Program of the Government of the Kyrgyz Republic on Development of the area of drugs circulation in the Kyrgyz Republic for 2014-2020

Background

The Constitution of the Kyrgyz Republic declares the right of every citizen to health protection. Providing access to drugs as an integral part of public health is one of the most important tasks of the state. Harmonious development of pharmaceutical sector is of great social and economic importance for Kyrgyzstan.

The Program of the Government of the Kyrgyz Republic “On development of the area of drugs circulation in the Kyrgyz Republic for 2014-2020” (hereinafter - the Program) defines the principles, goals, objectives and priorities, set by the Government of the Kyrgyz Republic in the field of drugs circulation to be used for prevention, diagnostic and treatment of humans. The period of implementation of three state drug policies has marked a substantial progress in the field of drugs circulation. With the adoption of the first State Drug Policy in 1998, the institutional framework for managing drugs and medical devices (hereinafter - MD) circulation has been built in the republic, including both establishment of the regulatory authority/body and establishment of procedures and mechanisms for regulation (registration, certification, licensing, control and analytical service, inspection). As part of implementation of the state drug policies, the legislation, regulating relations in the field of drugs and medical devices circulation was revised. In order to reduce public/people’s expenditures on drugs, measures were introduced to provide benefits-based drug supply, promote good practice of prescribing and rational use of drugs: drug supply under the State Benefits Program (SBP) to provide the citizens of the Kyrgyz Republic with health care; Additional program of Mandatory Health Insurance (MHI) to provide people with drugs on an outpatient basis (hereinafter – MHI ADP); selection of drugs for inclusion into the Essential Drugs List (hereinafter - EDL); development of the Formulary of basic drugs; development of Clinical Guidelines and Clinical Protocols (hereinafter - CG/CP). Within the framework of benefits based drug programs- the practice of prescribing and dispensing/sale of drugs under generic names has been implemented.

The foundations were laid to ensure geographical and physical accessibility of drugs and the network of pharmacies has expanded significantly, including the one in rural areas.

The principles of evidence based medicine and rational use of drugs (RDU) have been integrated into the medical educational curricula. The process of introduction of Information Technologies has started at the level of Department of Drugs Supply & Medical Equipment/Drug Regulatory Authority (hereinafter – DRA), Mandatory Health Insurance Fund (MHIF) of the Kyrgyz Republic and health care organizations (HCOs).
Despite the above achievements, a number of issues still persist in Kyrgyzstan. The most severe of these is the growing financial burden of the population, which is directly related to expenditures for drugs and limiting of their accessibility. Unethical marketing practices of pharmaceutical companies, including active promotion and advertisement of drugs in mass media leads to further drug prices rise and excessive use of drugs by the population, both at doctor's prescription and as a result of self-medication. The need remains to further improve registration processes related to safety, efficacy and quality of drugs, as well as promotion of RDU principles in healthcare practice. Weak institutional capacity of governance in the area of drug circulation along with continuing inspections of the regulator cause the lack of coordination and transparency in this area, weak inter-agency cooperation and presence of legal conflicts in the legislation.

The Program and Plan of Actions for its implementation will contribute to implementation of the objectives of the National Health Sector Reform Program "Den Sooluk", approved by the KR Government’s (GoKR) Resolution № 309 dated May 24, 2012, in terms of improving health outcomes in priority areas and quality of the key individual services delivery.

Chapter 1. Purpose and Objectives of the Program

The goal of the Program is to ensure accessibility of essential, safe, effective and quality drugs for the citizens of the Kyrgyz Republic and their rational use.

The Program Objectives are as follows:

1) to ensure affordability of basic drugs and medical devices;
2) to ensure presence on the market of safe, effective and quality generic drugs of equal original clinical efficacy;
3) to increase the responsibility and role of the Ministry of Health of the Kyrgyz Republic (hereinafter – MOH) in drug policy coordination and optimization of the management structure of drugs circulation;
4) to recognize drugs as a special kind of products with an impact on health, the quality and efficacy of which can’t always be objectively evaluated by either the doctor, prescribing drugs, or by the patient;
5) to ensure efficiency and transparency of drugs and medical devices procurements in all health care organizations;
6) to develop efficient pricing policy;
7) to develop countermeasures against unethical marketing of drugs and medical devices;
8) to ensure accessibility of the drugs, included into the EDL for the population;
9) the phased implementation of good practices rules in the area of drugs circulation;
10) to ensure effective and timely postmarketing control of safety, efficacy and quality of drugs;
11) to ensure coordination of the activities of the concerned state structures in the fight against illegal market of drugs and medical devices;
12) to ensure transparency in the area of circulation and regulation of drugs and medical devices through building of single information system;
13) to strengthen cadre capacity in the area of drugs circulation.

Implementation of the Program shall be based on the following principles:

1) continuity of the policy of health care reforms;
2) focus on ensuring equity in access to essential drugs, especially for vulnerable populations;
3) further support of the generic drugs use policy;
4) focus of the drugs circulation sphere on ethic norms compliance;
5) transparency at all stages of drugs circulation;
6) wide engagement of all stakeholders in the process of formation, implementation, evaluation of policy and feedback in the sphere of drugs circulation.

Chapter 2. Ensuring Affordability of Drugs and Medical Devices

§ 1. Approaches towards improvement of drugs affordability

One of the important expected results of this Program is improvement of drugs affordability through improving the current procurement procedures and practices to implement internal economy reserves and rationalize the expenditures, affecting the demand for drugs, as well as through introduction of new approaches of state influence on their prices.

It is proposed to regulate the demand for drugs by:
- Implementation of efficient strategy for selecting essential drugs and improving the demand for cheaper generic drugs, while ensuring equal clinical efficacy;
- Rationalization of drugs consumption practice;
- Improving the Drug Benefit Program;
- Optimization of the public drugs procurements system.

The system of state influence on prices will be determined by the presence of a balanced state pricing policy in respect of pharmaceutical products to ensure affordable prices for the population to drugs, especially the ones from the EDL.

