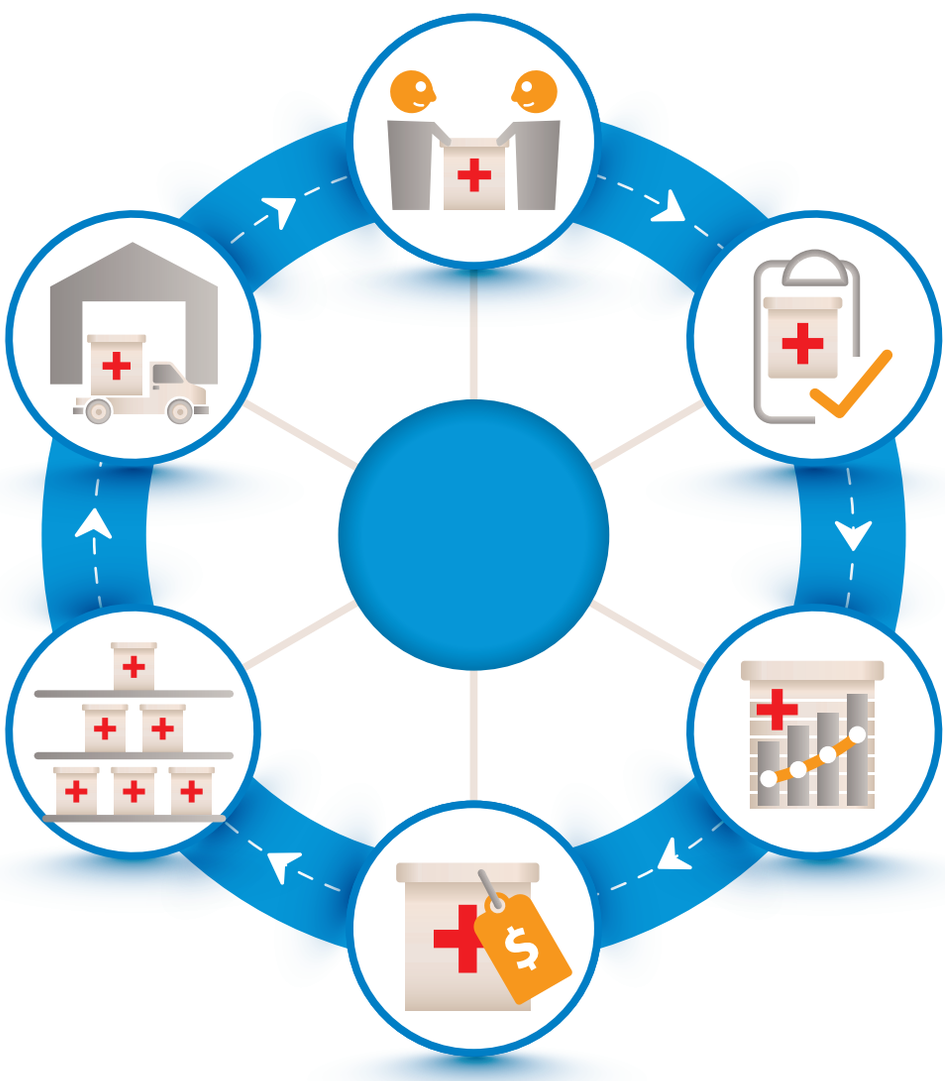
SITUATIONAL ANALYSIS OF PHARMACEUTICAL SUPPLY CHAIN MANAGEMENT INCLUDING CONTRACEPTIVES



