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Pharmaceutical Policy Process: Lessons from the Newly Independent States

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Pharmaceutical Policy Process: Lessons from the Newly Independent States

Capstone Report

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ABBREVIATIONS

CAPS - Competitive Armenian Private Sector

DRA - Drug regulatory authority

DURG – Drug Utilization Research Group

EML - Essential medicines list

EU – European Union

FDA – Food and Drug Administration (in the United States)

GLP - Good laboratory practice

GMP - Good manufacturing practice

GPP - Good pharmacy practice

MoH – Ministry of Health

NMP – National medicines policy

NA – National Assembly

PPP – pharmaceutical policy process

RA – Republic of Armenia

SCDMTE - Scientific Centre of Drug and Medical Technology Expertise (in Armenia)

STG – Standard treatment guidelines

VAT – Value-added tax

WHO – World Health Organization

WFP - World Food Programme

EXECUTIVE SUMMARY

Although the pharmaceutical sector in Armenia is currently mainly established, some challenges still cause a big concern. Such facts as a lack of important policies on pharmaceuticals, an outdated legislation and a lack of regulation suggest that the pharmaceutical policy process in Armenia is not effective enough and its insufficient effectiveness is one of the most important barriers for successful implementation of pharmaceutical reforms in the country. The goal of this capstone was to analyze pharmaceutical policy process in Armenia and other Newly Independent States and to develop recommendations for Armenia. Data and information were obtained from publication searches and unpublished sources; two interviews with key informants were conducted – one from Armenia and one from Russia.

It was defined that the main challenges in in the Armenian pharmaceutical sector are a lack of access to medicines, appearing of counterfeit products and irrational use. The results of assessment of the current pharmaceutical policy framework in Armenia have shown that 17 of 44 policies recommended by the World Health Organization (WHO) are approved and additional 11 are implemented although are not formally approved. The results of the assessment also shown that the number of policies introduced in the different components varies: the best ratio of approved to recommended policies is observed in the area of Regulation and Quality Assurance while the no policies have been developed on Monitoring; only a few policies are available in the fields of Affordability and Rational Use. Assessment of effectiveness of Pharmaceutical policy process (PPP) in Armenia conducted according to process and outcome indicators developed has shown that PPP in Armenia is not sufficiently effective because process often do not reach its outcomes – well developed

and actively discussed drafts of policy documents are not approved without any clear reason, plans for implementation of those that were approved are conducted only partly and evaluation is never done. Strengths and weaknesses of PPP in Armenia were defined based on analyzing the situation in the country.

Based on studying experience of Newly Independent States (NIS) on PPP some lessons that can be used by policy-makers in Armenia were formulated: having formally approved document of NMP can be considered to be useful for improving the situation in the pharmaceutical sector; it is preferable to approve a NMP document at the governmental or higher level; it is important to make a draft of NMP document publicly available and provide conditions for wide consideration with involving different stakeholders; it is also important not only collect suggestions, but also to take them into account; due to absence of system of monitoring and evaluation countries are not able to evaluate their progress in the pharmaceutical sector even if they fix changes of some indicators; patients' including consumers' organizations are currently not able to make a difference in the pharmaceutical policy process in NIS. Framework of pharmaceutical policy process involving advocacy coalition was developed.

Recommendations for different stakeholders were developed. *For the Government:* to create a Multi-sectoral Commission responsible for pharmaceutical policy issues; to ensure that the Commission consists of representatives of different stakeholders including organizations representing patients' rights; to ensure an access of media to meetings; to ensure transparency of the commission's activity; to create and introduce mechanisms for enforcement of existing legislation in the pharmaceutical sector. *For the Ministry of Health:* to implement comprehensive assessment of the pharmaceutical sector; to create a working

group consisting of leading national experts and representatives of different stakeholders to develop a draft of a National Medicines Policy document; to develop a draft of the five-year Implementation plan together with NMP and present it together with a policy document draft; to consider drafts with all the interested stakeholders during initially decided period of time, make changes based on presented comments and approve it as a Government Resolution; to create in MoH a special unit responsible for monitoring and evaluation of NMP; to create a Public Commission (involving representatives of patients', consumers' and other non-governmental organizations) to be involved in considerations of the results of policy monitoring and evaluation; to provide transparency of unit's activity and results received; to monitor PPP according to indicators suggested and to provide the results to above- mentioned Public Commission for consideration and revision; to calculate, identify and ensure funding needed for policy implementation. *For Public (Non-Governmental) organizations - both professional associations and representing patients' interests:* to participate actively in pharmaceutical policy formulation and consideration; to be informed about the results of monitoring and evaluation and possible changes in policy; to create a strong advocacy coalition involving professional associations and consumer's rights organizations, media and so forth, that would be able to defend interests of patients. *For International Non-Governmental) organizations:* to provide some funding to ensure active participation of NGOs in policy process and their independence.

INTRODUCTION

Armenia is one of twelve (of the total fifteen) former Republics of the Soviet Union which were and are still referred to as the Newly Independent States (NIS). In 1991, Armenia formally declared its independence and started the transition process from socialist to market-oriented economy. In its attempts to reach quick achievements Armenia selected a strategy of rapid reforms in economic and other sectors. Similar to other NIS, Armenia has faced numerous political, economic and social challenges. “Transition has had a serious and long-term impact on the income and well-being of the population.” (Hakobyan, 2006, p.xv).

Today the socioeconomic situation in the country is much improved, including the area of health care. However, many challenges still exist because implementation of unique comprehensive reforms (cardinally changing the legislation, an organization structure, supply system, financing, pricing and payment systems, etc.) under the conditions of additional difficulties of the transitional period (such as the collapse of the former supply systems, lack of funding, lack of experience, some wrong assumptions, psychological transformation, etc.) was an extremely difficult task and the twenty years period of time was not sufficient to overcome completely problems appeared due to transition to another economic system and the collapse of the country (the former USSR). For example, although the pharmaceutical sector in Armenia is currently mainly established, a lack of access to medicines, appearing of counterfeit products and irrational use still cause a big concern.

At the same time it seems that although objective difficulties (lack of funding, lack of resources, etc.) including those caused by the transition time have been and continue to be a significant barrier for improvement of the situation, outcomes in the pharmaceutical sector could be better if the Government and other main stakeholders would make more efforts in

this field and if these efforts would be better managed. Recently the President of Armenia S. Sargsyan has criticized the situation in the health care including issues related to pharmaceuticals as well as inaction of officials in the Ministry of Health and other organizations (Regnum, 2012). This clearly indicated a lack of efforts at the Governmental level that can be a serious constraint for successful pharmaceutical policy. Furthermore, such facts as a lack of important policies on pharmaceuticals, an outdated legislation and a lack of regulation suggest that the pharmaceutical policy process in Armenia is not effective enough and its insufficient effectiveness is one of the most important barriers for successful implementation of pharmaceutical reforms in the country.

There are currently some political signs in Armenia (attention from the President to problems related to medicines and his promises about improvements in this field expressed during election campaign; increased support on the part of the Public to representatives of policy opposition that forces the Government to pay more attention to social problems including health care) and opportunities (relatively new Minister of Health who is interested in improving performance in the pharmaceutical sector and is able to provide necessary political will, recently approved Governmental decision on the program addressing problems in the pharmaceutical policy) which are able to bring issues related to medicines to policy agenda and create conditions for reform implementation. Nevertheless, it is hard to expect that a comprehensive pharmaceutical reform will be implemented successfully until the pharmaceutical policy process in Armenia is changed.

Background

National pharmaceutical policy as a framework to address challenges in the pharmaceutical sector

According to the World Health Organization (WHO) recommendations, a national medicines policy (NMP) provides a common framework within which various problems related to pharmaceuticals, especially those which are complicated and interdependent, can be addressed (WHO, 2001). NMP presents the medium- to long-term goals and strategies aimed at achieving them for the pharmaceutical sector which are set by the government; it “is a commitment to a goal and a guide for action” (WHO, 2003, p.1). When suggesting having a comprehensive pharmaceutical policy, WHO recommends countries have a formally approved NMP document covering the following components: selection of essential medicines, affordability, financing options, supply systems, regulation and quality assurance, rational use, research, human resources, monitoring and evaluation (WHO, 2001; WHO, 2003). “WHO recommends that all countries formulate and implement a comprehensive national drug policy (NDP)” (WHO, 2001, p.4). According to the WHO data, in 2007 62 (of 118 covered) countries had an official NMP (WHO, 2009). Currently mainly low- and middle- income countries develop such a comprehensive policy. Australia was one of the first developed countries that approved an official comprehensive NMP in 2000 (WHO, 2003). In 2011 “Medicines policy 2020” was approved in Finland (MSAH, 2011). Comprehensive NMP seems to be especially important for countries carrying out large-scale reforms, and all the Newly Independent States are such countries.

The approaches to a nation’s pharmaceutical policy used by Roberts & Reich (2011) and Seiter (2010) are slightly different from those of WHO; in particular, when considering

pharmaceutical policy these authors do not focus on a comprehensive National policy document. Roberts & Reich (2011) mean by pharmaceutical policy “conscious efforts of national governments to influence the functioning of these subsystems”; these subsystems are the following: R&D, clinical trials, registration, manufacturing and packaging, procurement and importing, supply chain, dispensing and sales, use (p. 5). Seiter (2010) defined policy as “conscious attempt of public officials or executives entrusted with public funds to achieve certain objectives through a set of laws, rules, procedures, and incentives” (p.1).

For this Capstone I define the pharmaceutical policy as the results of ~~conscious~~ attempts of national legislators, the Government and other public officials to influence the functioning of the pharmaceutical sector through a set of or separate law(s), regulation document(s), orders and/or actions including approval and implementation a comprehensive National medicines policy document.

Based on key attributes of public policy suggested by Birkland (2010), I would suggest the following attributes of the pharmaceutical policy:

- Pharmaceutical policy is made by public official even if ideas/suggestions/drafts of documents come from outside or are developed through collective efforts with other stakeholders.
- Pharmaceutical policy is intended to be implemented not only by public officials, but also by different public and private institutions having their own interests.
- Pharmaceutical policy is mainly made in response to the problem(s) related to medicines.
- Pharmaceutical policy is both - what the government choses to do and not to do.

Approaches to Pharmaceutical Policy Process

According to Birkland (2011), the term “policy process” suggests existence of a system “that translates policy ideas into actual policies that are implemented and have positive effect” (p.25). My experience with evaluating the pharmaceutical policy process suggests that policy ideas are not always implemented even if policy is approved, and the effect of policies is not always positive even if positive outcomes have been planned. Roberts & Reich (2011) suggest three types of possible government failures related to the pharmaceutical sector: goals/priorities failure (wrong goals/priorities are chosen), policy design failure, and implementation failure; these three types have been defined based on the proposition to divide the governments’ actions into three main stages and then evaluate whether appropriate actions are made at each stage. Because lack of action is also a policy, I would add to these three failures also failure to identify and define problems requiring attention due to what nothing will be done to solve them.

Thus, I would define policy process for this capstone as all the actions (made or not made/although were necessary by legislators and public officials from governmental institutions) intended to identify/define problems and approve, implement and evaluate pharmaceutical policy(s). It can be a system if actions are defined in some way and relatively sustainable such as a pharmaceutical policy process suggested by WHO for NMP or if it is a regulatory process used for approval of legislative documents through which a country introduces its policies. However, if the efforts are chaotic and sporadic and lead to nowhere, the way they are made cannot be defined as a system, although I would consider them as a policy process because they include some stages of it, for example developing/considering a policy proposal.

According to WHO's recommendations (WHO, 2001), NMP process includes three main stages: formulation/development, implementation and monitoring. The development process leads to formulation of NMP document; implementation means realization of strategies and measures intended for achieving objectives/tasks on the basis of the plans developed; monitoring and an evaluation allow to identify progress towards meeting goals/objectives and, if necessary, to bring in appropriate correctives.

Roberts & Reich (2011) describe the pharmaceutical reform cycle as consisting of 6 steps: identifying problem, diagnosing the causes, developing a plan, getting political approval, implementing, monitoring and evaluating. They suggest 5 "control knobs" as a guide for the process of policy developing (financing, payment, organization, regulation, persuasion). In his book Seiter (2010) tries to avoid any of the above mentioned two frameworks; he replicates an order in which the World Bank diagnoses and addresses issues - he uses stakeholder analysis to identify the actors and understand their motives and a "pattern recognition" approach - to understand complex problems in the pharmaceutical sector.

Why worry about Pharmaceutical policy process?

Understanding importance of the pharmaceutical policy process (PPP) is an important lesson learned by the countries during a National Medicines Policy formulation and implementation. It is difficult to expect good policy outcomes if process of policy formulating, implementing and monitoring is not appropriately organized and managed. It is also important to remember that there are certain factors (stakeholders' interests, political dynamics, the current situation in the pharmaceutical sector and other local conditions, etc.) influencing PPP and being able to cause policy success or failure; so they should be taken

into account and carefully addressed through appropriate strategies during policy process. It is difficult to expect real progress in the pharmaceutical sector without ensuring that such important activities as consultations and discussions, involving all interested parties, collecting evidences, planning implementation, and others were incorporated in PPP. WHO in particular stresses that a medicines policy “without an implementation plan remains a dead document” (WHO, 2001, p.11).

According to MSH (2011), although PPP should be manageable yet few countries have implemented all aspects of their policies successfully because of existing constraints. The following factors are considered to be the main constraints: lack of political will, lack of resources, opposition, and corruption; and the following are expected to be facilitating factors: support of domestic and international interest groups, technical expertise, the presence of committed people in the MoH, shared values (MSH, 2011).