§ 2. Drugs Selection System

To reduce expenses for the ineffective types of pharmaceutical care and focus efforts on ensuring equal access for the citizens to the most effective, evidence-based and safe drugs against the available resources, the Government of the Kyrgyz Republic periodically approves the Essential Drugs List, taking into account the WHO recommendations.
Since the state policy involves provision of citizens with drugs primarily from the Essential Drugs List (hereinafter - EDL), based on which all the implemented drug supply programs are formed, as well as all public procurements are carried out, it is important to secure high quality of drugs, included into the EDL. Inclusion of drugs into the EDL should be the result of selection, the main criteria of which should be safety, proven clinical efficacy and cost-effectiveness. At that, the epidemiological situation in the country and priorities in the field of drugs circulation should be taken into account.

Hospitals form their Drugs Lists for procurements independently, on the basis of the EDL. To improve accessibility of drugs, taking into account the local and specific needs, hospitals are allowed to include up to 20% of drugs, which are not in the EDL, into their procurement drug lists. At the same time, the amount of funds to be allocated for procurement of additional drugs is not clearly defined at the moment. It can also lead to unnecessary and irrational waste of resources.

This Program implies development of drug selection procedures with formation of the EDL based on the following principles:

1) social fairness, equal access to basic medication care. The EDL should primarily include the drugs to be used for treatment of socially important diseases with the greatest burden on the state, society and individual;
2) selection of drugs should be based on proven clinical value and safety, taking into account cost-effectiveness criteria. Scientifically justified, safe and effective drugs, confirmed by scientific evidence and medical practice should be included into the EDL;
3) transparency and involvement of general public into the process of drugs selection.

Evaluation and justification of drugs selection conclusions should be open and widely available for public review, discussion, criticism and administrative appeals procedure. The procedures for drugs selection should be improved through development of appropriate regulatory-legal documents. When developing restrictive lists or formularies it is necessary to minimize the possibilities of abuse, and improve responsibility for making decisions. To eliminate distortions in the evaluations and conclusions, the organizations and professionals conducting the evaluation, selection and procurements of essential drugs, should make decisions without involvement of the people with potential conflict of interests, for example, professionals, linked with manufacturers and distributors of drugs;

4) drug programs, envisaging partial reimbursement of the cost of drugs, should be based on the EDL;
5) procurements of drugs against the state budget should be carried out on the basis of the EDL. Hospitals should be allowed to procure up to 20% of drugs off the EDL, however, all drugs should have evidence of clinical efficacy, safety, cost-effectiveness and documented justification for the need for additional inclusion of these drugs into the hospital drugs lists according to the local or specific characteristics of health care organization. With that, amounts of funds to
be allocated for procurement of drugs off the EDL, should be compulsorily regulated.

Procedures/order for basic drugs selection will be developed, which will cover the integral system of drugs selection for all health care system levels in the KR; define the inclusion / exclusion criteria and procedures for the EDL compiling and updating, based on the country’s health care system priorities, data of pharmacovigilance, post-marketing control and WHO recommendations. The position/place and role of all participants of selection should be defined, taking into account the potential conflict of interests. The process of forming hospital drugs lists, lists of drugs to be provided under the drug benefit programs, and other lists will also be regulated.

It is necessary to train of specialists to be involved in selection of drugs (members of the National Drug Committee, Committees on Quality and Safety of health care in health care organizations) in the principles and methods of selection of basic drugs and critical evaluation of medical information, search for evidence and drugs cost-effectiveness calculation.

§ 3. Public procurements

Health Care Organizations (HCO) in the Kyrgyz Republic are the largest purchasers in the pharmaceutical sector, procuring drugs and medical devices in health care organizations and reimbursing the costs of drugs within the framework of State Benefits Program to provide citizens of the Kyrgyz Republic with health care and HIF AD Program. According to the estimates, the share of public procurements of drugs and medical devices makes about 30% of total sales in the pharmaceutical industry. Seeking ways to improve the affordability of basic drugs to the public, the state may put influence on the prices for drugs in exchange for guaranteed sales, i.e. offering mutually beneficial conditions for all market participants. Another most effective way to reduce the prices for drugs and medical devices is to ensure transparency in the procurement process, including data on prices and volumes/amounts of procured drugs and medical devices. Introduction of principles of transparency, accountability and integrity into public procurements will reduce health care expenditures and improve the affordability of basic drugs. Given these conditions, the selection of interventions to implement the capacity of the largest purchaser in the sector should be based on fair and responsible approach, without damage and prejudice to bona fide market participants.

Implementation of the State Benefits Program on supply of the KR citizens with health care, HIF AD program implies regulation of the demand through cost recovery/reimbursement mechanisms. Introduction of the drug benefit supply for the citizens on ambulatory basis under mandatory health insurance system has become the key element in addressing the problems of low accessibility of citizens to treatment with effective modern drugs. The main tool in the drug supply system is reimbursement of the significant part of the drug cost by the state.

The country has gained experience in implementing drug benefit program - the HIF AD Program and drug supply under the State Benefits Program on provision of the KR citizens with health care, where the MHIF is the primary payer. The drugs to be sold under the drug supply benefit programs are selected from the drugs, not included into the
EDL, and this selection is guided by the KR MOH strategy on determining the priority, including the monitored diseases in the country, use of clinical protocols for patients’ management and price factor. However, so far, the methodology and criteria for selection of drugs have not been developed for their proper circulation under the current drug benefit programs.

Contractual process between the insurer and providers of pharmaceutical services does not cover the issues of drug pricing. Lack of transparent information system for monitoring of prices does not enable physicians and patients to be oriented in the prices of drugs. Along with this, drug benefit programs, if properly regulated, have a great impact on controlling/holding public spending on drugs and on improving affordability of drugs for the population, especially for socially disadvantaged groups. General population has low awareness about or does not always have access to the drug benefit programs. Commitment of local governments in development of pharmacies chain and implementation of drug benefit programs is not sufficiently high. The existing targeted social assistance programs in Bishkek City to supply socially vulnerable and chronic patients with drugs require coordination with state drug benefit programs in the terms of approaches and mechanisms for implementation.

To strengthen the role of state drug benefit program for citizens on ambulatory basis, as one of the factors deterring public spending, the principles and mechanisms of drug benefit programs will be revised, including the criteria for defining the target exempt population groups. Contractual relationships with pharmaceutical services providers will be improved with a clear definition of the rights and responsibilities of both parties, development of financial incentives for pharmacies to control prices for drugs.

Drug benefit programs should be developed under the condition of transparency and accountability, wide informing on drugs pricing of patients and physicians through the media, including radio and television, informational educational campaigns.