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LIST OF ABBREVIATIONS AND ACRONYMS. GLOSSARY OF TERMS

Abbreviations, acronyms, terms	Decoding, definition
HIV	Human immunodeficiency virus
IUD	Intrauterine device
WHO	World health organization
UHC	Universal health coverage
GP	General practitioner
FDG	Family Doctors Group
SE	State enterprise
ADP MHIF	Additional Drug Package of Mandatory Health Insurance
DPSME	Department of pharmaceutical supply and medical equipment
EAEU	Eurasian Economic Union
Single payer	A state body implementing public policy on essential public insurance and mandatory health insurance and authorized to finance essential public and mandatory health insurance programs
EU	European Union
EEC	Eurasian Economic Commission
WRA	Women of reproductive age
MIS	Management information system
LMIS	Logistics management information system
CM	Cabinet of Ministers
COCs	Combined oral contraceptives
KR	Kyrgyz Republic
Cs	Contraceptives
FPAC	Консультативный совет ПС Family Planning Advisory Council
HPU	Heath Promotion Unit
Ms	Medicines
Local Kenesh	Representative body of local self-governance in the Kyrgyz Republic
MoH of KR	Ministry of Health of the Kyrgyz Republic
HC	Health commodities
MSRG	Medical and social risk group
INN	International Nonproprietary Name
MEC	Ministry of Economy an Commerce of the Kyrgyz Republic
NCDs	Noncommunicable diseases
NCO/NGO	Noncommercial organizations/non-governmental organizations
CIP	Costed Implementation Plan
NSC of KR	National Statistical Committee of the Kyrgyz Republic
NCP	National Center for Phthisiology
HCO	Healthcare organization
MHI	Mandatory health insurance
SGBP	State guaranteed benefits package program
EML	Essential Medicines List
Program 2030	Program on the protection of public health and the development of the health care system in the Kyrgyz Republic for 2019-2030 "Healthy Person — Prosperous Country"
Program 2040 (Strategy 2040)	National Development Strategy of the Kyrgyz Republic for 2018-2040
Program 2026	National Development Strategy of the Kyrgyz Republic until 2026
SW	Software
PHCQIP	Primary Health Care Quality Improvement Program for the Kyrgyz Republic
FP	Family Planning
RH	Reproductive health
CIS	Commonwealth of Independent States
TB	Tuberculosis
SCM	Supply chain management
MHIF	Mandatory Health Insurance Fund under the Ministry of Health of the Kyrgyz Republic
RBF	Results-Based Financing project of the World Bank
GMPC	General Medical Practice Center
SC	Supply chain
FMC	Family Medicine Center
SDG	Sustainable Development Goals
EHC	Electronic Health Center under the Ministry of Health of the Kyrgyz Republic
UNFPA	United Nations Population Fund
UNAIDS	The Joint United Nations Programme on HIV/AIDS
UNICEF	United Nations Children's Fund

INTRODUCTION. BACKGROUND

Strong system for supply chain management (SCM) in healthcare is one of the fundamentals for enhancing population health and attaining Sustainable Development Goals (SDG 3.8). Current situation on efforts taken to manage national supply chain of medicines and health commodities including contraceptives has some gaps and obstacles related to regulatory limitations, public procurement rules, storage, transportation and inadequate management or lack of transparency of all SCM cycles. Regulatory documents and tools for all supply chain management cycles in Kyrgyzstan are not institutionalized by the Ministry of Health, and are either introduced into some vertical programs, or are underway towards an organized and structured phase of supply chain management including contraceptives. This process should be jointly carried out with key entities of the MoH of KR and other state agencies in cooperation with development partners to ensure that decisions taken meet the national requirements for improvement of population health including reproductive health.

In general, the country needs a unified national document targeted at unification of all cycles of national supply chain of medicines and medical products mechanism including contraceptives based on public budget, which will serve as basis and accelerator for effective implementation of health programs as contribution to achievement of universal health coverage.

Goal of this research is provision of sound arguments and solutions to design national document on management of unified national supply chain of medicines and health commodities, including contraceptives, which will enable decision-makers and development partners to identify proper investments to supply chain to enhance their capacity. The goal also encompasses performing a national situation analysis of supply chain including forecasting, planning, procurement, storage and distribution of pharmaceuticals and health commodities to create sustainable and robust system for healthcare supply chain management with a focus on coverage of target vulnerable groups and increase allocation of public revenues to family planning.

Objectives of the research are as follows:

- Situation analysis of supply chain management of pharmaceuticals and health commodities including contraceptives to identify gaps in existing national supply chain mechanisms including Logistics Management Information System;
- Situation analysis of reproductive health at country level;
- Review of statutory documents regulating supply chain of medicines and health products including contraceptives;
- Provision of key recommendations with draft Action Plan for development of national document on management of unified national supply chain of medicines including contraceptives.