Due to insufficient attention to PPP some countries have not been able to reach the objectives established successfully, despite the fact that a NMP document has been formulated and authorized. For example, the generics labelling and advertisement policy in Thailand failed because of the resistance of the pharmaceutical industry; policy was aborted despite a ministerial order for its promulgation (the Juridical Council ruled that the Order was unconstitutional (Phanouvong et al. 2002). This example illustrates the importance of involving all the main stakeholders, in this case - the pharmaceutical industry, in a process of policy formulating. WHO suggests that “The policy process is just as important as the policy document” (WHO, 2001, p.5). The analysis of the situation in Yemen where the policy on creating an effective public pharmaceutical supply system failed in 2005 showed that the revolving fund proposal has not been adequately implemented through a detailed

implementation plan, the government had shown insufficient commitment to funding, corruption took place and expected patients' contributions were not realistic (MSH, 2011). This example illustrates the importance of planning, government's commitment, and developing evidence-based policy that takes into account the results of local situation assessment.

There are also known examples of success in implementing NMP when appropriate strategies are used for providing good PPP. For example, the success of the implementation NMP introduced in Lao P.D.R. is considered to be due in part of emphasis on operational research; it was built in the pilot program in order to bridge gap between policy and practice and to provide evidence for further policy making. Building the research component in NMP made possible to monitor and evaluate implementation of pilot in five districts and compare the results with control districts, to find out continuing problems and to use the results of the research when revising NMP in 2001(MSH, 2011). Another well-known example is collaborative approach used by Australia (Phanouvong et al. 2002, MSH, 2011). In 1991 the Minister formed two advisory groups to involve all the interested parties to contribute positively to the development and implementation of policy. After several years of work in late 1999 a policy document taking into account elements of social and economic policy was launched; it has four objectives based on active partnership. The policy also recognizes a role of consumers and all partners have committed to consult with consumer representatives. In 2010 the policy was still active (MSH, 2011). Consumers and other partners continue to work together; in 2009 the first NMP Partnerships Forum was organized to identify key areas where there is need for improvement and then they are organized every year (Walsh, 2011). According to Walsh, a member of the Australian

National Medicines Policy Committee providing consumer expertise, “The policy can only achieve its objectives and result in real benefits for consumers through partnership and collaboration” (Walsh, 2011, p.2).

Based on the results of a special study entitled *Medicines for All? The challenge for developing and implementing national medicinal drug policies in Australia, Thailand, the Philippines and Laos* and implemented in Australia in late 90s authors suggested considering five essential elements for effective policy implementation. They found out that although successful implementation of NMP depends on many important prerequisites “such as adequate funding, effective organizational structures, committed and qualified human resources, and the recognition of the plurality of opinions” certain elements were notable in experience of all countries studied. These elements were: “setting realizable goals and objectives; political will and commitment on the part of governments; legislative and regulatory frameworks; legitimacy; and the cooperation (and if necessary co-option) of stakeholders” (Phanouvong et al. 2002, p.26).

According to authors, political will is one of the most important elements. They believe that commitment should be provided not only on the part of the government, including the health minister, the prime minister and the cabinet, but also by the main stakeholders because success of policy depends on willingness and capability of the key players at all levels including ministerial and parliamentary levels. Authors suggest reformers develop some skill in mobilizing and convincing main government officials and political figures. Some informants suggested that government officials should all be actively involved in the NMP formulation process.

Some countries use numerous strategies to ensure appropriate PPP (Box 1).

Box 1.**Thoroughly developed NMP process in Philippines**

Six special strategies intended to overcome main problems and create consensus among partners were used in Philippines at the stage of NMP formulating.

1. *Active use of consultations and participation.* The Government took on the leading role in formulating NMP. During the first year of developing policy two national meeting were organized; twenty five documents were presented; ninety nine persons from sixty one organizations were involved. This strategy created a sense of collective “ownership” of the planning reforms among all involved and increased their readiness to defend policy.
2. *Institutionalization of policy through law and regulation.* The law on generics of 1988 was the most important one; it was approved in 18 months after NMP approval, included guidelines on main aspects (generics, supply, formulary, etc.) and created a rear basis for NMP providing long term sustainability for it.
3. *Formulating possibly comprehensive and practical policy.* The working group used experience of other countries and developed comprehensive policy covering 4 main components with the objective to provide access to essential medicines.
4. *Involvement of the most qualified persons.* It was planned that the policy is promoted by high level officials included minister, several deputy-ministers, members of the working group which were selected based on their high competence.
5. *Collection of adequate and evidence based data.* Data collected by the working group provided support in debates on NMP.
6. *Mobilization and use if international support.* The support from WHO and some countries (Japan, Australia) was important when policy was attacked within and outside the country.

Thoroughly developed and comprehensive process of policy formulating was necessary because policy was intended to reform the pharmaceutical sector in whole.

Source: Quick J.D., 1997

Authors who has slightly different from WHO's approach to pharmaceutical policy also emphasize importance of pharmaceutical policy process. When considering pharmaceutical reforms intended to improve performance and equity, Roberts and Reich (2011) underline that they "strongly believe that process influences both product and politics" (p.86).

Although the value of PPP is widely recognized and underlined in publications including WHO and MSH guidelines (WHO, 2001; WHO, 2003, MSH, 2011), sufficient attention is not always given to it. Lack of attention and, correspondingly, poor management of PPP can be the result of very different factors, including insufficient understanding, lack of knowledge, experience or motivation of the main participants, political dynamics. Good PPP would assist not only in reaching better outcomes, providing a quicker solution of existing problems, but also in ensuring the best use of resources.

Effectiveness of Pharmaceutical policy process

Based on the experience of countries described in the above-mentioned examples we can suppose that success of the pharmaceutical policy depends on effectiveness of the pharmaceutical policy process. In this capstone effectiveness means ability to reach appropriate outcomes, in particular, for the pharmaceutical policy process it will mean that policy(s) have been approved and implemented (law, regulation, programs, initiatives, orders, etc.). It should not be confused with effectiveness of the pharmaceutical policy that will mean that the policy objectives have been achieved (such as improved access to medicines or their more rational use). To monitor progress of the pharmaceutical policy and process towards to objectives different indicators/measures can be used. WHO has developed different sets of indicators. The latest set - a core indicator package (three

different levels) is intended for monitoring and evaluating country pharmaceutical situations. It includes few indicators measuring the situation with NMP (WHO, 2007):

1.1. Is there a National Medicines Policy (NMP) document?

a) If yes, is it an official or draft document?

b) What year was it last updated?

1.2. Is there an NMP implementation plan that sets activities, responsibilities, budget and timeline?

a) If yes, when was it last updated?

1.3. Is the NMP integrated into or included in the published/official national health policy/plan?

a) If yes, when was the national health policy/plan last updated?

1.4. Has a national assessment/indicator study been conducted?

a) If yes, which topics have been studied and when was the most recent study covering each topic conducted:

Overall pharmaceutical situation:

Rational use/prescription audit:

Access (i.e. prices, affordability and/or availability) to medicines:

1.5. Is there a code of conduct that applies to public officials and staff involved in pharmaceutical related activities or posts, such as persons working in pharmaceutical services, medicines regulation, procurement and supply of medicines and other pharmaceutical divisions of the health ministry?

There is also a special set of indicators developed by WHO for monitoring NMP (Brudon, 1994) which was published in 1994, however they are mainly intended to monitor

outputs and outcomes of policy implementation, not outputs and outcomes of policy process itself.

However, WHO and MSH suggest certain recommendations related to the pharmaceutical policy process which have been developed based on countries' experience. Based on these suggestions as well as my own experience I have developed the following process and outcome indicators for the pharmaceutical policy process intended to define whether PPP is effective and identify its strengths and weaknesses. Those process indicators should not be confused with process indicators suggested by WHO for monitoring policy during the process of implementation.

Process indicators

Stage of formulation:

- Responsibilities and time-frame for policy formulation are defined (the period for preparing a draft should not exceed 6 months and overall time by the final consideration should not exceed a year).
- Operational research is implemented to provide baseline data (not always applicable for legislation/regulation documents).
- A policy paper on the issue considered is presented (should include brief description of the current situation, evidence based policy options and be developed by experts).
- Stakeholder analysis is implemented.
- Draft of a final document is presented (if it is a policy document it should include goals and strategies to achieve these goals; if it is legislation/regulation document, it should include appropriate provisions).
- Legal basis for policy enforcement is ensured.

- Draft is made publicly available.
- A national conference/meeting is organized to present the final draft (all stakeholders including patient/consumer organizations as well as media are invited).
- Strategies for political support are developed and implemented.

Stage of Implementation and Monitoring

- Draft of Implementation plan (can be called differently) is presented.
- Draft of evaluation program is presented.
- Drafts are circulated for consideration.
- Funding is provided.
- Mechanisms providing transparency and accountability are introduced.
- Draft of Implementation plan is formally approved.
- Draft of evaluation program is formally approved

Outcome indicators

Stage of Formulation

- Policy (policy or legislation/regulation document or program) is formally approved.

Stage of Implementation and Monitoring

- All activities in the Implementation plan are implemented.
- The final evaluation document is presented and distributed.

Why worry about Pharmaceutical policy process in Armenia?

Despite the fact that the WHO suggested developing a comprehensive NMP as a written document and Armenian experts and policy-makers were mainly agree with this approach, there is still no officially approved NMP in Armenia. Although several drafts of a

comprehensive NMP document have been developed in Armenia since 1992 and considered at different high levels (Ministry of Health, Ministry of Economy on behalf of the Government), none have been formally approved. There is also no strategic plan on improvement of the pharmaceutical sector in Armenia. Since 1992 some reforms have been implemented, mainly in the early 90s. However some of them, for example privatization of pharmacies, were not well prepared. Privatization and licensing of pharmacies were implemented due to changes in the country's economic system (transition to a market-oriented economy) in whole; however, necessary regulation to allow the pharmaceutical sector to perform well under the conditions of the market-oriented system are still not in place. Reforms related specifically to pharmaceuticals have been sporadic. The creation of the Scientific Center of Drug and Medical Technologies Expertise (SCDMTE) in 1992 was the most important of these reforms. SCDMTE was organized to carry out functions similar to those of the Food Drug Administration in the U.S. (only on medicines, but not on food), and several other functions. Because SCDMTE has a very well qualified staff of professionals and access to resources (registration fees), the best improvements in Armenian pharmaceutical sector were achieved in the area of drug authorization and related fields. Several important strategies were initiated by the Ministry of Health; however, their outcome is not really known due to absence of a system of monitoring and evaluation. The current legislation is already obsolete and a draft of a new law has been under consideration for 7 years. Regulation is still incomplete and there are no clear policies on pricing, distribution, rational use of medicine and other important aspects related to medicines. Although SCDMTE has developed a set of regulatory documents, they cannot be considered until a new law is approved. A Value added tax (20%) was introduced on medicines (in this

case it was quite rapid decision) despite serious opposition. It has led to price increases. The special social fund that was expected to be created based on the additional money flow coming with the new tax has never been established. The fact that stakeholders have not been involved in policy development and that there is no system to monitor implementation of policy decisions have been major factors explaining policy failure.

Why compare the pharmaceutical policy process in the Newly Independent States?

The systems of medicines supply have changed significantly since 1992 in the NIS. Although countries are now quite different in their size, social and economic level and other characteristics, at the beginning of reforms in early 90s they had a very similar situation in the pharmaceutical sector due to a common legislation and regulation, a common supply system, the same education curriculum and so forth. After the collapse of the former Soviet Union in 1991, the Independent States started reforms which were necessary to transform the pharmaceutical system in a way it will be able to operate under the conditions of market-oriented economy. The speed and a content of reforms differed. These variances definitely have led to differences in outcomes which have become more significant with the time passing. At the beginning of 2000s differences between countries were observed with regard to the structure of the sector, pricing and reimbursement systems, etc. (Drugs and Money, 2003, p.134). Now variations have become even more significant due largely to the different socio-economic conditions achieved by countries. It can be said that the pharmaceutical sectors of these countries are currently mainly established; however such challenges as a lack of access to medicines, inappropriate use and some issues related to safety of medicines still cause a concern in all the countries of the region. Countries continue their efforts to improve medicines supply system and achieve the main objectives of the pharmaceutical

sector - providing the population of the countries with effective and safe medicines of appropriate quality and their rational use. Appropriately formulated and approved National pharmaceutical policy can make these efforts effective and improve outcomes. “In all CCEE and NIS countries, continuing improvements in sector management should strengthen recently established structures and create sustainability. National drug policies will continue to play a stimulating strategic role.” (Drugs and Money, 2003, p.134).

There are only a small number of publications on the pharmaceutical policy process from which lessons can be learned. There are certain recommendations developed by WHO based on the countries’ experience that can be considered relevant to Armenia. There are certain important recommendations related to PPP for improving policy implementation in two very relevant recent publications of leading experts in this field - Roberts and Reich (2011) and Seiter (2010). Their approaches differ slightly from those suggested by WHO. Studying the experience on PPP of other Newly Independent States which went through a transition process similar to the process that Armenia went through, seems to be very useful.

Goals and Objectives of this Capstone

The goal of this capstone was to analyze pharmaceutical policy process in Armenia and other Newly Independent States and to develop recommendations for Armenia Research questions:

- What are the main challenges related to pharmaceuticals in Armenia?
- What is the current pharmaceutical policy framework in Armenia?
- What are strengths and weaknesses of pharmaceutical policy process in Armenia?
- What are the similarities and differences in the pharmaceutical policy process in the NIS and what lessons could be learn for Armenia?

- What changes in pharmaceutical policy process in Armenia could make it more effective?