*Procurement of drugs and medical devices for public health sector.* There are such problems in the field of public procurement of health care system as inadequate legal and regulatory framework, governing the procurement process; low quality of planning of the nomenclature and amounts of procured goods, works and services; frequent inadequate competency of tender commissions members; low level of awareness in providers/vendors about the ongoing public procurements and lack of an automated system of monitoring and analysis of the use of budgetary funds, allocated for public procurements. Health care organizations should be able to select the most effective drugs based on clinical experience, information on side effects and cost of treatment course, which requires use of specific approaches.

Drugs and medical devices have a limited shelf life, specific requirements for transportation/delivery and storage, which implies the necessity of creating an integrated management system of stocks and supply of drugs and medical devices to ensure uninterrupted supply without accumulation of surplus stocks.

Health care organizations in the Kyrgyz Republic do not have a clearly developed system of control and monitoring of drugs procurements. Lack of publicity in the conduct of procurement procedures is a serious threat to the drugs and medical devices supply system, as the risk of purchasing of low quality drugs and medical devices at excessive
prices increases due to the influence of various interest groups on the procurement processes.

To arrange an efficient procurement of drugs and medical devices, it is necessary to expand the current procurement methods to account the specifics and needs of various health care organizations:

1) independent procurements of health care organizations, covering the bulk of their needs in drugs and medical devices;
2) centralized procurements at the national level following the List, to be defined by the Ministry of Health;
3) joint procurements of health care organizations, merged by the principle of close location or level of health care organizations;
4) procurements through UN agencies and other international organizations, which specialize in procurement of specific goods (vaccines, drugs to treat tuberculosis, HIV/AIDS, Malaria);
5) procurements through the framework agreement procedures, to be applied by the KR MOH jointly with the MHOF for the limited agreed set of drugs and medical devices.

Within the framework of this Program implementation, measures will be taken to improve public procurements system; a package of regulatory-legal documents will be developed to govern public procurements, taking into account the specific characteristics of pharmaceutical products and procurement arrangements of health care organizations based on the principles of transparency and accountability. Management of all these stages of the public procurement cycle should be automated and harmonized with the system of electronic public procurements. Introduction of monitoring of drugs and medical devices procurements is an important mechanism of influence on the procurement practices and improvement of the efficiency of spending of the allocated public funds. It is necessary to pay special attention to building of cadre capacity on management of procurements at all levels, including the issues of development and evaluation of technical specifications.

Measures will be taken to ensure strict compliance with all procurement procedures. An important condition for rationalization of public spending, reduction of corruption risks and ensuring openness and transparency of public procurements is strengthening of public control. To this effect it is necessary to ensure engagement of representatives of civil society and non-commercial organizations in the procurement procedures and their access to the detailed information on the held tender procurements through the websites of the MHIF, Ministry of Health, Ministry of Finance of the Kyrgyz Republic, which will enable to trace down the amounts of procurements and prices of drugs.

§ 4. Regulation of Drug Prices

The activity of the Government of the Kyrgyz Republic is focused on formation of a market economy and competitive environment, so the pharmaceutical market independently sets prices, based on the demand and population’s purchasing power. The KR’s pharmaceutical market is characterized by a limited capacity, which makes the market unstable to sharp price fluctuations due to interrupted supplies, leading to
shortages or overstocking of drugs and medical devices. Low level of development of information technologies and the lack of continuous monitoring of prices for drugs in pharmacies does not allow aggregating and analyzing the prices at the pharmaceutical market.

According to the Integrated Household Survey, conducted by the Health Policy Analysis Center (hereinafter - HPAC) in 2009, during the last 10 years, the population’s "out of pocket" expenses for health care have increased by 3.5 times from 1.5 billion soms in 2000 up to 5.6 billion soms in 2009; expenses for drugs make 60% in the structure of these expenses for health care. Monitoring of implementation and efficiency of the KR State Drug Policy for 2007-2010 (according to HPAC data) has indicated that in the expenses structure of citizens over 50 years of age, expenses for drugs comprise about one third of their income, which largely degrades socio-economic and psychological situation of population groups with low incomes.

Thus, there is a necessity in the country to introduce mechanisms of state influence on pricing processes through a) reduction of the supply chain and improvement of services quality; b) mechanisms of setting prices for drugs and medical devices from the EDL.

**Strengthening of requirements towards wholesale suppliers/providers of drugs and medical devices to reduce the supply chain.** The domestic/local pharmaceutical market is characterized by a limited capacity, yet about 300 pharmaceutical providers and suppliers operate at the market. Abundance of wholesale of drugs providers and suppliers leads to the fact that the total volume of trade margins (wholesale or retail), from the moment of entry into the country to the moment of sale to the main consumer, varies widely compared to the purchased price.

It is necessary to improve the regulations, licensing requirements aimed at improving the quality of operation of wholesale companies. Good faith working wholesalers should remain on the market, observing good rules and maintaining high professional standards to ensure safety, quality and high level of competence of the pharmaceutical sector workers, but with that, monopolization of the market should not be allowed. All stages of drugs delivery to the consumer require adherence to strict professional standards. At the same time, requirements towards the rules of wholesale trade should be strengthened, and monitoring of operation of wholesale pharmaceutical suppliers should be developed.

The selection of pricing policy should be based on continuous monitoring of prices for drugs and medical devices. Directions or areas of pricing policy should be based on internationally recognized best and most efficient practices of regulation of prices for drugs and should be pursued by (a) state control over taxes, duties and other markups on drugs and (b) establishment of mechanisms for regulation of prices.

The practice of value added tax (hereinafter - VAT) exemption for drugs, medical devices, medical equipment, consumables, reagents, active pharmaceutical substances and ingredients by the lists, determined by the Government of the Kyrgyz Republic, improves affordability of drugs and medical devices for the population and competitiveness of local pharmaceutical manufacturers. Criteria and procedures to streamline the process of forming the above-mentioned lists will be developed.

