Implementation of the MOU

By signing this MOU the Parties do not create a partnership or other legal entity and do not enter into joint venture or other contractual relations.

The present MOU does not create financial or other pecuniary liabilities for the Parties.

Participation in the present MOU shall not affect potential procurement of consulting services by giving a more or less preferential status to the NGOs.

The present MOU cannot be interpreted as a guarantee, positive assessment or promise to support given by the Agency for the benefit of the NGOs.

In implementing the present MOU, the NGOs shall contribute to the development of the law for the benefit of the Republic of Armenia and its people and shall not pursue the interests of separate individuals or small groups.

The Parties agree that information on signature and operation of the present MOU can be distributed without restrictions, including by means of press releases, websites, and information booklets. If the present MOU is terminated the Parties shall eliminate within two weeks all indications of the MOU from the said mediums (websites, booklets, etc.).

Article V

Terms, Termination, Amendments

Cooperation provided for by the present MOU does not grant any exclusive rights, and each Party is free to establish similar relations with other persons.

The present MOU is valid for one year and is deemed to be renewed for one-year successive periods, unless before the end of the period a Party notifies other Parties of its decision to terminate the MOU. In that case the MOU is deemed to be terminated with regard to the Party in question two weeks after submitting the necessary notices.

Consent of all Parties is required for amendments to the present MOU.

Article VI Notices

Any notice or other communication between the Parties under the present MOU shall be made in writing and delivered in person, through courier or by mail, telex, telegram or e-mail at the addresses listed below.

Agency - Tamar Minasyan, Public Relations Specialist, email: t.minasyan@regulations.am; telephone: (+37410) 532287 (107).

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Article VII Miscellaneous

Failure by any Party to fulfill a provision of the present MOU cannot be interpreted as rejection of the MOU or any other provision.

Impossibility of a provision of the MOU does not affect the validity of other provisions, they can operate without the application of the problematic provision.

The present MOU is a memorandum of intentions, which expresses the willingness and readiness of the Parties to cooperate and does not contain legally enforceable provisions, except for the provisions in Article III of the present MOU on preserving the confidentiality of information.