The objectives are:

- To review literature available on pharmaceutical policy process
- To examine key elements of pharmaceutical policy process in twelve NIS countries: existence of approved NMP document, participation of main stakeholders in its development, existence of implementation plan and system for monitoring of NMP
- To develop recommendations for improving the pharmaceutical policy process in Armenia

Methods

Data and information were obtained from academic searches, Google search, search of web sites of the World Health Organization, its Office for Europe, the Observatory (HiT series), and various published and unpublished sources in NIS. Two interviews with key informants were conducted – one from Armenia and one from Russia.

Part I. Pharmaceutical policy in Armenia

1. The main challenges in the Armenian pharmaceutical sector

Lack of access to medicines. Although total pharmaceutical expenditures increased significantly during the last 20 years, they are still quite low when compared with other countries. According to the Armenia Pharmaceutical Country Profile (2010), in 2008 the total pharmaceutical expenditure per capita was AMD 7,030 (US\$ 23). The total pharmaceutical expenditure includes public spending (mainly provided from the State Budget) and private spending (mainly out-of-pocket payments of patients). The rough

estimates based on the results of analysis of data received from the annual Integrated Living Conditions Survey of Households (ILCS) suggest that the total out-of-pocket expenditures on medicines per capita per year consisted of about 21 USD in 2008 and 2009, and then sharply increased totaling 37 USD in 2010. The share of spending on medicines also increased in 2010 and totaled 4% of the total expenditures of surveyed households (3.3% in 2009 and 1.8% in 2008). This sharp increase in pharmaceutical spending is not supported by the data on imports for 2008, 2009 and 2010 that vary with the biggest value in 2008 (Foreign trade, 2009, 2010, 2011) and can be only partly explained by price increases.

Expenditures on pharmaceuticals per household member depend on family income. In 2010, out-of-pocket expenditures on medicines per member of non-poor households (49USD per capita per year) were 3 times higher than those of the poor (16USD per capita per year) and around 8 times higher than of those extremely poor households (6USD per capita per year). This clearly shows that individuals from families with low income have very limited access to medicines. Although there is a pharmacy reimbursement system in place that covers certain social groups and patients with certain diseases (children under 7, disabled persons, etc.), the list of social groups does not include individuals from families living in poverty.

Public pharmaceutical expenditures are also very low in Armenia. According to the Report on implementation of the State Budget of the Republic of Armenia for 2011, the total public pharmaceutical expenditures of 4.1 billion Armenian drams is about \$11 million or 3.4USD per capita per year. Two recent studies have shown that this is not enough to cover needs of even a restricted population eligible for receiving medicines free of charge or with discounts. The study by the Economic Development and Research Center (EDRC) has

shown that more than 40 percent of sick people mentioned that they received only 10 percent of medicines needed for treatment. Only 45 percent of households who have members from any social group or disease eligible to receive drugs with privileges, exercised their rights (EDRC, 2011). According to the data of the Drug Utilization Research Group (DURG) that implemented study among households in all the regions of Armenia in 2011, patients with certain diseases eligible to receive pharmaceuticals free of charge got only 23% of the free medicines they used during the last 2 weeks, in particular less than 25% of medicines for children under the age of 7 were provided for free (Melikyan, 2011). During the study in 2008 “Health officials acknowledged that allowances to polyclinics for adult drugs were inadequate, and many patients entitled to free outpatient drugs were forced to purchase them in the market.” (PHCR, 2010, p.7).

Because the majority of patients pay for medicines out-of-pocket, pharmaceuticals are not affordable for many individuals and families. The 2008 survey has shown that approximately one third of the surveyed households did not get a recommended service after they contacted the health system; in particular for medicines, 35% of those who did not get a recommended service said they failed to do so “because of finances” (PHCR, 2010). In August 2009, many households reported foregoing medications due to financial difficulties, in particular 21% reduced or stopped buying the medicine they required (WFP, 2010). “Most households did not seek health care or did not purchase prescribed medicines for lack of income to cover the cost” (World Food Programme, 2010, p.32). Although private pharmaceutical expenditures increased in 2010, only 50 % of representatives of households studied noted that they can usually afford to buy all the medicines they need (Melikyan, 2011).

High prices are one of the main factors affecting the affordability of medicines and treatment. Very large differences in prices of originator brand products (and brand name generics) and the lowest-priced generics lead to different affordability of these products. For example, the number of days the lowest-paid government worker needs to work in order to be able to pay for a standard course of treatment for arthritis (diclofenac, 50 mg capsule or tablet) is 10.8 days if originator brand product is used and 0.78 day for the lowest-priced generic (Kazaryan, 2011). It should be noted that physicians often prefer to prescribe originator brand products or brand name generics.

Irrational use of medications. Although there is a lack of research on medication use in Armenia, inappropriate use of pharmaceuticals can be easily predicted based on the existence of the majority of factors known to lead to misuse of medicines, in particular, lack of updated treatment guidelines or their monitoring, inadequate knowledge among professionals and population, unrestricted distribution of Prescription Only Medicines (POM - medicines which can be dispensed only if prescription is available) from pharmacies despite an appropriate provision in the law on medicines, aggressive promotion by pharmaceutical companies and so forth. The results of household surveys have shown that 68% of POM used by any of household's members during the previous 2 weeks, including antibiotics, were bought without prescription (Melikyan, 2011). Another study has shown that only 58.5% of antimicrobial medicines sold by pharmacies in Yerevan were prescribed by physicians, 10.5% were advised by pharmacist/technician, 31% - by other persons; 77.2% of prescription only antimicrobials were sold without prescription (Hakobyan, 2011).

The essential medicines list (EML) was firstly introduced in Armenia in 1992 and was updated on a regular basis until 2007. However after 2007, a revised version was not

approved. In 2006, a new mechanism requiring physicians to prescribe medicines from EML to patients covered by the reimbursement system was introduced. However, physicians continue to prescribe pharmaceuticals out of the EML. Analysis of medicines used by members of households studied shows that only approximately 43% of medicines were from the EML (Melikyan, 2011).

Although clinical guidelines for the most primary health care diseases were developed and approved in early 2000s, the majority of them have not been updated. The study in 2006 showed that prescribing practices vary widely among providers. Treatment guidelines were not available at all facilities studied and actual prescribing practices for studied conditions varied significantly from treatment recommendations (Lee, 2007).

2. Brief history of Armenian pharmaceutical reforms

Early years

In 1992, after the proclamation of independence, the Republic of Armenia started to formulate its own pharmaceutical policy. Recommendations of the WHO, as well as local conditions were taken into account as the basis for policy development. Armenia was faced with the need to implement comprehensive pharmaceutical reform covering almost all the components of the pharmaceutical sector. The early years were very successful. In 1992, the Government established the Armenian Drug and Medical Technology Inspection (then it was renamed and called SCDMTE, and then renamed again as the Scientific Centre of Drug and Medical Technology Expertise - SCDMTE), which was partly modeled on the United States Food and Drug Administration (FDA) (Hakobyan, 2006) taking into account the recommendations of WHO for small countries and local conditions. SCDMTE (then Drug Inspection) was the first organization with National Drug Regulatory Agency's functions

created in the Newly Independent States. Before that time all medicines evaluation and authorization functions had been managed by a single set of institutions in Moscow. Armenia created a new system for medicines evaluation and registration soon after independence, creating the opportunity for the country to authorize medicines and control their quality on the pharmaceutical market. SCDMTE was also responsible for licensing and inspecting producers, wholesalers and pharmacies, monitoring drug adverse reactions and some other functions. A new laboratory was also created at SCDMTE with support of the Gulbenkian Foundation. The new laboratory was supplied with modern equipment and became the best equipped quality control laboratory at the Drug Regulatory Agencies created on the territory of the former USSR.

SCDMTE proposed to the Ministry of Health that it should adopt the Essential Drugs concept recommended by WHO as the basis for national policy on medicines. As the result, in 1992 the first version of Armenian Essential Drugs List (EDL) and some corresponding strategies were approved by a special Decree of the Minister of Health. After long consideration a draft of the first law “on medicines” was approved in 1998. It was developed by SCDMTE in 1994 and then was discussed with some stakeholders including the Ministry of Health, other ministries, and the Armenian pharmaceutical association.

The former state “Armpharmacy” Republic Association which comprised all the pharmacies and one warehouse in Armenia was reformed. All pharmacies were privatized and numerous new private pharmacies were founded and licensed which created the opportunity for increasing the availability of medicines. In 1993 the Department of Pharmacy was established at the National Institute of Health for providing continuing education for Armenian pharmacists.

The success in reforming the pharmaceutical sector in Armenia during the early years of independence was possible due to some important factors: leadership by the Head of SCDMTE, high level of motivation and high competence of SCDMTE's staff (the best local professionals were involved); relying on evidences as much as possible (the most of the staff were researchers) when developing policy suggestions, political will provided by the Ministry of Health.

Recent years

The Ministry of Health has introduced system of reimbursement based on the Essential Medicines List (MoH, 2006) and some other initiatives. Some strategies intended to improve national security in the area of Health care and, in particular in the pharmaceutical service, were approved by the appropriate Government Decree (RA Government, 2010a).

The USAID-funded Competitive Armenian Private Sector (CAPS) project together with local manufacturers initiated the development and approval of regulations on Good Manufacturing practice (RA Government, 2010b) and some other documents important for development of pharmaceutical industry in Armenia.

In 2012 the Government formally recognized and addressed some urgent challenges in the pharmaceutical policy, including ineffective centralized and not centralized procurement, lack of state control in the Health care system, and ineffective system of medicines evaluation (RA Government, 2012).

3. National medicines policy document in Armenia

Drafts of National medicines policy document and their content

Armenia's first NMP document - "Concept of a program of the pharmaceutical sector development in the Republic of Armenia" appeared in 1993 (Kazaryan & Melikyan,

1998/99). It was based on the WHO recommendations and the local situation. The document was comprehensive and included the following sections: introduction (problems in the sphere of medicines supply and their reasons, the aim and tasks - long-term and mid-term for the first five years' period); the main principles of public policy in the pharmaceutical sector at the early stage (1993-1997) - separately for nine components; the brief characteristics of resources; the main mechanisms of NMP implementation (strategies) for the first stage – again separately for nine components; structure of pharmaceutical management (a scheme of management, units responsible for each of mechanisms); plan of implementation (for 1993-1997) . The main components determined were the following: legislation, policy and management, pharmaceutical industry, medicines supply, rational use, quality assurance, research, human resources, and information. In fact, the Concept was a first draft of NMP for Armenia. The document was developed by the group of leading experts based on detailed assessment of the current situation and opportunities for development. A draft was successfully approved by the Ministry of Health and then by the Ministry of Economy on behalf of the Government (Kazaryan & Melikyan, 1998/99). However, due to political changes in the Government and changes in policy development approaches in the country, the developed document has never become an official strategy.

The next drug policy development was the “Document of Armenian National Drug Policy” that emerged in 1995. The document included the following sections: introduction; objectives and tasks, NMP elements and guidelines for their introduction (ADMTA 1995; GPHCDP 2006). Although this document was not approved by any formal authority in Armenia and, correspondingly, could not be considered an official NMP document that is

obligatory for implementation by other organizations in the country, it became a very good guide for further activity of SCDMTE that started to implement strategies described there.

In early 2000s, two different drafts of NMP were developed to become a part of National Health Policy document and submitted to the Ministry of Health. A draft submitted by NGO DURG included a brief assessment of the current situation, goals, objectives and strategies intended to solve main problems revealed from the assessment. Strategies were developed for all components suggested by WHO for NMP document.

The last data available about the NMP document comes from the Armenia Pharmaceutical Country Profile (Armenia Pharmaceutical, 2010) that states “The National Health Policy Document is a draft. The NMP is a part of this document” (p.41). This means that NMP was formulated as a part of a draft of the National health policy document however the latest is still a draft because has not been approved yet. The Armenia Pharmaceutical Country Profile also informs that the draft was updated in 2006. Because the Profile was submitted in 2010, it is evident that the draft has not been approved yet at that time and we have to assume that there were no officially approved NMP in the country in 2010.

Thus, despite numerous efforts, Armenia does not have a formally approved comprehensive National Medicines Policy document.

Formulation of NMP document

The process of NMP formulation began in Armenia in 1992 when the Government charged the ministries to design the concepts of corresponding sectors development. MoH started developing two documents: the concept of a program of health care development and the concept of a program of pharmaceutical sector development. Two working commissions

of experts were created. The working group on the pharmaceutical service development consisted of representatives of various sectors: research institutes of the Academy of Sciences and the MoH, the state enterprise, “Armpharmacy” at MoH, and the State Medical University. An economist (expert at the Standing commission on health care and social affairs at the Supreme Council of Armenia) was also included in the working group. The vice-president of SCDMTE was selected to be the Chairman of the working group. The group worked under supervision of the Chairman of SCDMTE; all the activities were implemented on voluntarily basis. A detailed analysis of the pharmaceutical sector was carried out, and the results were submitted as a separate detailed review. A draft of the document “Concept of pharmaceutical service development in RA” was developed. Works in progress and drafts were discussed at meetings at MoH and the meeting of the Ministry of Economics Board when a draft was approved on behalf of the Government. The whole process took about one year.

The “Document on a National medicines policy of RA” produced in 1995 was formulated by SCDMTE’s staff. It was considered and approved at the joint meeting that took place in SCDMTE with participation of representatives of various interested parties of the pharmaceutical sector: MoH RA, SCDMTE, and the WHO Regional Office for Europe.