Price regulation in pharmaceutical industry should be implemented by:
- Regulation of trade margin (wholesale and retail) of drugs, taking into account geographical criteria;
- Development and implementation of the mechanisms of internal reference prices for drugs, included into the EDL. Reference pricing is part of a comprehensive state system of reimbursement of the citizens’ expenses for purchased drugs. It is inextricably linked with the implemented programs of drug benefit supply programs on ambulatory basis, mechanisms and culture of rational drug consumption, sustainable market infrastructure, adequate funding. The internal reference pricing envisages establishment of the limit state reimbursement rate for drugs;
- Regulation of prices for drugs included in the EDL, through agreements concluded by the Ministry of Health/MHIF or a group of health care organizations, and pharmaceutical suppliers by identifying limited drug prices for a fixed period. The volume of procurements and payment terms for drugs are determined by each health care organization independently, based on its needs and financial capabilities.

Development of information technology and continuous monitoring of prices for drugs and medical devices at all levels is the prerequisite for introduction of the state regulation. As part of the drug benefit programs it is necessary to further improve information systems on drugs and medical devices to be sold in pharmacies and be reimbursed. This includes building of a single information network between the MHIF and pharmacy facilities to ensure transparency and improve the mutual accountability of all structures; formation of a stable system of monitoring of drug prices by specific groups, sold under these programs, as well as ensuring free access to the database of retail drug prices for the public.

§ 5. Rational Use of Drugs

Irrational use of drugs is a topical problem in the Kyrgyz Republic, including the issues of unjustified simultaneous administration of a large number of drugs by doctors, without consideration of their interaction (polypharmacy), and behavioral pattern of the population of self medication, when they take drugs without consulting doctors.

In the framework of this Program, measures are envisaged to address the problem of irrational drugs use, including development and introduction of clinical protocols, along with improvement of education system and continuous training on rational use of drugs; ensuring dispensing/sale of prescription list drugs following prescription; change of people's attitude through media towards irresponsible use of drugs.

**Introduction of clinical guidelines / protocols and improvement of educational system at all levels regarding rational use of drugs.** Currently the methodology for developing evidence-based medicine clinical guidelines is approved; and the processes for review and approval of CG/CP are improved. However, the activity on development of CG/CP is still limited, mechanisms for their introduction are not developed yet, namely: the procedures and instructions for development of CG/CP are not approved; the capacity of expert bodies/authorities is not adequate; timely publication, dissemination
and training in CG/CP are not developed; appropriate monitoring of introduction of CG/CP is lacking and is not financially secured. Strict methodology should be followed at each stage of development and introduction of CG/CP. When introducing CG/CP into clinical practice, the most effective research-based introduction methods should be used, taking into account the needs of the target audience and local conditions.

There is a need to create a sustainable system of development, introduction and monitoring of CG/CP and their further promotion in health care and education system of the Kyrgyz Republic. Educational standards in the field of professional training and postgraduate training of medical and pharmaceutical experts will include the issues of rational use of drugs and pharmacological-economic analysis, further strengthening of the concept of generics use and ethical promotion of drugs. Operation of the Committees on Quality and Safety of Care in health care organizations will be activated in the areas of rational use of drugs (hereinafter – RDU), pharmacovigilance, interchangeability of drugs and a critical evaluation of information coming from pharmaceutical companies.

**Prescription dispensing/sale of drugs.** Introduction of prescription dispensing or sale of drugs aims to limit the uncontrolled use of drugs by population, especially antimicrobial drugs. Currently, despite the availability of appropriate regulatory legal documents, compulsory required prescription of drugs virtually does not exist, and one can freely purchase almost any drug without doctor’s prescription in pharmacy facilities. Failure to follow the established rules of drug prescribed dispensing in respect of certain drugs, especially the antimicrobial ones, implies a potential threat to the health of every citizen and society in general.

This Program provides for restoration of prescription dispensing/sale of drugs, with changing the approaches through development of a limited list of prescription drugs. Implementation of this list should be accompanied by the strengthened measures of administrative influence, necessary trainings of specialists and education of population.

Introduction of compulsory limited list of prescription drugs can increase the pressure on the drug benefit programs, that’s why it would be necessary to evaluate this intervention and conduct appropriate activities, such as exclusion of antibiotics from the list of drugs under the Mandatory Health Insurance Additional benefits package, except for children under 5 years of age.

**Building commitment of rational drug use to fight against unethical marketing of drugs in health care workers and population of the Kyrgyz Republic.** Improper and unethical promotion of drugs by pharmaceutical companies leads to excessive use of drugs.

As in many countries, excessive administration of expensive drugs is observed in the Kyrgyz Republic, caused by unethical marketing. The most expensive drugs are promoted at the market, the cost of which include the costs of drug promotion, making them unnecessarily expensive. The activities of pharmaceutical companies include all marketing tools: dissemination of information materials and organization of presentations, provision of free samples of drugs and accrued bonuses, as well as uncontrolled advertisement of drugs in the media.

RDU is the primary mechanism to counter the unethical marketing. Therefore, under this Program measures will be taken on further RDU introduction, building of a single information-directory system on reliable methods of treatment and characteristics of drugs for medical and pharmaceutical workers, strengthening of the requirements for
certification of medical and pharmaceutical workers by incorporating RDU issues into the questionnaires, development of RDU indicators for evaluation of HCO performance.

One of the effective tools for counteracting unethical marketing is provision of objective systematized information on drugs in the format of National Formulary of basic drugs. It is necessary to determine the status of the national formulary, to institutionalize the process of its development and implementation into practice, with identification of the sources of funding. Implementation of programs to counter unethical marketing by providing independent, reliable information on drugs for health professionals and population require cooperation with local administrations and local authorities, development of measures to strengthen the responsibility of advertisers, advertisement agents and advertisement-distributors for posting information on drugs without proper permits.

Chapter 3. The System of Drugs Circulation

§ 1. Improving Quality, Safety and Efficacy of Drugs and Medical Devices

Under the Law of the Kyrgyz Republic "On Drugs" the state system for ensuring quality, safety and efficacy of drugs and medical devices has been built, including the following stages:
- State registration;
- Evaluation and validation of compliance of drugs and medical devices;
- Licensing of production, manufacture and sale of drugs and medical devices;
- Pharmaceutical inspection (surveillance);
- Pharmacovigilance.

During the past period, measures were taken for comprehensive improvement of the system of state control of quality of drugs and medical devices and strengthening of its institutionalization. Technical Regulations have been introduced on Safety of Drugs and Medical Devices. A new laboratory complex has been launched into operation, expanding the scope of accreditation of the DRA Certification body.

Registration system requires further improvement to create conditions for presence of essential drugs and medical devices at the market; the system of post-marketing control of drugs and medical devices market also requires strengthening of pharmacovigilance.