Research period is identified as 2021–2023 since this period is characterized by accelerated and transformative actions attributable to series of events:

- Healthcare development strategy of

Program 2030[1] requires conducting a mid-term review for interim assessment of strategy effectiveness with a particular focus on impact of actions on its goals and targeted corrective actions due to change in socio-economic context;

- Regulatory inventory for healthcare legislation including reproductive health system;
- In 2020, Government Program on development of the sphere of circulation of medicines in the Kyrgyz Republic for 2014-2020 was completed, and it was required to take new measures in public pharmaceutical policy which were not taken on time due to objectively reasonable causes;
- These and other impactful economic and political factors since 2021 (response to consequences of COVID-19, adopting new decisions of EAEU on pharmaceutical supply, changes on legislation of the KR on procurement and healthcare, emergence of new key actors in medicine provision ("Kyrgyzfarmatsiya" SE), strengthening of "Eastern Vector" in supply of medicines and health commodities, the ongoing situation with decline in contraceptive procurement from public budget) have contributed to this research period.

Research covers situational analysis of reproductive health and supply chain of medicines and medical products with a focus on contraceptives at country level. It also encompasses review of national normative legal acts and international guidelines in the specified context.

Research methodology. Analytical reviews of national normative legal acts and draft legislation, international and national guidelines, and analytical materials that were valid at the time of survey were performed; technical consultations and meetings with representatives of stakeholders were held. Open data from National Statistical Committee of KR, Electronic Health Center under MoH of KR, Department of pharmaceutical supply and medical equipment under MoH of KR, National Center for Phthisiology and Republican AIDS Center were explored. A brief review of best international practices on supply chain of stable provision with medicines and medical commodities to achieve universal health coverage was undertaken.

CURRENT SITUATION AND REGULATORY FRAMEWORK FOR REPRODUCTIVE HEALTH IN KYRGYZSTAN

National Development Strategy of the Kyrgyz Republic for 2018-2040 places a major focus of healthcare on attaining healthcare system with the following features: available, quality, safe, using innovative approaches, people-centered; whereas population of Kyrgyzstan has maximally improved health status. The 2040 Strategy is aimed at reducing maternal mortality by **25%**, and child and infant mortality rates should not exceed 18 and 12 cases per 1000 live births respectively. Pathways for reaching these targets allow creating national policy for health system development, and tracking the progress towards achieving SDG on RH.

National goals for reproduce health of population are closely intertwined with SDGs:

Goal 3. Ensure healthy lives and promote well-being for all at all ages;

1 Resolution of Government of KR as of 20 December 2018 #600 "On the Program of the Government of the Kyrgyz Republic on public health protection and development of the healthcare system for 2019-2030 "A healthy person - a prosperous country".

SDG 3.7. Ensure universal access to sexual and reproductive health-care services, including for family planning, information and education, and the integration of reproductive health into national strategies and programmes;

SDG 3.7.1. Proportion of women of reproductive age (aged 15-49 years) who have their need for family planning satisfied with modern methods.

Health and preventive services on RH and FP are provided by family doctors, obstetrician-gynecologists of FMS/GMPC in the frame of their functional duties[2], where there is no specific indication of family planning issues and preventive measures on RH (there are health points for pregnancy and birth care and general preventive measures). Overall, FP and RH issues are outlined in the 2020 clinical guidelines on safe abortion[3], and are part of section on postpartum contraception in the 2018 clinical protocol on antenatal and postpartum care.[4]

Family planning units and youth-friendly units that were previously functioning in the structure of FMC/GMPC were cancelled, and their functions were delegated to overloaded family physicians and family nurses, HPU, antenatal and child birth classes, which partly cover FP and RH issues. In general, at PHC level, there is a substitution of FP and RH issues with maternal health issues. Moreover, there are almost no measures on men's reproductive health.

Key indicators of reproductive health include fertility, infant and maternal mortality, abortion rates and frequency of using different types of contraception by reproductive age population.

As per data from NSC of KR, as of early 2023, de-jure population of the Kyrgyz Republic comprised 6 975, 2 thousand people, of them - 3 526, 4 thousand are women, including 1 731, 2 thousand women of reproductive age. According to NSC of KR, within 2022, fertility rate has declined and reached 21,5 per 1000 population (2021-22,4, 2020 - 24,0), and the number of births within the year was equivalent to 150225, which is higher by 61 versus 2021. The rate of natural increase of population has risen insignificantly reaching 17,0 per 1000 population by the end of 2022 (2021-16,6; + **2,3%**).