The third time the issue of a NMP document was on the policy agenda was in 2002 – 2003. The MoH RA initiated the development of a health policy document. It was planned that document would be approved by a Resolution of the RA Government and become a guide for the sector’s development. One of chapters of a document was planned to cover the issues related to supply of medicines (in fact NMP). Two independent drafts covering pharmaceutical policy issues were submitted to the MoH. One of them was presented by the

Armenian nongovernmental organization, “Drug Utilization Research Group” (“DURG”). A draft was developed on the basis of a detailed assessment of the pharmaceutical sector (Kazaryan 2003) and included interviews with representatives of various Ministries, in particular, Economics and Finance, Industries and Trade, Social Affairs, as well as professionals from the National Institute of Health, pharmaceutical associations, and consumer organizations. This draft was discussed with representatives of WHO and international experts from the Department of Public Health at the London School of Hygiene and Tropical Medicine. Another draft was developed by SCDMTE. A draft health policy document was discussed at several meetings organized by the MoH RA with some interested parties.

Implementation and monitoring of NMP

Because no draft was formally approved and adopted, there has been no plan implementation. However, SCDMTE started implementing some important strategies and tried to promote them through MoH. For example, the EML has been regularly updated. Standards Treatment Guidelines for many diseases have been developed.

From 31st May till 1st July, 2001 a special meeting took place in SCDMTE that was dedicated to analysing SCDMTE’s activities to implement a medicines policy since 1994 by the SCDMTE and MoH in a close cooperation with the Regional Office for Europe. More than 60 persons, including representatives of the various interested parties, attended the meeting. The special report was developed and distributed (ADMTA, 1995).

4. Pharmaceutical policy framework

According to the World Health Organization’s approach, a National Medicines Policy is “a comprehensive framework in which each component plays an important role in achieving

one or more of the general objectives of the policy” (WHO, 2001, p.6). WHO suggests the following main components: selection of essential medicines, affordability, financing options, supply systems, regulation and quality assurance, rational use, research, human resources, monitoring and evaluation and also provides the key policy issues for each component (WHO, 2001; WHO, 2003). Although there is no approved NMP document in Armenia, some important policies have been adopted through legislation and regulatory documents. There are two types of documents: legislative (laws approved by the National Assembly) and sub-legislative (Government Resolutions and Decrees of Ministers approved by the Ministry of Justice). Assessment of the current pharmaceutical policy framework in Armenia in this capstone is conducted by identifying whether key pharmaceutical policy issues recommended by the WHO are approved or, although not approved, are implemented in Armenia (Table 1). The set of key policies, listed in the WHO issue of the Policy Perspectives on Medicines series “How to develop and implement a national drug policy” (WHO, 2003) was used for this assessment.

The data presented in the table 1 indicate that although many key policies are approved and implemented in Armenia, some of them have not been adopted. According to this assessment 17 of 44 policies recommended by WHO are approved and additional 11 are implemented although are not formally approved. It is important to increase the number of approved and implemented policies in order to improve medicines use. A special study was recently implemented to demonstrate evidence of NMP effectiveness (Holloway, 2012). Authors have had the objectives to determine whether medicine use is better in those countries with certain pharmaceutical policies compared to those without and whether

medicines use improves with increasing number of policies. The results have demonstrated that the more policies are implemented, the better the drug use.

The results of this assessment show that policies are mainly introduced through legislative and sub-legislative documents (Law “On Medicines”, certain RA Government Resolutions and Decrees of the Minister of Health). In 2012, a program aimed to solve certain problems in the pharmaceutical policy was approved as a policy document by the Government (Government, 2012). Some policies, although not adopted, are implemented, mainly by the staff of SCDMTE. Currently, the results of this practice are positive because it allows Armenia to achieve certain important outcomes. For example the (unapproved but adopted) use of the effective medicines selection process and objective selection criteria provide the opportunity to ensure development of appropriate EDL. However, it is important that such practice be changed and appropriate policies be introduced to provide sustainability and decision-making that is independent from personal ethical and professional preferences of the SCDMTE staff.

Table 1. Status of key pharmaceutical policies in Armenia

Selection of essential medicines

Key policies suggested by WHO	Policies existing in Armenia	Corresponding document and its link	Notes about policies that are not approved or do not exist
Adoption of the essential medicines concept to identify priorities for government involvement in the pharmaceutical sector	<p>The essential medicines concept was accepted from the first years of Independence. The first List of Essential Medicines (EML) in Armenia was authorized in 1994. It is periodically updated (mainly every 2 year until 2007; the last approved EML is of 2007 as developed drafts were not approved; currently a new draft is developed and three is command from MoH to speed the process).</p> <p>Law “On medicines” (Article 18) states that availability and affordability medicines from EML is ensured in the Republic of Armenia.</p>	<p>Law “On medicines”, 1998 (Article18) English version is available at http://pharm.am/files/juris_tdocs/20080306_151440_en_drug_law.pdf</p> <p>The last EML was approved by the Decree of the Minister of Health N 854-N of May 16th, 2007. http://pharm.am/basis.php?pg=5&langid=1</p>	<p>Although the concept is accepted and commitment is stated in the Law, mechanisms necessary for implementing the concept, are mainly not developed; the only exception is requirement to prescribe medicines from EML to patients who receive medicines free or with privileges.</p> <p>Also, SCDMTE ensures a priority registration for the essential medicines.</p>
Selection of essential medicines in a two-step process: (1) market approval; (2) selection of essential medicines relevant to the national morbidity pattern			There is currently no formally approved policy on selection process. However, the staff currently involved in the process of selection, try to follow these and other important principles for selecting medicines for EML
Defining the selection criteria (i.e. sound and			There are no currently formally approved selection criteria.

adequate evidence, cost-effectiveness, etc.)			However, the staff, currently involved in the process of selection, try to follow recommendations of WHO for selecting medicines for EML; Armenian EML is mainly based on the WHO Model EML and local morbidity data
Defining the selection process (i.e. appointment of a standing committee, etc.)	A special committee - Pharmacological Commission responsible for selection of medicines for EML and other related issues, is appointed at MoH	RA Minister of Health Order N 965 of 2006 (there is no link available)	There is only policy on the Pharmacological Commission, but not other aspects of selection process
Ensuring a selection mechanism for traditional and herbal medicines.			Only products that can be defined as a “medicine” are considered for including in EML. Traditional and herbal products can get a “medicine” status only if they are evaluated and authorized like other products. Thus, there is no need for a separate mechanism. It is not an issue for Armenia because modern medicines are used in a great majority of cases.

Affordability

Key policies suggested by WHO	Policies existing in Armenia	Corresponding document and its link	Notes about policies that are not approved or do not exist
Government commitment to ensuring access through			There is no such commitment

increased affordability			
For all medicines: removal or reduction of taxes and tariffs on essential medicines; control of distribution margins; pricing policy			<p>Since 2001 there is a 20% VAT (until 2000 medicines were exempt from VAT) (Hakobyan, 2006).</p> <p>There is neither control of distribution margins nor any pricing policy. There are no duties on imported raw materials or on imported finished products. (Armenia Pharmaceutical, 2010).</p>
For multi-source products (generic medicines and branded generics): promotion of competition through generic policies, generic substitution and good procurement practices			<p>There is no a special generic policy.</p> <p>Generic substitution is not regulated (there is no any special provision, but generic substitution is traditionally used because it was allowed by the soviet time regulation).</p> <p>There is no good procurement practice policy on medicines.</p>
For single-source products: price negotiations, competition through price information and therapeutic substitution, and TRIPS-compliant measures such as compulsory licensing, “early workings” of patented medicines for generic manufacturers and parallel imports.	Current laws contain (TRIPS) flexibilities and safeguards (not specified for medicines (Armenia Pharmaceutical, 2010).	Law “On inventions, utility models and industrial designs” of June 10 th , 2008 http://www.parliament.am/legislation.php?sel=show&ID=3324&lang=arm	<p>There is no policy on price negotiation or competition through price information and therapeutic substitution.</p> <p>TRIPS safeguards have never been used.</p>

Financing options

Key policies suggested by WHO	Policies existing in Armenia	Corresponding document and its link	Notes about policies that are not approved or do not exist
<p>Commitment to measures to improve efficiency and reduce waste</p>	<p>There is a general policy on efficiency of centralized procurement. According to Law “On procurement” the State agency on procurement organizes centralized procurement (mainly through tenders) of certain goods including medicines, those are determined by the MoH; Agency also carries out tenders for individual health facilities (Armenia Pharmaceutical, 2010).</p> <p>In 2012, a new approach to providing efficiency in procurement of medicines was approved.</p> <p>There is a policy to restrict reimbursement to EML (medicines in EML are listed under generic names).</p>	<p>Law “On Procurement” of December 22th, 2010 http://www.parliament.am/legislation.php?sel=show&ID=3985&lang=arm&enc=utf8 (in Armenian)</p> <p>Decision of RA Government meeting “On approval of program on solving problems in state control in the area of Health care, as well as in pharmaceutical policy; and list of measures ensuring implementation of program” of October 18th, 2012 (protocol 42) http://www.moh.am/?section=static_pages/index&id=214</p> <p>RA Minister of Health Order N 74-N of January 27th, 2005 “On adopting the order of free or privileged provision of</p>	<p>There are still no clear requirements to medicines’ procurement that correspond to Good procurement practice.</p> <p>It is accepted now (Government, 2012) that practice of medicines procurement (both centralized and not centralized) is very inefficient.</p>

		medicines” http://pharm.am/jurdocs_list.php?pg=3&id=4&langid=2 (in Armenian)	
Increased government funding for priority diseases, and the poor and disadvantaged	Medicines for some diseases and for patients from certain social groups are provided free of charge or with privileges	RA Government Resolution N 1717-N of November 23rd, 2006 “On adopting the list of diseases and social groups of population entitled to free or privileged purchase of medications” http://pharm.am/jurdocs_list.php?pg=3&id=2&langid=2 (in Armenian)	There is no policy on funding medicines for poor, pregnant and not disadvantaged elderly
Promotion of medicine reimbursement as part of public and private health insurance schemes			There is no public insurance, only voluntary private insurance (very small % of population); there is no special policy on medicines
Use of user charges only as a temporary drug financing option			There are no user charges. The majority of medicines are bought out-of-pocket; those that are reimbursed – are provided to patients for free or with 50% or 30% discount
Limiting the use of development loans within identified national priorities			There is no special policy; however, loans are not used for funding medicines
Following national or WHO guidelines for medicine	There is a policy on donations that correspond to WHO guidelines		

donations			
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Supply system

Key policies suggested by WHO	Policies existing in Armenia	Corresponding document and its link	Notes about policies that are not approved or do not exist
Promoting a public-private mix in medicine supply and distribution systems			All pharmacies and wholesalers in Armenia are private. There is only one public warehouse responsible for distribution of donations
Committing to good pharmaceutical procurement practices in the public sector			There are no any special provisions covering procurement of medicines, including those suggested by good pharmaceutical procurement practice
Publishing price information on raw materials and finished products			There is no special policy requiring publishing prices. Some wholesalers publish medicines' prices voluntarily.
Ensuring medicine supply systems in acute emergencies			There are no special provisions.
Carrying out inventory control, and taking measures for prevention of theft and waste			There is no special policy. However, being private all wholesalers and pharmacies take their own measures.
Ensuring disposal of unwanted or expired medicines	There is a special policy in place covering rules on disposal of medicinal products and pharmaceuticals.	“Law on waste” and Order of the Minister of Health N 03-A of March 4, 2008 “On adopting sanitary rules and norms N 2.1.3-3 “Hygienic and anti-	It was a serious problem for Armenia as a huge amount of expired medicines were kept in the country after receiving donations due to Earthquake in 1988.

		epidemic requirements to the usage of medical wastes in RA”.	There is no policy on collection and disposal unused medicines from patients.
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Regulation and quality insurance

Key policies suggested by WHO	Policies existing in Armenia	Corresponding document and its link	Notes about policies that are not approved or do not exist
Government commitment to drug regulation, including the need to ensure a sound legal basis and adequate human and financial resources			There is no a special statement about such commitment
Independence of the regulatory authority to ensure that there is no conflict of interest	Some functions of Drug regulatory authority (DRA), including medicines evaluation, quality control and some others are implemented by SCDMTE – a special organization at MoH. It is independent because mainly has evaluation functions; it is not responsible for any function related to medicines supply.	There is no legislation or regulatory document clearly defining responsibilities and functions of SCDMTE.	
Commitment to good manufacturing practices, inspection and law enforcement	Good manufacturing practice (GMP) was introduced in 2010 by approval of a Government Decree. Policy on inspection was approved by the RA Government meeting in October 2012.	RA Government Decree N 1603-N of November 25 th , 2010 “Rules of Good Manufacturing Practice” http://www.moh.am/?section=static_pages/index&id=586&subID=617 (in Armenian)	There is no detailed/specific policy on law enforcement in the case of incompliance with GMP standards

	<p>General statement on “Responsibility for the violation of drug preparation and manufacture order” is included in the Law “On medicines”</p>	<p>RA Government Decree N 734-N of May 26th, 2011 on “Approval of timeline for introducing rules of GMP in RA and implementing reforms in the pharmaceutical sector”.</p> <p>http://www.pharm.am/files/juristdocs/20110622_174340_am_gamanakacujc.pdf</p> <p>Decision of RA Government meeting “On approval of program on solving problems in state control in the area of Health care, as well as in pharmaceutical policy; and list of measures ensuring implementation of program” of October 18th, 2012 (protocol 42)</p> <p>http://www.moh.am/?section=static_pages/index&id=214</p> <p>Law “On medicines” (Article 7)</p> <p>http://pharm.am/files/juristdocs/20080306_151440_</p>	
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		en_drug_law.pdf	
Regulation of traditional and herbal medicines	Some aspects related to herbal medicines (licensing requirement for culturing and sale medicinal herbs) are regulated	Law “On medicines” (Article 3) http://pharm.am/files/jurisdocs/20080306_151440_en_drug_law.pdf	There is no special regulation on traditional medicines
Ensuring adverse drug reaction monitoring systems	There is policy on adverse drug reaction (ADR) monitoring system – the statement in Law.	Law “On medicines” (Article 17) http://pharm.am/files/jurisdocs/20080306_151440_en_drug_law.pdf	Although there is only one sentence in the law, a system works well. A national Pharmacovigilance center exists at SCDMTE (Hakobyan, 2006)
Commitment to regulation of information and drug promotion	There is detailed policy on medicines information and promotion covered by two laws and specific regulation document	RA Law “On medicines” (Article 11) http://pharm.am/files/jurisdocs/20080306_151440_en_drug_law.pdf RA Law “On advertising” http://pharm.am/jurdocs_list.php?pg=3&id=1&langid=2 (in Armenian) RA Government Decree N 1608-N of November 2, 2006, “On adopting the order of granting permission to advertise medicines, medical equipment and methods of treatment and requirements made to these advertisements”	

		http://pharm.am/jurdocs_list.php?pg=3&id=2&langid=2 (in Armenian)	
International exchange of information			There is no special policy on this issue for medicines; however Armenia provides information to WHO in scopes of International agreements

Rational use

Key policies suggested by WHO	Policies existing in Armenia	Corresponding document and its link	Notes about policies that are not approved or do not exist
Mandated multidisciplinary national body to coordinate medicine use policies			There is no such policy in place.
Development of clinical guidelines as the basis for the selection of essential medicines and training of health professionals			There is no any approved policy on clinical guidelines. However, it is valued by SCDMTE and, currently, by MoH. In early 2000s around 40 clinical guidelines were developed under supervision of SCDMTE, however some are already obsolete.
Problem-based training in pharmacotherapy in undergraduate training			There is no special policy, however problem-based training is provided (Armenia Pharmaceutical, 2010)
Continuing in-service medical education as a licensure requirement	Continuing education is required, however not as a licensure requirement, as there is currently no licensing system for health professionals in place	RA Government Decree N 867 of June 29 th , 2002 of 29.06.2002 on “Rules on Licensing Production of Medicines, Pharmacy	In practice this requirement often ignored.