Improving the system of registration of drugs aimed at ensuring equal therapeutic efficacy of generics. The original drugs make up less than 3% of the pharmaceutical market in the Kyrgyz Republic. The market is mostly represented by generics.

The market authorized generics have similar quality and efficacy from the legal point of view. However, according to the study on the factors, influencing the use of generics (HPAC, 2009), there is evidence of nonequivalence of therapeutic efficacy of generics and distrust of doctors and patients towards cheaper generics.

Lack of information about therapeutic equivalence of the registered generics in the Kyrgyz Republic in the public domain also hinders proper therapeutic choice for doctors.
The procedure for registration of generics in the Kyrgyz Republic is simplified compared to the one for the original drugs. The Law of the Kyrgyz Republic "On Drugs" stipulates the additional regimen of simplified registration for generic drugs. In addition, there is the possibility of importing drugs waiving registration in accordance with the List, approved by the KR Ministry of Health, and in cases of threat of epidemics and emergencies. There are no clearly defined criteria for applying the above regimen of market authorization for drugs and medical devices.

In general, the process of registration of drugs and medical devices will be improved in compliance with the internationally recognized standards. It is necessary to legislate clear procedure and criteria for market authorization of drugs and medical devices, including registration of analogues of biological preparations (biosimilars).

The current simplified procedure for state registration of generics should be applied only to the drugs, registered in the countries - members of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human (ICH), or in the countries, that are part of the International System of the Pharmaceutical Inspection Cooperation (PIC/S). The Government of the Kyrgyz Republic will determine the procedure and periodicity of compilation of this list of countries. It will be rational to include those countries into this list, with which the Kyrgyz Republic has interstate agreements, particularly in the field of drug supply. Also it will be necessary to develop and approve the procedures, which will enable to verify the origin of the drug (supporting documents from the regulatory authority, inspection of the production, etc.). As the capacity of national GMP inspectors is built to be included into the International Register of GMP/ GDP Inspectors, the simplified registration might be also extended to the drugs, approved by them.

To improve confidence in the registration system, it is necessary to ensure the provision of publicly available relevant information on the registered products, with the exception of the confidential part of the registration dossier. To ensure the rights of patients and physicians to obtain reliable information about drugs, the criteria for classifying information as confidential should be revised.

Decision-making process for registration of drugs and medical devices should be transparent, with obligatory publication of publicly available summary report on the registration / refusal of registration of drugs and medical devices.

To improve the efficiency of the registration process, the competence of experts should be continuously improved, including the skills in interpreting bioequivalence studies, as well as increasing personal responsibility of experts for decision-making.

Implementation of the Rules of Good Practices (pharmacy, industrial, laboratory, clinical, distribution) (hereinafter - GPR), set by the Technical Regulations "On Safety of Drugs for Medical Use," approved by the KR Government’s Resolution #137 as of April 6, 2011, will lead to a significant improvement of the system of drugs and medical devices circulation at all stages, quality assurance of drugs and medical devices in the country, resumption of prescription drugs dispensing. The processes of development, implementation and observance of good practice rules will require mandatory participation of professional pharmaceutical associations.

Currently, GPR are developed in the pharmaceutical sector based on international guidelines, and their widespread introduction is pending.
The subjects of pharmaceutical activities (pharmacies, pharmaceutical units/points, pharmacy kiosks, wholesale pharmacy warehouses, optical and medical equipment shops, manufacturing enterprises) should organize their activities in compliance with the approved Rules of Good Pharmacy Practice.

Introduction of GPR should be phased, with allocating sufficient time required by the subjects of pharmaceutical activities to upgrade skills and competence of the staff and quality management system and upgrading the material-technical base in line with the new adopted rules. Transition of the pharmaceutical activities subjects towards the GPR should be completed no later than 2020; for the subjects of pharmaceutical activities, which introduced the requirements of the adopted GPR within the first 7 years after the publication of the said Rules, preferences will be given during their participation in public tenders for procurement of drugs and medical devices and drug benefits programs.

The provisions of the Law "On Licensing System in the Kyrgyz Republic" should be harmonized in the part related to production, manufacture and marketing of drugs and medical devices, in line with the GPR in the field of drugs circulation. In addition, the GPR should be aligned with the international good practice guidelines and should be continuously improved to reflect changes in the international guidelines.

System should be built to assess pharmaceutical operation subjects’ compliance with GPR requirements, with issuance of appropriate authorization document. For this it is necessary to establish continuous training of the regulatory authority professionals in the skills of GPR requirements compliance assessment.

Due to the fact that drugs can cause irreparable damage to people’s health when used incorrectly, and that drugs might lose medicinal properties under improper transportation and storage, the extensive network of wholesale and retail pharmaceutical organizations of the republic should be constantly monitored.

Furthermore, according to research of drugs quality in the sector of public procurements in the Kyrgyz Republic (WHO, 2008), there is an illegal drug market in the country, as evidenced by a wider range of drugs in pharmacies compared to the officially registered imported drugs. The existing legal and regulatory framework stipulates the requirement to notify the entities on the forthcoming audit ten days prior to the inspection. As a result, the Pharmaceutical Inspection can’t fully perform its functions, in particular, there is no element of sudden-“unprepared for the entity” inspections. The activity of the Pharmaceutical Inspection should ensure lack of unregistered, uncertified, expired, substandard and counterfeit drugs and medical devices at the market. Frequency of inspections should be based on risk management principles in the field of drugs and medical devices circulation and regulated by the legislation on state control and surveillance.

Market control system will be aligned with the standards of good regulatory practices, with organization of a comprehensive system of surveillance over the market. With that public access to information on the results of pharmaceutical inspections should be provided.

Continuous professional training of Pharmaceutical Inspection specialists will be introduced. Also mechanisms will be introduced to provide increased responsibility and transparency of pharmaceutical inspectors’ operation.

To reduce the amount of substandard and counterfeit products on the market of drugs and medical devices, feedback will be developed and implemented in the form of
spontaneous reports/messages from pharmaceutical and medical organizations and public regarding the quality of drugs and medical devices, this feedback system will be harmonized with the tools of pharmacovigilance system.