As per official statistics, total fertility rate in 2020 was on average 3,0 children per 1 woman of reproductive age (WRA), in 2021-2022 it comprised 2,8. Regarding regions, within the survey period, the lowest rate was registered in Naryn province - 2,1 (2021), and the highest - 5,3 (2022).

Dynamics of infant mortality rate remains sustainable and decreases from year to year compared with 2021 (21,7), nevertheless, the rates are alarming: 2020-14,4; 2021-15,2; 2022-14,3 per 1000 live births.

Maternal mortality rate remains one of key challenges of sustainable development (SDG 3.1.1). Despite a positive dynamic achieved in recent years, maternal mortality is still high in Kyrgyzstan, particularly in 2020, when 67 women died, which comprised 42, 4 deaths per 100 thousand live births. In 2021, 57 women died of complications during pregnancy, at delivery and after delivery, or 37,1 deaths per 100 thousand live births. In 2022, the rate was equivalent to 41 women and 28,1 deaths respectively (data from MoH of KR).

2 Order of MoH of KR # 902 as of 27.07.2022

3 Clinical guideline. Safe termination of pregnancy. MoH of KR. 2020

4 Order of MoH of KR # 243 as of 04.04. 2018

In addition to leading causes of maternal mortality (hypertensive disorders of pregnancy, sepsis, hemorrhage), a percentage of maternal deaths due to extragenital diseases is still significant: in 2020-2022, their rates were equivalent to **58,2%**, **29,8%**, and **39,0%** respectively. Within the research period, annual rates of abortion-related death of women comprise **3%**, **1,8%**, **12,2%**. In 2022, 1 case of maternal deaths due to abortion was registered in 5 regions of the country (Batken, Issyk-Kul, Osh, Talas and Chuy).

It ought to be noted that as per official data of MoH of KR, number of abortions during the survey period increases from year to year - 14906, 17075, 18645, which, in conversion to 1000 births represented 95,9, 110,6 and 127,1, respectively. Abortions are registered among 12-14 year-old girls and in 2022, the rate of abortions among girls under the age of 18 was **0,21%**. Among 20-40 year-old women, the proportion of abortions in 2022 comprised **85,1%** of the total number of abortions.

Over the last years, there is a persistent trend towards increase in abortions as a form of family planning in combination with low uptake of contraceptives per 1000 WRA. It should be mentioned that official statistics on abortions is contradictory, with a significant variation in data. Thus, for instance, total rate of abortions in the KR range from 2,7 (Osh city to 13,1 (Chuy province) per 1000 WRA, and medication-induced abortions from 2,1 (Bishkek) to 64,8 (Jalal-Abad province). Such data require validation and systematic monitoring at the level of healthcare organization and local office of MHIF (considering new SGBP, which is declared as being focused on preventive measures)[5].

Interpregnancy interval remains short which is also associated with increased risk of maternal and child mortality, particularly when spacing between childbirths is less than 24 months. Almost 1/3 of deliveries (**32,1%**) occur less than 24 months after previous childbirth.

Coverage of women of reproductive age with modern contraception methods is an essential element of sexual and reproductive health.

Three countries of Eastern Europe and Centrals Asia – Kyrgyzstan, Tajikistan and Uzbekistan made commitments in the frame of UN movement "Every Woman Every Child" aimed to implementation of Global UN Strategy for Women's, Children's and Adolescents' Health in support of SDG (UNFPA 2017). Kyrgyzstan has also made the following commitments in line with global partnership Family Planning 2030 (FP2030)[6]:

- creating the conditions that enable the population to exercise their SRH rights for enhancing the quality of their lives and meeting their FP needs;
- enhancing availability of medicines and heath commodities for reproductive health;
- ensuring delivery of reproductive health supplies to customers and facilitating the development of contraceptive supply chain;
- FP is integrated into PHC and is funded in the frame of ADP MHIF. To fulfill these commitments, the country must invest not only in procurement of medicines and health commodities, but also in building sustainable and effective health supply chain[7].