		Practice, Health Service, Implementation of Medical Professional Education Curricula, as well as on Approve of Licensing Forms for Implementation of Mentioned Activity”. http://www.pharm.am/jurdocs_list.php?pg=3&id=2&langid=2	
Independent and unbiased medicine information	Issue of medicine information is slightly covered by Law “On medicines”	Law “On medicines” (Article 11) http://pharm.am/files/juristdocs/20080306_151440_en_drug_law.pdf	Two Formularies (containing unbiased medicine information, not just lists of medicines) were prepared by SCDMTE staff and published, the latest in 2010.
Public education about medicines			There is no special policy. SCDMTE sometimes implement public education campaigns.
Avoidance of perverse financial incentives to prescribers and dispensers			There is no special policy. Unfortunately, in practice such initiatives are successfully used.

Research

Key policies suggested by WHO	Policies existing in Armenia	Corresponding document and its link	Notes about policies that are not approved or do not exist
Operational research in medicine access, quality and rational use			There is no such policy, some organization initiate such research

<p>Drug development and clinical research</p>	<p>There is special policy on clinical trials.</p>	<p>RA Law “On medical aid and population services” of May 4th, 1996 http://www.moh.am/?section=static_pages/index&id=235&subID=59 (in Armenian)</p> <p>RA Government Decree N 63 of January 24th, 2002 “On Rules on Implementation of Clinical trials of new medicines in the Republic of Armenia”.» http://pharm.am/jurdocs_list4.php?pg=16&id=2&langid=2 (in Armenian)</p> <p>RA Minister of Health Order N 05-N of 17 May, 2011 “To approve the list of required documents for obtaining authorization to conduct clinical trials and the statute of the ethics committee.” http://pharm.am/jurdocs_list4.php?pg=16&id=2&langid=2(in Armenian)</p>	<p>Approved requirements only partly cover set of requirements suggested by the majority of GCP rules</p>
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Human resources development

Key policies suggested by WHO	Policies existing in Armenia	Corresponding document and its link	Notes about policies that are not approved or do not exist
Government responsibility for planning and overseeing the development, training, team building and career planning of human resources needed for the pharmaceutical sector	There is a policy on licensing implementing Medical Professional Education Curricula	RA Government Decree N 867 of June 29 th , 2002 of 29.06.2002 on “Rules on Licensing Production of Medicines, Pharmacy Practice, Health Service, Implementation of Medical Professional Education Curricula, as well as on Approve of Licensing Forms for Implementation of Mentioned Activity”. http://www.pharm.am/jurdocs_list.php?pg=3&id=2&langid=2	There is no special policy on development human resources for the pharmaceutical sector
Definition of minimum education and training requirements for each category of staff	There are certain requirements on education for those who is implementing pharmaceutical service.	See above-mentioned RA Government Decree N 867.	
The need for external technical cooperation (national and international)			There is no policy approved, however, there is an active cooperation with the WHO Special Project for Pharmaceuticals in NIS at the WHO Office for Europe

Monitoring and evaluation

Key policies suggested by WHO	Policies existing in Armenia	Corresponding document and its link	Notes about policies that are not approved or do not exist
Explicit government commitment to the principles of monitoring and evaluation			There is no any policy on monitoring and evaluation
Baseline survey of the whole country carried out early in the implementation of the policy			Never implemented by authorities. Some survey were implemented by NGOs with funding of International organizations
Monitoring of the pharmaceutical sector through regular indicator-based surveys			The one-time assessment (not-indicator-based) was initiated by SCDMTE in 2001. An indicator-based assessment was carried out by NGO called “DURG” in 2002
Independent external evaluation of the impact of the policy on all sectors of the community and the economy, preferably every 2 to 3 years			There is no such policy

Many important key policies were introduced through provisions for the Law “On medicines” of 1998. The law covers the following areas: pharmaceutical activity and its licensing, manufacturing, labelling, import and export, information, advertisement, destruction, registration, quality assurance, state guarantees of medicines ensuring to population and some others. However, all policies which are stated there, describe the main approaches very briefly - in one or few sentences. According to this law more than ten regulatory documents should be developed and introduced by the Government and the Ministry of Health in order to provide detailed requirements and procedures. Only some of these exist as drafts (labelling, state guarantees of medicines ensuring to population and some others).

The results of this assessment also show that the number of policies introduced in the different components varies (Table 2). The best ratio of approved to recommended policies is observed in the area of Regulation and Quality Assurance (5 of 7) while the no policies have been developed on Monitoring. Only a few policies are available in the fields of Affordability and Rational Use. This is especially alarming because a lack of access to medicines and inappropriate use are among the most important challenges in Armenia.

Although a special policy on antibiotics was not included in the list of key policies used for assessment, it is necessary to mention that this area currently cause a great concern however is not covered by any policy or regulation document.

The results of this assessment concerning differences in numbers of approved policies among the various components are consistent with the opinion of a key informant from Armenia who indicates that introducing systems ensuring quality and safety of medicines is a strength of Armenia’s policies while the absence of systematization and interlinked activities especially

among those aimed to provide access to medicines and improve rational use are the weaknesses of pharmaceutical policy in the country.

Table 2. The number of key policies on pharmaceuticals approved in Armenia, by components

Component	Number of key policies recommended by WHO (WHO, 2003)	The total number of those recommended by WHO key policies which are approved in RA including one-sentence provisions	The number of clearly defined and described key policies	Number of approved policies which are implemented	Number of not-approved policies which are implemented as initiatives
Selection of Essential Medicines	5 (1 of 5 is not applicable for Armenia)	2	0	2 (1 –partly)	2
Affordability	4	1 (not specific for medicines)	0	0	1
Financing options	6	3	2 (mainly)	1	0
Supply System	6	1	1	1	0
Regulation and Quality Assurance	7	5	2	3	1
Rational use	7	2	0	2	3
Research	2	1	1	1	1
Human resources development	3	2	0	2	1
Monitoring and Evaluation	4	0	0	0	2

The uneven policy development can be explained by numerous factors, in particular by differences in attention paid by policy-makers and input received in development of various components. The higher ratio of approved to recommended policies in the sphere of regulation

and quality assurance can be explained by (1) the large input provided by SCDNTE to this field, (2) the tradition established in early 90s and then supported by the MoH and the Government that registration and import require a strong legislative basis, (3) the fact that these issues were very technical and it became possible to provide a relatively broader coverage for them in the Law “On medicines” while other more understandable components have caused more disagreements between stakeholders and were extremely shortened in the law’s text, and (4) the fact that the SCDMTE’s political power was greater than of many of their opponents. After its creation in 1992, SCDMTE became the Centre of Excellence that employed highly qualified and motivated professionals who started to develop policies and rules in order to be able to carry out their routine functions. Because at that time the country needed to have its own independent system of registration as soon as possible it was developed and introduced very rapidly. High professional competence of the staff, a motivation to provide patients with quality medicines, and technical cooperation with WHO made it possible to introduce systems which were able to assure the quality of registered and imported medicines. As an organization responsible for implementing regulatory functions, SCDMTE became interested in having an approved legislative basis for its activity and certain regulatory documents were developed and approved. Being rather technical and based on the Law’s requirements these documents faced minimal opposition and were accepted by decision-makers quite rapidly. It is also important that as a state joint-stock company funded from registration fees, SCDMTE has been able to finance activities it is interested in, including hiring staff it needs.

Other policy components, in particular affordability and rational use, have not become priority issues although everyone understands that these are significant problems. A general approach was that people in poor country (even now when Armenia became a low middle-

income country) cannot afford medicines. For a long time policy-makers have not thought that although Government cannot provide access to medicines at the level that high-income countries do, it can improve the situation by introducing some cost-effective strategies which are able to save money and improve performance. Because the Ministry of Health is generally responsible for health policy in the country and policy on medicines is an integral part of health policy, it would be logical to suppose that the Department of Pharmaceutical Policy in MoH is responsible for this issue. Unfortunately, this Department has not usually had the necessary human resources to develop policy suggestions. The Department consists of only a few people and has been focused on its routine functions mainly related to managing some medicines supply issues (donations, centralized procurement, etc.).

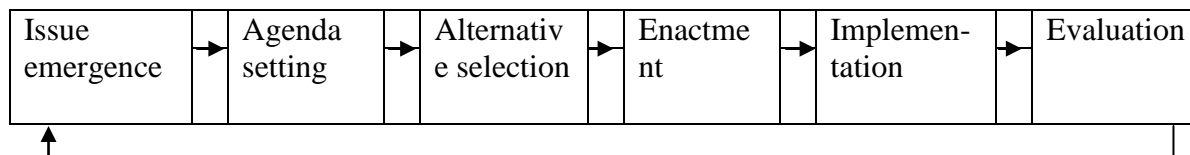
Although no single organization is formally responsible for rational medicines use it has been promoted by the SCDMTE for a long time. A lot of work was done by them separately and in collaboration with experts from other health care organizations to develop Standard Treatment Guidelines (about 40 were approved and published). In addition, two National Formularies were developed and published and drug and therapeutic committees were established in many medical organizations. These activities were implemented as initiatives not supported by any legislative basis. SCDMTE cannot draft regulatory documents containing appropriate policies these documents would not be supported by existing legislation.

Thus, it can be said that two important challengers in the pharmaceutical sector, affordability of medicines and their rational use, have not received necessary attention and are poorly addressed. Developing and implementing a comprehensive NMP would require that the main challenges are carefully and equitably considered and addressed, appropriate strategies are identified to achieve defined objectives and responsibilities are clearly stated.

5. Pharmaceutical policy process in Armenia

There are different models of the policy process. One of them is the “stages model”. This model (Figure 1) suggests that the policy process proceeds step by step starting from “Issue emergence”, then it reaches agenda and so on. The results of evaluation provide feedback after what it starts again. This model was criticized, in particular, because not every idea passes the stage of “Agenda Setting” and, thus, some ideas do not reach further stages, or because implementation and evaluation stages cannot be separated (Birkland, 2011). Nevertheless, this model seems to be the most suitable for describing policy process, in particular, pharmaceutical policy in Armenia. It is also the closest to approaches suggested by WHO for NMP process and by Roberts & Reich (2011) for pharmaceutical reforms.

Figure 1. The Stages Model of the Policy Process



Source: Birkland, 2011

Step 1- Issue emergence.

During this stage different public problems emerge in a society (Birkland, 2011). In Armenia there are still many small and big problems in the pharmaceutical sector that emerged in 90s and are well-known for many years. The specific difference in the pharmaceutical policy process in Armenia is that in the majority cases the policy process starts not from issue emergence but from the problem’s solution emergence, for example from submission of a draft of policy or regulatory document developed by any reformer to MoH. Pharmaceutical policy ideas were developed in Armenia by different initiators. In 1992, the first pharmaceutical policy ideas were

initiated by individuals. After SCDMTE was established, policy ideas were made mainly by this institution where the majority of reformers were employed. In 2000s, SCDMTE's staff was developing drafts of sub-legislative documents and then presented them to the Ministry of Health. Few policy proposals were developed and presented to MoH by the NGO "Drug Utilization Research Group". Some proposals were initiated by MoH. Drafts of sub-legislative documents (on Good manufacturing practice, labeling, a new system of registration) have been developed based on the analogous documents of EU.

The most recent policy development that led to approval of a program to address certain pharmaceutical policy problems in 2012 was initiated very differently. The problems related to medicines were pointed out by the President and the policy development process started in the MOH after direct instructions to improve the situation from the top policy officials - the President and the Government (Dumanyan, 2012).

Step 2 – Agenda Setting

The great majority of ideas (proposals) reached the agenda (meaning that proposals gain sufficient attention from state officials, at least at the MoH level). The majority of recommendations/drafts have been considered and discussed at least for some time. For example, a draft of the Essential Medicines List for Children submitted by DURG is currently actively under consideration in the MoH and SCDNTE.