The state system for detection, collection, analysis and evaluation of scientific information on adverse reactions to drugs, registered in the Kyrgyz Republic, during their medical use for appropriate regulatory decision making regarding potential advantages and risks of their use - pharmacovigilance, aims to ensure safe use of drugs and medical devices.

Pharmacovigilance is carried out through the system of spontaneous reports on the detected adverse events using "yellow cards". There are few spontaneous reports on drugs quality coming, which indicates low commitment of doctors and pharmacists, as well as low efficiency of communications on pharmacovigilance issues. This is evidenced by the decrease of the number of spontaneous reports forwarded by doctors – from 57 reports in 2007 to 17 reports in 2012 (DRA website, 2013).

Early detection of risks, associated with the use of drugs in normal consumption, requires the system of pharmacovigilance to be improved. The mechanisms of transfer of the information on drug side effects from health care organizations to the RDA and feedback on each report will be revised. The mechanisms of transfer of reports should envisage both reports in electronic and paper formats, with introduction of computerized database on cases of side effects. Particular attention will be paid to improving the capacity of health care organizations in the area of drugs safety.

§ 2. Improvement of the System of Drugs and Medical Devices Supply

Accessibility of narcotic and psychotropic drugs in the country is currently limited for various reasons:

    Imperfect regulatory standards and their misinterpretation, excessive control by the competent authorities, shortage of knowledge among health workers on palliative care delivery and use of narcotic drugs, which significantly limits prescriptions of narcotic drugs for patients in need of palliative care.

    Another reason is low accessibility of narcotic and psychotropic drugs in pharmacies, where patients with prescriptions can’t buy these drugs. This problem is particularly acute in remote regions of the country.

    Since this sphere is regulated by number of agencies, the problem of improving access to narcotic and psychotropic drugs should be addressed comprehensively and jointly with all stakeholders in the interests of patients in need. To reduce the unnecessary suffering of patients who need narcotic drugs for pain relief, it is necessary to adopt a Strategy, aimed at removing regulatory legal and administrative barriers to delivery of palliative care.

    Program will be developed to improve the provision of narcotic and psychotropic drugs for patients in need for short and medium terms, and measures will be taken to train the stakeholders involved.

    Supply of essential drugs with limited physical accessibility. State policy in the sphere of drugs circulation should be aimed at ensuring the presence of essential drugs on
the market of the country. However, some essential drugs are not presented in the Kyrgyz Republic for a number of reasons:

1) limited demand for drugs, used for treatment of rare diseases (orphan drugs);
2) limited purchasing power of the majority of the population due to high cost of drugs, needed for treatment of serious diseases;
3) lack of demand for some affordable and effective essential drugs due to the changes in drug prescribing practices by physicians for various reasons, including the pressure of pharmaceutical companies. About 10 of this type of drugs are not included into the current EDL due to the lack of registration in the country and, accordingly, the physical absence on the market.

With regard to costly essential drugs (including orphan drugs), the state sets the objective to expand access to these drugs through development of comprehensive strategies and technologies, which are aligned with the available resources, which include measures to optimize the prices for new patented drugs, generics and improvement of the practice of their procurement. Work will be done to identify the List of "rare" diseases and orphan drugs and appropriate modifications will be entered into the Laws of the Kyrgyz Republic "On Protection of Public Health in the Kyrgyz Republic" and "On Drugs" to ensure access to essential drugs and to limit speculation of the concept of "rare" diseases. To reduce the cost of expensive drugs, the mechanisms will be developed to ensure availability of information on prices and suppliers, proper planning and forecasting of needs, supply management. To reduce prices of generic drugs, the state will use negotiations and will promote competition between drugs manufacturers and producers. Reduction of prices for the patented drugs will require review of international experience of negotiating with their manufacturers to get the lowest procurement prices, as well as use of compulsory/forced registration based on the rules, described in the TRIPS Agreement, ratified by the Law of the Kyrgyz Republic "On Ratification of the Protocol on the Accession of the Kyrgyz Republic to the Marrakesh Agreement establishing the World Trade Organization" № 146 dated November 17, 1998.

Since many essential drugs are not registered in the country, the Ministry of Health should develop the procedure for compilation of the list for all of the above drugs importable without registration for a specified period of time. To this effect criteria for compilation of the list will be developed, which should ensure high safety, efficacy and quality of these drugs.

The system of monitoring of the above drugs accessibility will be built, including incorporation of the drugs in CG/CP, registers of patients in need, prices both inside the country and outside, forecasts of volumes of consumption, regulatory status of drugs.

Disposal of unfit drugs. The drug supply system faces the problem of disposal of drugs, which have become unusable at various stages of drug supply chain. Accordingly, the measures should be developed to prevent use of such drugs (timely recall from the market, collection, storage and disposal).

The procedure of disposal of unusable drugs, set in the Technical Regulations "On Safety of Drugs for Medical Use", approved by Decree of the Government of the Kyrgyz Republic No137 as of April 6, 2011, is applicable only in cases of unfit drugs in wholesale supply chain or due to the fault of wholesale suppliers/manufacturers.
There are a number of circumstances with uncertainty about the procedure of disposing of unfit drugs that increases the risk of their accidental use: retail pharmacies periodically accumulate expired drugs in small quantities, for which application of the established disposal procedure is costly. Health care organizations do not have procedures for collection, storage and delivery of unfit drugs to the disposal points. Disposal of unfit drugs implies extra costs.

To facilitate the processes of drugs disposal due to the necessity of getting a large number of permits and other bureaucratic barriers, centralized procedures will be developed for disposal of unfit drugs, taking into account the volumes and location of unsuitable drugs accumulation (wholesale warehouses, retail, hospitals, places of unauthorized trade of drugs).

§ 3. Measures to Eliminate Illicit Sale of Drugs and Increase Penalties for Violations of Rules and Regulations

Illicit sale of medicines is a serious threat to life and health of the population. At the same time, in contrast to consumer goods, ignorance of the rules of storage and sale of drugs can lead to serious consequences for consumer’s health. Along with this problem, there are cases of forgery or sale of expired drugs even in the area of legal drugs circulation. All this happen due to high income compared to small penalties for the offense, i.e. penalties for such offenses do not match the severity of the damage caused, and the benefits from this activity are quite significant.