Step 3 – Alternative selection

Proposals are generally submitted as drafts of policy or regulatory documents, not as a policy papers suggesting different options. Alternative selection has been mainly made between three choices: to focus on adoption and implementation of policy/regulation (this includes its approval), to start considerations, or do nothing. The second decision was quite popular. The

interesting example is the List of EML. Until 2007 it was updated every 2 years and each new version was issued as a Decree of the Minister of Health. The last version developed by SCDMTE in 2009 and submitted to MOH has been under consideration so long that has become obsolete. Currently a new version of EML has been developed by SCDMTE and will be submitted to the MoH very soon.

Step 4 – Enactment

Only parts of policy proposals have been enacted. Some proposals have been discussed effectively and soon became policies (for example, GMP requirements in 2010). Some drafts were under consideration for a very long time and have not been a priority among other competitive tasks for a particular official, or because the consensus has not been reached, or because the administration has changed and a new one was not interested (for example, a Draft of Decree of the Minister of Health “On approval of Rule and conditions of narcotic and psychotropic substance use for medical purpose” appeared in the late 2000s, has not been passed yet and, it seems, even is not actively discussing). Some drafts were considered for years and have not been accepted due to technical reasons (regulation on labeling has not been approved by the Ministry of Justice due to various reasons and, finally, because of discrepancy between its title and provision in the Law “On medicines”).

Step 5 – Implementation

Approved documents that cover issues related to medicines evaluation, quality and safety have been developed by SCDMTE. These policies are generally implemented very well as drafted. However, even in the cases when SCDMTE does not agree with the decisions approved by the authorities, the staffs strongly follow them. For example, some changes on import rules initiated by local wholesalers and approved by the Government in 2011 have been not welcomed

by the SCDMTE staff, however new rules are strictly implemented. However, some provisions clearly stated in the law have been never implemented in the private sector. For example, all the prescription-only medicines (excluding those containing narcotic and psychotropic substances) are dispensed from pharmacies without prescription although it is not allowed by the Law “On Medicines”. Another example is the policy to prescribe medicines from EML to out-patients who receive medicines in retail pharmacy free of charge or with privileges; nevertheless, almost half of prescribed medicines are out of EML (Melikyan, 2011).

Step 6 – Evaluation

In Armenia there is no the system of monitoring and evaluation of pharmaceutical policy (Armenia Pharmaceutical, 2010). Individual pharmaceutical policies introduced by MoH are usually not monitored or evaluated.

6. Effectiveness of the pharmaceutical policy process in Armenia

Effectiveness of the pharmaceutical policy process in Armenia can be assessed according to process and outcome indicators developed and presented in the Background. The results of assessing policy process for selected policies are presented in the Table 3. The following four policies were chosen: those which have led to developing a draft of NMP in 2003 and a draft of new Law “On Medicines”, as well as to approval of the Government Decree “Rules of Good Manufacturing Practice” (2010) and the Decision of Government meeting “On approval of program on solving problems in state control in the area of Health care, as well as in pharmaceutical policy; and list of measures ensuring implementation of program” (2012). These four policies were selected because of the following reasons: the first two documents are the most important ones for the country (national overall pharmaceutical policy and national law on medicines) however, although drafts were developed long ago, they are not approved yet; the

second two policies were recently developed and approved during a short-lasting policy process although they cover only certain issues in the pharmaceutical sector.

It is seen from the table that PPP in Armenia has some strengths and weakness (strengths are those activities for which appropriate indicators in the table get positive respond). Examples of strengths are the following: international experience is taken into account when developing a draft; also, drafts are mainly widely circulated for consideration with stakeholders. At the same time, an evaluation system is never used and this is an important weakness of policy processes in the country.

Based on the data in the table it can be said that PPP in Armenia is not effective because process often do not reach its outcomes – well developed and actively discussed drafts of policy documents are not approved without any clear reason, plans for implementation of those that were approved are conducted only partly and evaluation is never done.

Data in the table suggest that drafts of policy documents are approved only when there is political will/commitment at the Government level or the National Assembly level. Such political will/commitment can be provided/rejected due to various reasons. On my opinion, the main general reasons of a lack of political will related to medicines issues in Armenia are the following: common wrong assumption shared by officials and the public that in a country with restricted budget access to medicines cannot be improved significantly, so there is no need to make efforts; medicines are not considered to be a priority among other pressing Health care problems. In two cases (examples) presented in the table 3 policy support was provided because at the time of approval these problems were widely considered in media, policy-makers were interested to demonstrate their readiness to implement social reforms and there were no strong opposition for such new policy among powerful stakeholders. It can be assumed that among

three necessary for policy window streams suggested by Kingdon (2003) – streams of problems, policies and politics, politics is probably the most valuable in Armenia because problems exist for a long time, solutions are suggested time to time (drafts of proposal), however due to lack of favorable political sources policy proposals do not become active. At the same time, when there are certain happenings in policy stream (for example, changes in the Ministry/Government or elections are expected), the Government becomes very active, makes social issues priority and provide political will/commitment at least for some time. The new Minister of Health initiated operative research in the pharmaceutical field; in addition, the President has paid more attention to health and pharmaceutical issues during his reelection campaign. All this has led to rapid development and approval by the Government of a new program addressing some problems in the pharmaceutical sector and also developing a new draft of a new Law “On Medicines” that is currently considered by the National Assembly. Thus, opportunity window that existed in 2012 created conditions for some positive changes at the Government level (approval of program, pushing a draft of law to the National Assembly). However, at present it is not clear whether the National Assembly will demonstrate enough political will/commitment and whether a new draft will be passed by the National Assembly, and even if so – when and with which deletions. The reason is well known – difficulties in reaching consensus on some important issues because stakeholders have conflicting interests in this field and some of them have support in the Parliament; also, a draft suggests numerous changes and not all provisions seem to be evidently useful or implementable. Due to political will at governmental and parliament level these considerations can continue years and years.

Thus, it seems that the most important factor influencing effectiveness of the pharmaceutical policy process in Armenia is political will/commitment. Without appropriate support any policy

proposal, does not matter how well-developed it is, will remain just good intent. It is important to identify and introduce strategies which could be able to improve political will/commitment regarding to the pharmaceutical policy in the country. In Australia consumers were at the heart of debate which have led to developing policy document (Walsh, 2011), however in Armenia there is no patient organizations and it would be naïve to expect that they will be founded and became strong in the near future; consumer organizations are relatively weak and have no enough power to press the Government. Creation of powerful advocacy coalition that would include many stakeholders which are sharing values and interests could be a more promising strategy. Such Coalition could support patient’s interests, and be much more influential due to involving professional organizations (which can always provide expertise), consumer and other NGOs (including international NGOs), political activists, representatives of media and other interested stakeholders.

Table 3. Process and outcome measures for the pharmaceutical policy process in Armenia (four examples)

Process measures	NMP (2003) - Draft	New Law “On Medicines” - Draft	“Rules of GMP” (2010)	Program on solving problems of Pharmaceutical policy (2012)
Responsibilities for policy formulation are defined.	No	Yes	Yes	Yes
Operational research is implemented to provide baseline data	Yes	No	Yes	Data were available from other sources
International experience on policy strategies is studied.	Yes	Yes	Yes	Unknown
A policy paper on the issue considered is written and presented to policy-makers (should include brief description of the current situation, evidence based policy options).	Yes	No	Yes	No

Stakeholder analysis is implemented.	No	No	Yes	No
Government or National Assembly commitment is ensured.	No	No	Yes	Yes
Draft of a final document is presented (if it is a policy document it should include goals and strategies to achieve these goals; if it is legislation/regulation document, it should include appropriate provisions).	Yes	Yes	Yes	Yes
Draft is made publicly available.	No	Yes	Unknown	No
A national conference/meeting is organized to present the final draft (all stakeholders including patient/consumer organizations as well as media are invited).	No	No	No	No
Draft of Implementation plan is presented.	No	No	Yes	Yes
Draft of evaluation system is presented	Yes	No	No	No
Drafts are circulated for consideration.	Yes	Yes	Partly	No
Funding is provided.	No	No	Partly (for regulation by the State)	No
Draft of Implementation plan is formally approved.	No	N/A	Yes (strategic plan)	Yes (strategic plan)
Draft of evaluation system is formally approved	No	N/A	No	No
Outcome measures				
Stage of Formulation: document is formally approved.	No	No	Yes	Yes
Stage of Implementation and Monitoring: All activities in the Implementation plan are implemented.	-	-	Partly	Partly
Stage of Implementation and Monitoring: The final evaluation is made and distributed.	-	-	No	No

7. Strengths and weaknesses of the pharmaceutical policy process in Armenia

This brief description of the pharmaceutical policy process in Armenia, the information presented in the case study (see below) and the previous sections indicate that there are important strengths and weaknesses in the Armenian pharmaceutical policy process.

Box 2.

Case study: Draft of a new Law “On Medicines”

Very soon after approval of the Law “On Medicines in 1998, it became evident that this first document did not cover many necessary issues (for example, functions of a Drug Regulatory Authority, a system of ensuring affordability of medicines) and, correspondingly, did not provide a reliable legislative basis for the Armenian pharmaceutical sector. It was clear that the country needed a new law providing more detailed provisions related to medicines and pharmaceutical services. A draft of a new law “On medicines” was formulated by the SCDMTE in 2003 and submitted to MoH for consideration. Many corresponding regulatory documents which suggest policies for different components of the Pharmaceutical sector have also been developed in order to be considered after approval of a Draft.

After being reviewed at the MoH level a Draft was submitted for the Government consideration and then – to the National Assembly (Armenian Parliament). It was widely discussed with involving numerous stakeholders: pharmaceutical associations, local industry, academia and so on. Considerations in the National Assembly (NA) have not been completed until its term of office for the acting was expired. In further years a draft was many times considered at the different levels: MoH, Government, NA, however, has not been passed yet.

Another draft of new Law “On medicines” was developed by SCDMTE in 2012 after Government’s decision that a new Law should be prepared. This new draft was submitted to MoH and became available for comments being presented at the MoH official web site. Comments were collected until December 2012, then they were carefully reviewed by SCDMTE and appropriate changes were made. Currently this draft is considered by the National Assembly. Thus, it can be said that a draft of new law “On medicines” is at the policy agenda already 10 years.

This new draft covers the following aspects: regulation, principles of state policy, a state system of ensuring medicines affordability, a system of medicines provision free and with privileges, price regulation, drug development, clinical trials, registration, adverse drug reactions monitoring, manufacturing, packaging, labelling, import and export, transportation, storage, distribution, information, advertisement, inspection. Numerous regulation documents providing detailed interpretation of Law’s provisions will be introduced soon after approval on a new law.

The most harmful effect caused by delay in approval of a new Law “On medicines” is impossibility to consider and approve numerous regulatory documents required by it. Both old and new drafts include numerous provisions requiring approval of regulation documents covering the most important policies in the pharmaceutical sector. The majority of these requirements is not included in the existing Law and, correspondingly, sub-legislative documents cannot be issued. Uncovered documents include such vital issues as the state system of ensuring affordability of medicines and price regulation.

Strengths

1. There are some organizations in Armenia in addition to MoH which are interested and capable to develop policy proposals including drafts of policy and legislative documents.

These organizations are able to move issues to policy agenda. SCDMTE is a very strong institution that has relatively good funding and human resources; it is able to develop drafts of legislative/regulation documents especially those which would serve as a basis for providing effectiveness, safety and quality of medicines.

2. Policy proposals are mainly well prepared and ready for considerations; the majority of them take into account International experience, recommendations of WHO, local conditions.
3. Many stakeholders are involved in a process of policy and regulation drafts consideration and have a chance to defend their opinion.
4. Drafts of the main legislative documents are available at MoH's official web site and any written comments on drafts can be submitted to MoH.

Weaknesses

1. Problems are rarely considered and/or addressed by state officials themselves; instead these officials consider ready proposals which could be seen by them not as a priority. An important exception is the situation in 2012 when certain problems were recognized and certain promises (Sargsyan, 2013) and decisions (Decision, 2012) were made. Other examples of initiatives which came from officials include those when the MoH staff drafted a policy on creating cost-effective mechanism for reimbursement in 2005, formulated rules on transportation and storage of medicines in 2010 and made couple other suggestions. These cases make a small but the most successful part of policy developments, because the proposals were rapidly discussed (if discussed at all) and approved. It seems that emerged interest to issue and support from decision-makers plays the most important role in the Armenian pharmaceutical policy process.

Problems may exist for a long time, be moved to policy arena, however, real steps to solve them are made mainly when a political will is provided.

2. Although policy consideration is an important and positive process, it is clear that policy-makers in Armenia have difficulties reaching consensus. Stakeholders in Armenia, like everywhere, have competing interests related to medicines, and this causes delay in approval of extremely important documents like it happened with a draft of Law “On medicines”.
3. Although many stakeholders are involved in policy deliberations, they have very different political power and, correspondingly, are able to defend their interest with very different success. For example, wholesalers were able to convince the Government to make some changes in rules on import although it may compromise the quality assurance system. The weakest stakeholder in the country is patients/consumers. There are no patient organizations in Armenia due to certain reasons: absence of such tradition; a small population and, appropriately, relatively small number of patients with the same disease; many patients are poor, fighting for survival and do not have time and knowledge to create or be involved in voluntary activities, a lack of trust in effectiveness of a public activity. Consumers’ organizations are poorly educated and not active in the area of the pharmaceutical policy. The patients’ interests are presented by state officials but these are among other competing interests. Some professional associations and representatives of Academy try to defend patient’s interest, however, these stakeholders have a little political power and, correspondingly, often ignored. Those organizations which are most interested in promoting affordability of medicines, their safety and rational use are often not

involved in policy discussions and, also, do not have any funding to support their activity in this area.