Suppression of illicit trade, fight against counterfeiting and sale of counterfeit drugs and expired drugs, and accordingly, reduction of risk of poisoning or other undesirable consequences are possible if the punishment/penalty for such offenses is heavy enough to overweight possible benefit from the illicit sale of drugs. To this effect measures/penalties of administrative and criminal liability will be strengthened for illicit sale of drugs. It is also necessary to expand the powers/authorities, functions and rights/powers of local state administrations and local governments to fight against illegal sale of drugs and medical devices, define the responsibilities of business entities for providing locations for illicit sale of drugs and medical devices.

Penalties will also be strengthened for counterfeiting and selling of expired drugs.

While strengthening liability for illegal sale of drugs, it will be necessary to consider the activities to reduce the demand for "black market" products in the public, including smuggled, counterfeited and expired drugs. To reduce the demand for "black market" products the population should be regularly informed about the dangers of purchasing drugs from illicit sellers and expired drugs. The population should also be informed and educated on how to determine if a pharmacy or a pharmacy point is legally operating, on how to get the information of the registered drugs and their shelf-life.
Chapter 4. Improving Management of Drugs Circulation Area

§ 1. Removing Contradictions and Loopholes in the Legislation

Efficient management of drugs circulation area presupposes the capacity and mechanisms for formation of state policy, relevant legal framework, availability of effective mechanisms for regulation of the processes and tools of control over the activities of the subjects in the area of drugs circulation and ensuring transparency and accountability.

The Laws of the Kyrgyz Republic "On the Procedure of Conducting Inspections of Business Entities" and "On the State Support of Small Businesses," regulating business activities, as well as administrative liability of the subjects in the area of drugs circulation should be harmonized with revision of the regulatory legal documents on drugs circulation in the Kyrgyz Republic.

With the purpose of developing entrepreneurship in the Kyrgyz Republic, the requirements and terms for stating business have been simplified during the last few years, part of the mandatory state standards were transformed into voluntary ones, the number of the required licenses got significantly reduced, and license requirements for the vast majority of types of operations were simplified, in addition, the public authorities were limited in their ability to conduct control-surveillance activities. These measures had a positive impact on development of “the shuttle”, wholesale and retail trade, and public catering and services. Unlawful checks of entrepreneurs got reduced, and hence - the opportunities for corruption were also decreased.

In the areas of business where strict measures to ensure safety of life and health of citizens are required, special rules, procedures and standards are applied. For example, the operation of the Law of the Kyrgyz Republic "On the Fundamentals of Technical Regulation in the Kyrgyz Republic" does not apply to the application of measures to prevent the occurrence and spread of mass infectious diseases, prevention of human diseases, delivery of health care. At the same time, drugs, medical devices and medical equipment that are part of measures to provide health care, are subject to the operation of the Law of the Kyrgyz Republic "On the Fundamentals of Technical Regulation".

The Ministry of Health in collaboration with the concerned state agencies will develop and propose amendments to be entered into the legislation on technical regulation and licensing to introduce the concept of "drug" as a special type of goods and associated medical services as a special kind of services, the handling of which should be carried out according to specific rules.

Amendments and modifications should, first, establish mandatory GPR compliance in the area of drugs circulation, and secondly, stipulate the clause that entrepreneurs, engaged in pharmaceutical activities, should be monitored more closely, compared with those which do business with common commodities. For example, no prior-notice inspections/ checks selective spot checks of drugs batches in pharmacies and warehouses should be applied to them, as well as other control-surveillance activities to detect smuggled, counterfeited, expired and unfit drugs.

Treating drugs and medical devices as common/ordinary goods hinders effective procurements of drugs and medical devices under the dynamic changes of modern
pharmaceutical market due to the fact that procurement legislation is mainly driven by the price, but not the quality, safety and efficacy of drugs and medical devices. Health care organizations should be able to select the most effective drug based on the clinical experience of using this drug and post-marketing control data. Also, it is planned to legislate the concept of specific procurement methods for drugs and medical devices - to get the best price for high-quality pharmaceutical products from the leading manufacturers on the world market.

Since drugs are considered as consumer goods in the Kyrgyz Republic, violations in the area of drugs circulation are also considered according to the general standards. However, in contrast to consumer goods, ignorance of the rules of storage and sale of drugs can lead to serious consequences for the health of the consumer. In this connection, liability for violation of drugs handling rules will be strengthened.

The definition of the “drug” in the current legislation also requires revision, as it has been repeatedly amended to respond urgent political and regulatory tasks. This resulted in inclusion of unreasonably large number of different types of products into the term "drug", which present separate groups of products (medical devices, dietary supplements, pharmaceutical substances and materials, chemicals, reagents, test kits an systems). This leads to the fact that requirements applicable to drugs are extended to many product groups, which actually are not the drugs. Artificial barriers are created to handle these products on the market. The situation is particularly difficult for domestic or local drug manufacturers, as they have to go through the process of double registration – upon importation of pharmaceutical substance, and then – upon registration of the drug, reproduced from this substance. The KR MOH addresses this issue by incorporating pharmaceutical substances into the List of unregistered drugs authorized for import and use on the territory of the Kyrgyz Republic, but this measure implies a number of bureaucratic barriers. A clear legal definition of drugs, medical devices, introduction of the concept of medical-pharmaceutical product in accordance with internationally accepted norms with subsequent amendments to be entered into the Technical Regulations "On the Safety of Drugs for Medical Use," approved by the Resolution of the KR Government #137 dated April 6, 2011, will solve many problems of the pharmaceutical market. It is necessary to amend the Law of the Kyrgyz Republic "On Drugs", setting the procedure and criteria for compiling the List of drugs authorized for import and use in medical practice on the Kyrgyz Republic territory – regarding drugs that are exempt from state registration (Articles 35 and 36 ).

§ 2. Institutional Strengthening

State management of the drug circulation system should meet the following management principles, providing efficient and uncorrupt governance:
1) clear definition/delineation of the functions from the function of policy development to functions of policy implementation;
2) public control of transparency of decision-making and implementation procedures;
3) strengthening of accountability of the DRA, creation of tools to measure the efficiency of the regulatory authority performance and operation;
4) co-financing of the regulatory authority at the expense of the republican/national budget;
5) creation of the internal quality assurance system of the DRA;
6) availability of the MOH capacity with the appropriate resources provision.

Thus, the Ministry of Health should ensure pursue of single state policy in the field of drugs circulation, monitoring and evaluation of its implementation, and the RDA-regulatory functions, including coordination, surveillance and control within its competence.