Part II. Pharmaceutical policy process in Newly Independent States

There are limited data on the pharmaceutical policy process in NIS. Unfortunately, it was impossible to find studies examining and analysing the direct outcomes of a NMP document approval. Although NMP are approved in many NIS, they are rarely monitored and the results are not published. In addition, it probably would be very complicated task to assess the role of having approved document because numerous other factors also influence the final results in very rapidly changing political, social, economic environment in these countries during the last 20 years.

The only publication available that presents the results of study intended to assess a role of NMP implementation in NIS, is one that covers four countries from the Middle Asia region – Kazakhstan, Kyrgyzstan, Tajikistan and Uzbekistan (Nurgojin, 2004). Based on the data collected mainly through interviewing key persons in mentioned countries authors have concluded that certain elements of NMP recommended by WHO were observed in all the countries studied; in Kyrgyzstan the concept of NMP was introduced more widely and the level of availability of medicines was higher.

Thus, due to lack of data on evaluation of NMP outcomes in NIS, only important elements of the pharmaceutical policy process itself have been examined and are presented here: existence of formally approved NMP document and implementation plan, its monitoring and evaluation, involvement of stakeholders. Some data are summarized in Table 4.

Table 4. National Medicines Policy documents in Newly Independent States

Country	Formally approved NMP document	Data of approval	Available at:	The last Draft of NMP	Implementation plan, year	System of monitoring and evaluation
Armenia				NMP as a part of NHP (2006) (Armenia Pharmaceutical, 2010)	No (Armenia Pharmaceutical, 2010)	No (Armenia Pharmaceutical, 2010)
Azerbaijan	No (Azerbaijan Pharmaceutical, 2011)				No (Azerbaijan Pharmaceutical, 2011)	Not regularly (Azerbaijan Pharmaceutical, 2011)
Belarus	Resolution of Council of Ministers № 1192 “About concept of medicines supply of Republic of Belarus” (Reutskaya, 2008)	August 13 th , 2001 (Reutskaya, 2008)	http://spravka-jurist.com/base/part-bz/tx_wsxeoy.htm			
Georgia	As a part of the National Health Policy (Chanturidze, 2009)	1999 (Chanturidze, 2009)				
Kazakhstan	Government Resolution № 584 – “Concept of a medicines policy of the Republic of Kazakhstan”	May 29 th , 2002		Concept of National medicines policy of Republic of Kazakhstan for 2012-2016 (2011) www.nv.kz/file		

				s/lekarstva..doc http://www.mz.gov.kz/page/proekty-dlya-obsuzhdeniya		
Kyrgyzstan	<p>1. Resolution of the Government №794 “On State medicines policy of KR”</p> <p>2. Resolution of the Government №704, NMP for 2002 – 2005</p> <p>3. KR Government Resolution N 11 "About National medicines policy of Kyrgyz Republic for 2007 - 2010" (Kyrgyzstan Pharmaceutical, 2011)</p>	<p>1. December 4th, 1998</p> <p>2. October 15th, 2002</p> <p>3. January 12th, 2007</p>	<p>3. http://pharm.kg/ru/policy/</p>	<p>2nd Draft. NMP2014-2020 (May 27th, 2013)</p> <p>http://metakg.org/upload/news/NDP_270513.pdf</p>	<p>1. 1998 (Kurmanov, 2006)</p> <p>2. 15th October, 2002</p> <p>3. KR Government Resolution № 11 of January 12th, 2007 (Kyrgyzstan Pharmaceutical, 2011)</p>	<p>1. 2001</p> <p>2. NPM implementation report, 2010 (Kyrgyzstan Pharmaceutical, 2011)</p>
Moldova	<p>1. “National policy in the field of medicines” approved by Board of Ministry of Health (Safta, in press)</p> <p>2. Decision of the Parliament of the Republic of Moldova nr.1352 approving the State Policy in the Field of Medicaments (<i>Cuza</i>)</p>	<p>1. 1997</p> <p>2. October 3rd, 2002</p>			<p>1. 2002 (after NMP approval in 2002)*</p> <p>2. 2007 (Republic of Moldova Pharmaceutical, 2011)</p>	<p>Yes (Republic of Moldova Pharmaceutical, 2011)</p>

Russia	Decree of Minister of Health N 66 “Strategy of medicines supply for the period until 2025”	February 13 th , 2013	www.consultant.ru/document/cons_doc_LAW_142725/			
Tajikistan	Decree No. 368 of the Ministry of Health on the National Drug Policy (Khodjamurodov, 2010)	August 28 th , 2003	http://dictaj.uz.ru/load/nacionalnaja_lekarstvennaja_politika_rt/1-1-0-2			
Turkmenistan						
Ukraine						
Uzbekistan	Resolution of MoH Board “National medicines policy of the Republic of Uzbekistan» (Nurgozhin 2001)	May 30 th , 1999 (Nurgozhin, 2001, Uzbekistan Pharmaceutical, 2011)	http://zakonuz.uzshar.com/?document=5947		Yes (Uzbekistan Pharmaceutical, 2011)	Yes (Uzbekistan Pharmaceutical, 2011)

Note: * (in the table and further in the text) - the data are provided by DURG PO (Armenia); these data were submitted by leading experts from six countries: Armenia, Belarus, Georgia, Kirghiz, Moldova and Ukraine to the DURG in 2003 during implementation of a special project.

1. Existence of NMP document

The data available indicates that NMP document has been formally approved in the majority of NIS (eight of twelve). NMP is mainly available as a document, in one case (Georgia) – a part of a document. In five countries (Kazakhstan, Kyrgyzstan, Moldova, Tajikistan, Uzbekistan) officially authorized document has the name including the term “medicines policy”, in two countries (Belarus and Russia) – “concept of medicines supply”. In one country (Georgia) – NMP is a part of the approved “National health policy” document. In six countries the current NMP has been authorized at a high level as a formal document: in four - by the Resolution of the Government/Council of Ministers, in one (Moldova) – by the Parliament and in one (Georgia) – by the Ukase of the President*. In three countries (Russia, Tajikistan, Uzbekistan) it has been approved by the Ministry of Health.

In many of the countries documents having a various status and name but in fact being a written description of comprehensive NMP, have been approved soon after independence. According to WHO data, nine countries have approved NMP still in the first five years (Saoutenkova, 2003). Recently the significant changes in situations alongside with understanding of that many problems have not been solved yet, have led to renewal of the interest to a medicines policy. Russia approved its document in February this year, Kazakhstan and Kyrgyzstan have developed drafts of new NMP in 2011 and 2013, correspondingly, and these documents are currently under consideration. In May 2013 Kyrgyzstan developed the Second draft that is intended for 2014-2020 (Kyrgyzstan 2nd Draft, 2013).

Analysis shows that some countries formulate and approve a new NMP when they consider their existing document to be obsolete. Thus, the last authorized NMP document in Kyrgyzstan is

already the third one and Kyrgyzstan formulated a draft of the fourth document for the period of 2014-2020; in Kazakhstan and Moldova the last approved document is the second one.

The interesting lesson from countries' experience is that in several countries (Kazakhstan, Kyrgyzstan, Moldova) where NMP has been initially approved at a level of Ministry of Health or as administrative document during advisory meetings, the further version of NMP has been passed as an official document (Kazakhstan, Kyrgyzstan) or at higher level (in Moldova the last document was approved by the Parliament). Existence of a document with the official status allows a higher level of performance and authorization by the Government/Parliament of the country allows the involvement of all the necessary sectors simultaneously. According to the opinion of key informant from Russia, the document was approved by the Health Ministry but not by the Government (as was originally expected), so in fact it is not a National Strategy, but rather an internal ministerial paper.

2. Formulating NMP

Formulating NMP in NIS took place to a certain degree according to the recommendations of the WHO. This is the result of the activity carried out by WHO, especially by the Regional Office for Europe from the beginning of the 90s. Organization of a process of formulating a NMP document was carried out mainly by the Ministry of Health/corresponding departments or Medicines Regulatory Authorities. In many cases drafts of documents have also been prepared by the MoH/corresponding departments, for example in Belarus, Georgia, and Kyrgyzstan. In Moldova, for example, a draft has been prepared jointly by the National Institute of Pharmacy, the Pharmaceutical faculty of the State Medical Pharmaceutical University named after Nikolay Testemitsanu and the MoH, Republic Moldova*. Document in Russia was prepared by MoH (key informant from Russia).

There is a lack of the information on whether development of documents has been based on an analysis of the situation. In the Kirghiz Republic, for example, formulating a draft of the second NMP document was based on assessment what was carried out with use of a set of the WHO indicators. According the opinion of key informant from Russia, the document adopted by MoH in February was not based on sound situation analysis and was not comprehensive, in particular, practically does not include plans for strengthening of the medicines regulatory system - the only indication was “international harmonization” .

Involvement of the interested parties, in particular, representatives of a legislative bodies, various ministries, departments, universities and so forth in discussions on a draft of a NMP document is noted in nearly all the countries. The example of Kazakhstan is interesting. As it was already mentioned, at the beginning the document “State policy in the sphere of medicines circulation” was approved by the Pharmaceutical section at the Conference in 2001; then in 2002 this document was published in the professional newspaper and journal in order to provide a wide involvement of interested parties in discussions. The suggestions submitted, for example, those suggested by the head of a professional nongovernmental organization, were published in the same newspaper (Berkman, 2002). Nevertheless, it is obvious, that almost everywhere the number of participants involved in development/discussion of a NMP is limited. Examples of cases of involving consumer or patient organizations, or other non-professional NGOs in pharmaceutical policy process have not been available in publications. Involvement of the public professional organizations in a process of NMP development is also limited. On the other hand, the professional community in some countries come with very serious initiatives on the issues connected to a medicines policy. An interesting example is approval of the document “Concept of developing the pharmaceutical sector” at the VI National congress of pharmacists in Ukraine

in 2005 (The concept, 2005). In Russia necessity of developing a NMP document and also possible approaches to its formulating have been actively discussed and moved ahead by leading experts (Meshkovsky 2000, Beregovikh 2005), presented at various conferences and sessions of public organizations, round tables, and also in professional publication. The Chamber of Commerce and Industry of Russian Federation of the Russian Federation has played an active role (RF CCI, 2004).

Today, in the NIS there is a significant number of public professional organizations involving many qualified and interested professionals. Although they basically have no significant experience participating in the pharmaceutical policy process, this huge potential of professionals can and should be involved in formulating and discussing drafts of a NMP. It is difficult to overestimate the contribution the army of professionals can bring to development of the pharmaceutical sector of their countries.

Countries have not organized active campaigns on launching NMP but in some of them the information about approval of the document was published or presented in the Internet, especially those approved in the last 10 years. For example, a detailed information about signing the Resolution of the Governments of Kyrgyzstan on KP NMP for 2007-2010 was submitted on 16th January, 2007 on the State Internet portal site; the article contains certain details of the document including the main observations and tasks. There is an access in the Internet to the full text in Russian of NMP documents of Belarus, Kyrgyzstan, Russia, and Tajikistan.

3. Implementing and monitoring NMP

Although NMP documents are available in the majority of the countries, implementation plans based on the policy are developed only in some of them, including Belarus, Kyrgyzstan, Moldova and Uzbekistan. This has not significantly changed compared with the 1990's when it

was also noted that most national drug policies lacked an operational implementation plan or adequate monitoring mechanisms (WHO, 1998). According to the WHO approach based on various countries' experience, without the plan of implementation medicines policy process remains a dead document (WHO, 2001). Accordingly, it is important for NIS to not only pay attention to developing the NMP, but also to continue work to develop an appropriate implementation plan to concretize actions, responsibilities, budget, and other terms.

It is also important to remember that implementation of NMP is a common task in which various ministries, the private sector and many other stakeholders are involved. Accordingly, coordination of actions, involvement of all interested parties to both formulating plans and their implementation and monitoring is necessary.

The Ministry of Health in most countries cooperates with other state bodies and provides public relations. For example, in Kazakhstan, after setting up the Committee on pharmacy, pharmaceutical and medical industry in its semi-annual report to the MoH Board a wide activity carried out in this area was specified. Agreements related to issues of pharmaceutical products between the MoH and other ministries and sectors have been prepared visits to regions and meetings with businessmen, nongovernmental organizations have been carried out. Problems were discussed in mass-media, including TV, on constant basis (Pak, 2002). However, to obtain the best possible outcome from PPP, it is necessary that implementation activities be carried out by all participants according to the discussed and approved plans based on a NMP.

For coordinating activity and also PPP monitoring a special division in the MOH could be expedient. In few NIS there are divisions/units responsible for medicines policy issues. In Uzbekistan, for example, there is "Centre of a policy of medicines and devices" of the MoH, the

main purpose of which activity is introduction and implementation of a strategy of the Ministry of Health in the field of the national policy on medicines and devices.

In nearly all NIS, studying and assessing the situation in the pharmaceutical sector is carried out to some extent and the results are published in scientific journals, other professional publications, and also in mass-media, on official sites of the Ministries of Health and Medicines Regulatory authorities of the countries, etc. Certain information on implemented reforms and the strategy are also presented. Nevertheless, the qualitative and quantitative data usually are not related to NMP or a plan of implementation's contents. Such data indicate some achievements and problems in the pharmaceutical sector, but do not provide the opportunity to carry out monitoring and evaluation, and, accordingly, to draw a conclusion about progress in achieving the NMP goals and objectives. According to the WHO, although quality evaluation is useful, it cannot replace the need for quantitative measurement of the factual data. Use of the fixed package of indicators is necessary for ensuring that repeated and compared monitoring can be carried out (WHO, 2004).