Based on the analysis of the regulatory system compliance with international good management practices standards, internal system of quality assurance of the DRA activities will be developed, and all business processes will be regulated. Public Steering Council of the Ministry of Health will strengthen control over transparency of the DRA procedures and its operation efficiency. General public will be provided with timely access to information on the DRA activities.

Currently, the DRA is financed only against the extra-budget funds. As the republican budget revenues become stable, financing of the DRA should be covered from the republican/national budget.

The cost of expert evaluation and tests for registration and certification will be based on the actual production cost of the work and services to generate incentives for development of scientific and intellectual capacity of expert bodies and authorities.

§ 3. Improvement of Human Resources Capacity

One of the prerequisites of sustainable development of the pharmaceutical industry is availability of highly qualified pharmaceutical staff. Under market economy the issue of planning of pharmaceutical personnel training for public health sector becomes topical. Is necessary to develop the methodic for determining the demand for these specialists to allocate budget quotas for higher and secondary educational institutions, as health sector is experiencing an acute shortage of specialists in hospital pharmacies and in remote regions.

Single/unified Register of pharmaceutical workers should be built to monitor qualifications of pharmacists in the system of continuous education, licensing of pharmaceutical activities according to WHO recommendations. Information on the certified professionals and graduates should be available in the public domain.

The program for human resource development in the pharmaceutical sector will be developed, taking into account the priorities of health care. The MOH jointly with the Ministry of Education and Science of the Kyrgyz Republic will audit educational institutions, involved in training of pharmaceutical cadre in the "pharmacy" specialty regarding their compliance with educational standards.

The nomenclature of pharmaceutical positions and the scope of work will be revised, corresponding incentives will be developed to attract specialists in hospital pharmacies, and mechanisms will be developed to retain graduates of the regional educational institutions in rural pharmacies.

Unethical promotion of drugs by pharmaceutical companies leads to excessive use of drugs. According to the "Ethical Criteria of Drugs Promotion", WHO does not recommend to use scientific and educational activities to promote drugs to the market, advertise drugs, prescribed or used in treatment of patients with severe diseases, which can be administered only by a qualified physician. Medical representatives should not offer "incentives" to health workers and pharmacists. At that, the latest, and therefore the most expensive and least studied drugs are promoted to the marketing most actively.

Availability of sanctions for violations in the area of drugs circulation does not guarantee compliance with the legislation under the absence of the system to regulate standards of ethical behavior. Since most of the professionals, working in the field of drugs circulation, are not civil servants, and staff of the pharmaceutical industry – are individuals, the Ethical code of civil servants and civil service legislation do not apply to them.

The Code of Ethics defining the conduct of the participants in this area, will be developed and implemented with wide involvement of associations and unions, health care system and pharmaceutical sector professionals. The Code will contain the following aspects of conduct when dealing with drugs:
1) definition of conflict of interests, its detection and elimination;
2) honesty in reporting, statement of facts, management of resources;
3) making decisions only based on facts;
4) principle of equity in the application of rewards and punishments;
5) transparency and openness in decision-making;
6) protection of persons/informants, providing information about the facts of unethical conduct;
7) implementation of the legislation banning inaccurate, misleading or unethical advertisement of drugs;
8) control of information provided to the medical staff by the representatives of pharmaceutical companies.

The Code of Ethics will include the system of selling/dispensing, including the organizational structures (for example, Councils on Ethics), penalties and publicizing the cases of violation of ethics in the area of drugs circulation.

§ 5. Ensuring Transparency in the Area of Drugs Circulation and Introduction of Monitoring of Pharmaceutical Sector and Prices for Drugs

Transparency of processes in the area of drugs circulation is ensured by automating the processes of collection, processing, transfer of information and providing
access to it. The Information systems of the DRA are used to facilitate implementation of the regulatory activities within the institution and to work with suppliers and vendors in the "Single Window" system. Fragmentation of information systems in the DRA does not enable to improve business processes in the authorized body itself and does not provide health care system with necessary information.

To expand access to information in this area, and to improve transparency and openness, it is proposed to build Single Information System of drug supply, to cover all aspects of circulation of drugs, starting from the date of registration till the date of their sale and disposal. Single information system will be developed that will provide access to information in two modes: for the authorized users and for all users. The mode for the authorized users with appropriate access should enable to track each batch of drugs, delivered into the country or produced in the country, so one can have opportunity to see online the location of this or that batch of drugs at any time.

Temporary (until the registration procedures are completed) online access to information will be provided, so applicants can track down the stage of the processing the submitted documents. During the procedures of registration, licensing or certification, pharmaceutical companies should receive all necessary information about the registration process stages.

Health professionals and pharmacists will be provided with authorized access to all information on drugs necessary for their work, including the information on their efficacy, adverse reactions, etc.

Development of tools for building an automated system is planned to collect and analyze information of the procured drugs in health care organizations.

§ 6. Monitoring and Evaluation System of the Program of Development of the Sphere of Drugs Circulation

Monitoring and evaluation system of the Program implementation considers the peculiarities and structure of this Program and is based on a consistent approach implying that receipt of results at one level will be followed by results at the next level, thereby ultimately implementing the common goal. The format of monitoring of the Program implementation is consistent with the M&E system of implementation of the National Health Sector Reform Program "Den Sooluk" for 2012-2016, approved by the KR Government’s Resolution № 309 dated May 24, 2012. Data will be collected on the indicators and milestones, reflecting the progress at each of these levels, and will be based on two types of sources: (1) indexes, collected regularly and in accordance with the approved statistical forms; and (2) assessment research and studies, which are necessary to assess the impact of the Program on the sphere of drugs circulation. Some studies are already conducted under implementation of the National Health Sector Reform Program "Den Sooluk" for 2012-2016. The topics or themes for other studies will be determined annually based on the Ministry of Health needs assessment.

Implementation of monitoring and evaluation of the Program also implies improving the capacity in the area of monitoring and evaluation. To this effect, regular training sessions are scheduled for the professionals, involved in monitoring and
evaluation of the sphere of drugs circulation, and for decision-makers. Wide access will be provided to the Program M&E results, key areas of activities of the pharmaceutical sector in general and prices of drugs and medical items. This will increase the transparency and efficiency of managerial decisions in the area of drugs circulation in the Kyrgyz Republic.