4. Factors influencing NMP

Political will. In a number of countries (Belarus, Kazakhstan, Kyrgyzstan, Moldova) NMP documents have been developed by corresponding departments of the MoH or Medicines Regulatory Authority with participation of the MoH, and then have been authorized at a level of Resolution of Government/Council of Ministers and even the Parliament (Moldova) that clearly demonstrates commitment and suggests the level of political will of the country's authorities to improve the situation in the pharmaceutical sector. Some countries specify the political will of authorities. For example, in Uzbekistan it is considered, that a dynamic development of the pharmaceutical sector in many respects was the result of explicit decisions by authorities of the

Republic, and in particular, the State joint-stock concern "Uzpharmsanoat" to support the development of this sector. Also, a number of the governmental decisions supported the establishment of a local pharmaceutical industry. Nevertheless, there is a lack of political will in many countries. In Russia, where the concept of NMP has been actively promoted by a number of leading professionals and organizations, an appropriate document appeared only this year. In the majority of countries the political will of the government was enough for documents approval; implementation plans have not been developed and/or systems of monitoring and evaluation have not been introduced, however.

Support and the technical assistance from WHO. The majority of the countries specify support and the technical assistance of the World Health Organization. Administration of the pharmaceutical service in the MoH of the Kirghiz Republic notes that the development of a NMP started in 1994 at the advisory meeting with the WHO experts participation, and then, in 2001 the evaluation of NMP introduction was carried out with the methodological support of WHO and based on the results of NMP implementation for the period of 1994-2000 a new draft was developed (Kurmanov, 2006). Support from the WHO Regional Office for Europe on issues related to formulating and implementing NMP is noted also by representatives of Kazakhstan (Kulakhmetova, I. 2000) and Tajikistan (Isupov, in press). Publication in Russian and English of the strategic document "The patient in Focus. A Strategy for Pharmaceutical Sector Reform in Newly Independent States", prepared by the WHO Regional Office for Europe and the WHO Action Programme on Essential Drugs has provided an important methodological assistance. "The publication describes pharmaceutical sector reform in the newly independent states and sets out strategies for its further development. This global strategy will function as a guideline for further reform at country level" (WHO, 1998). Numerous consultations, seminars and other

support intended to increase a level of knowledge of countries' experts in this sphere have been also carried out. A fortnight training seminar organized in 2002 in Tashkent should be noted along with other presentations in the area of NMP, including the special lecture "Process of a medicines policy".

Existence of resources. In many NIS there are insufficient resources for NMP implementation. In the opinion of the expert from Moldova, for example, the absence of a state financing intended for introducing NMP is the main weak link in their NMP*. According to the data available* in many countries special funding for introduction of NMP has not been planned. It is important to note, that in Kyrgyzstan where the pharmaceutical policy process is organized better than in many other counties of the region (e.g. an updating of the document on a regular basis - each 4-5 years, regular approval of appropriate implementation plans, monitoring according to indicators), a special financing on implementing a policy in the sphere health care has been allocated (the credit from the World bank)*. Absence of a specially allocated budget seems to be an important barrier influencing an active implementation of NMP in other NIS.

Human resources. Numerous highly skilled professionals are employed in the NIS by different public and private organizations. In many cases individual experts and institutions initiate and support issues related to NMP. In the early 90's professionals from the countries of the former USSR heard the term "NMP" for the first time. Due to support from the WHO the concept of NMP has quickly spread in this region; however, initiatives of the countries were also very important. Ukraine and Kazakhstan, for example, have published the important materials including translation into Russian of the last WHO guidelines «How to develop and implement a national drug policy in their main professional editions. However, there are certain factors connected to human resources which will influence PPP: insufficient number and, accordingly,

excessive overload of officials by routine activity; need to solve at once many unresolved problems in the pharmaceutical sector, including improving legislation; a low motivation due to an inadequate payment; a lack of knowledge and experience in sphere NMP and a lack of access to the appropriate information; a lack of researchers and, appropriately, necessary data.

Therefore, increase of a level of knowledge in the area of NMP and the pharmaceutical sector management remains an actual task. Increase of a level of motivation and responsibility and promotion of ethical standards among the experts involved in the sphere of management and regulation in the pharmaceutical sector also seems essential.

5. Lessons learned from PPP in NIS

Some lessons can be learned from the experience of NIS on developing and implementing pharmaceutical policy; these lessons can be useful for Armenian policy analysts and policy-makers.

1. Having formally approved document of NMP can be considered to be useful for improving the situation in the pharmaceutical sector (eight of twelve countries have formally approved document, three of them have approved also the second one or developed a draft for approval; in two of four countries where there is no formal document, NMP document has been approved by professional bodies and countries have been trying to have a formal document; all this suggests that NIS found out having a formally approved document to be useful).
2. It is preferable to approve a NMP document at the governmental or higher level (in five of eight countries formal documents including the second/third ones were approved by Government, Parliament or President; new drafts in these countries are also intended to

be approved at the same level; this suggests that countries found out this high level to be appropriate).

3. It is important to make a draft of NMP document publicly available and provide conditions for wide consideration with involving different stakeholders; it is also important not only collect suggestions, but also to take them into account (drafts of NMP documents considered and approved during the last decade were available through professional or other media; opportunity to submit comments was provided; it is unclear whether suggestions were taken into account, and there is opinion (informant from Russia) that comments were accommodated in an inconsistent manner).
4. Due to absence of system of monitoring and evaluation countries are not able to evaluate their progress in the pharmaceutical sector even if they fix changes of some indicators (Kyrgyzstan is the only country among NIS that implements monitoring of NMP).
5. Patients' including consumers' organizations are currently not able to make a difference in the pharmaceutical policy process in NIS, so it is important to identify an organizational framework that would be able to influence PPP in order to improve it and provide appropriate outcomes of the process and pharmaceutical policy.

Part III. Discussion and recommendations on pharmaceutical policy process

in Armenia

Discussion

The results of analysis of process and outcome indicators as well as other data presented in the Part I have shown that the pharmaceutical policy process in Armenia is not effective because it does not provide appropriate outcomes – the necessary law and regulation documents, policy documents and actions; correspondingly, not-existing policies cannot be implemented;

even those policies which are approved are implemented only partly and not monitored. The main reason can be lack of political will because other elements important for successful policy implementation and known constraints do not currently cause much concern as possible barriers. MSH (2011) suggests the following main constraints for successful NMP: lack of political will, lack of resources, opposition and corruption. Lack of resources that is always an important factor in middle-income countries is not an important barrier for formulating and implementing the majority of not-existing in Armenia but cost-effective policies in particular those addressing rational medicines use. It is well-known that there are many highly-qualified professionals in the country that could be involved in policy formulating and implementing, so lack of human resources is also cannot be considered as an important constraint. Opposition to pharmaceutical policy issues in Armenia is not very strong because different organizations have various interests even if they represent a single stakeholder, so they rarely join to defend their common interests; however, opposition is able to create barriers now because the Government and the National Assembly do not provide necessary political will and commitment (there are numerous strategies allowing to diminish or eliminate efforts of opposition which are currently not used). Corruption is considered to be very active in Armenia, and certainly can be a constraint for approval of certain policies and policy enforcement, however, if the Government would demonstrate appropriate political will through introducing transparency and accountability mechanisms and through evaluating policy implementation, corruption can be easily eliminated in the majority of areas dealing with medicines. For example, some physicians ignore the rule requiring to prescribe medicines from the Essential medicines list to those patients who receive medicines free of charge, due to corruption. MoH could easily require reports from appropriate medical

establishments and analyze the situation. Being accountable, physicians would be afraid to break the rule and will stop to ignore it.

Lack of political will and commitment is frequently met issue everywhere and rarely is provided sufficiently or for a long time. Phanouvong with co-authors (2002) identified that in four countries they studied the ministers of health and the cabinet played a crucial role in medicines policy initiation, however, once the policy was launched in Laos, Thailand and the Philippines a decrease in political will and commitment had occurred, and this had slowed the progress of NMP. In Australia, where governments demonstrated commitment to continued funding of NMP, the policy was implemented more effectively.

It is not easy task to improve political will in the country. It is considered that in 90s the development of the Australian NMP was the result of strong consumer (civil society) advocacy and lobbying (Robertson, 2012). Thus, we can assume that continuing government commitment was caused and supported by efforts of consumer (civil society) organizations and possibly this experience can be useful for other countries. Unfortunately, consumer activism in other countries (such as India, Thailand and China) was less successful due to a lack of financial support for consumer groups and poor access to policy makers. Summarizing the results of the Asia Pacific Conference on National Medicines Policies Robertson and co-authors (2012) concluded that “Consumer groups have an important role in ensuring policies are implemented.” (p.190), however engaging civil society to pressure governments to deliver appropriate medicines policies remains a key challenge.

Experience of Armenia and other NIS suggest that in this region patients/consumers groups are not sufficiently strong (for example, in Ukraine NMP document is not approved despite advocacy provided by consumer organizations), however there are many different other

NMP advocates such as academy, professional NGOs and associations. It seems that only joint efforts could be able to pressure the Governments sufficiently to provide appropriate political will and commitment on issues related to medicines. Advocacy coalitions involving different stakeholders having same interests and similar values at least on some important issues could provide enough pressure through evidence-based advocacy. Involved professional organizations could provide data and analysis of situation, consumer/patients organization could provide the results of case studies, media could be responsible for competent distribution of information, some partners could provide necessary funding to ensure financial sustainability of the coalition. Value of joint efforts was recently noted also at the Workshop “The role of NGOs in the development and implementation of National Medicines Policy” that was held in December 2012 in Latvia (Workshop, 2012). Based on the results of discussion they arrived to various ideas including that “Those non-governmental organizations which protect the interests of patients should work together on problems where their opinions and needs are similar or identical, which would increase their chances of being heard and empower them (especially when it comes to organizations of patients).” MSH also supports such approach in its latest publication - “Mobilizing alliances and coalitions and creating constituents inside and outside the government are necessary to mobilize political will over the process” (MSH, 2011, p.4.5).

Based on the above-described approach I developed a pharmaceutical policy process framework involving advocacy coalition (Figure 2). Although this suggested framework has some similarities in main idea with the well-known Sabatier’s Advocacy Coalition Framework (ACF) – an important model of the policy process which is based on the idea that different interest groups can be organized in policy communities (Birkland, 2011), it is quite different in interpretation. In the ACF 2 or 4 advocacy coalitions can form a particular policy

domain joining around shared set of core values and beliefs. The framework suggested by me is developed particularly for PPP; it, correspondingly, includes coalition and those stakeholders which are typical for the pharmaceutical sector. Policy making in suggested framework is not a straight process like it is in ACF, but is a cycle because, the results of monitoring can reveal a new problem or because one policy cycle is not always able to solve problem completely - so policy cycle starts again. In the ACF policy process is influenced by two big groups of parameters – “relatively stable” and “external (system) events”. In the framework suggested the policy process is influenced by a coalition itself, other stakeholders in the sector, as well as more broadly by policy environment (policy environment: “The structural, social, economic, political, and other factors that influence and influenced by policy making”. Birkland, 2011, p.27). Policy process outcomes (laws, regulations, policies, etc.) are influenced by and influence the coalition, other stakeholders through PPP; and links between coalition and these outcomes are more numerous and more strong than between outcomes and separate stakeholders. These additional comprehensive links reflect additional opportunities of coalition to affect PPP and achieve policy process outcomes.

Because a lack of political will is one of the most important constraints, but not a single reason of PPP ineffectiveness in Armenia, certain recommendations for the policy process improvement were developed and presented below.

Figure 2. Framework of pharmaceutical policy process involving advocacy coalition



Recommendations for different stakeholders

For the Government

1. To create a Multi-sectoral Commission responsible for pharmaceutical policy issues; to ensure that the Commission consists of representatives of different stakeholders including organizations representing patients' rights; to ensure an access of media to meetings; to ensure transparency of the commission's activity.
2. To create and introduce mechanisms for enforcement of existing legislation in the pharmaceutical sector

For the Ministry of Health

3. To implement comprehensive assessment of the pharmaceutical sector in order to get reliable data necessary for (1) defining the main problems and their causes; (2) developing evidence-based policy; (3) providing baseline data for a further policy evaluation.
4. To create a working group consisting of leading national experts and representatives of different stakeholders to develop a draft of a National Medicines Policy document that will include: goals (long-term and medium-term), tasks, strategies to achieve goals (for all selected components), sources of funding and timeline, a program of evaluation including indicators for monitoring outcomes; to select the following components: legislation, regulation, financing, pricing and reimbursement, supply, distribution, pharmaceutical care, rational use, antibiotics, controlled medicines, waste, research, human resources.
5. To develop a draft of the five-year Implementation plan together with NMP (not after policy approval) and present it together with a policy document draft in order to provide a

clearer picture of further actions and expected results; to include in the plan the following information: activities, responsibilities, input, outcomes, timeline.

6. To consider drafts with all the interested stakeholders during initially decided period of time (possibly 6 months), make changes based on presented comments and approve it as a Government Resolution.
7. To create in MoH a special unit responsible for monitoring and evaluation of NMP; to create a Public Commission (involving representatives of patients', consumers' and other non-governmental organizations) to be involved in considerations of the results of policy monitoring and evaluation; to provide transparency of unit's activity and results received.
8. To monitor PPP according to indicators suggested and to provide the results to above-mentioned Public Commission for consideration and revision.
9. To calculate, identify and ensure funding needed for policy implementation.

For Public (Non-Governmental) organizations - both professional associations and representing patients' interests

10. To participate actively in pharmaceutical policy formulation and consideration.
11. To be informed about the results of monitoring and evaluation and possible changes in policy.
12. To create a strong advocacy coalition involving professional associations and consumer's rights organizations, media and so forth, that would be able to defend interests of patients.

For International Non-Governmental) organizations

13. To provide some funding to ensure active participation of NGOs in policy process and their independence.

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