5 Population health and activities of healthcare organizations of KR for 2022

6 Strong supply chains is a key investment for choice, health and human rights. https://eeca.unfpa.org/sites/default/files/pub-pdf/55379_unfpa-eecaro_policybrief_ru-web.pdf FP 2030 https://fp2030.org/kyrgyz-republic

7 https://fp2030.org/kyrgyz-republic

Contraceptives provision in Kyrgyzstan is formed from several sources, until 2015, the major share of the total quantity was represented by contraceptives procured through UNFPA. Previously, retail sales and provision of subsidized contraceptives comprised an insignificant share of contraceptive uptake. However, contraceptive supply by UNFPA has stopped since Kyrgyzstan is able to address reproductive health and family planning issues independently as long as effective supply chain is in place, which allows ensuring uninterrupted supply of contraceptives, which are physically accessible and economically affordable for every woman who needs them. Moreover, new amendments to national legislation on public procurement[8] enable undertaking procurement through the UN agencies including UNFPA.

Under the current situation with contraceptives, the shares of provision of subsidized contraceptives in line with MHI programs and publicly funded contraceptives for women from из benefits-entitled population[9] are inconsiderable.

8 Law of KR "On amendments to certain legislative acts of the Kyrgyz Republic on public procurement" as of 25.07.2023 #147

9 Statistics of Sustainable Development goals of the Kyrgyz Republic. NSC of KR. 2022 – page 180.

In PHC practice, when prescribing publicly funded contraceptives, information is coded as per ICD 10 (International Statistical Classification of Diseases and Health-related Problems: 10th revision)[10]:

- **Z30.0** – Encounter for general counselling and advice on contraception
- **Z30.1** – Insertion of (intrauterine) contraceptive device
- **Z30.2** – Sterilization;
- **Z30.3** – Menstrual extraction;
- **Z30.4** – Surveillance of contraceptive drugs;
- **Z30.5** – Surveillance of (intrauterine) contraceptive device;
- **Z30.8** – Other contraceptive management;
- **Z30.9** – Contraceptive management, unspecified.

Two types of COCs with INN are included into national EML of KR: Levonorgestrel + ethinyl estradiol (Rigevidon, Gedeon Richter Plc, Hungary) and Norethisterone + ethinyl estradiol, the latter is not registered in the country.

10 ICD-10 Classification — EHC under MoH of KR

The proportion of women of reproductive age using contraceptives, 2020-2022 (table 1)

	2020	2021	2022
Women of reproductive age	1633,2 thousand	1593 thousand	1731 thousand
Number of WRA using contraceptives	265633	248979	244738
Share of WRA using contraceptives	16,3%	15,1%	14,1%

Source: EHC under MoH of KR

It should be noted that the share of women from MSRG of the total number of WRA comprised **6,8%** in 2020, **7,2%** in 2021 and **7,0%** in 2022. Of them, the share of contraceptive users is **79,2%**, 74,1 %, and **78,3%** respectively.

In Kyrgyzstan, provision of contraceptives is subsidized through Additional Drug Package of MHI[11], which allows insured women to procure contraceptives based on electronic prescription[12] in the retail pharmacy network with a significant discount at up to **49-62%**. Three contraceptives were included into the list of pharmaceuticals and health commodities for subsidized treatment: IUDs, Rigevidon, and Depo-Provera. Nonetheless, uninsured population, e.g. low-income and/or young, sexually active population (learners, students, unemployed persons of reproductive age) do not have access to subsidized medicines and contraceptives since according to experts, in 2019, only **69%** of population were covered by mandatory health insurance.

As per data from MHIF, in 2021, in line with Additional Drug Package of MHI, 163 prescriptions for contraceptives were issued in the amount of 1,253 thousand Kyrgyz Som; 128 prescriptions were used (**78,5%**); in 2022, 232 prescriptions were issued in the amount of 1,743 thousand Kyrgyz Som, 185 of them were used (**79,7%**); for 6 months of 2023, 101 prescriptions were issued in the amount of 0,820 thousand KGS, and 64 prescriptions were used (**63,4%**) (Note: as per MHIF data, within 6 months, more than 870 thousand prescriptions were issued in line with ADP MHIF). Contraceptive pills were prevailing in the prescribed contraceptives.

Indicator of Program 2030 "Share of population that is aware of subsidized pharmaceutical programs (SDG 3.8.2)" is tracked in the frame of assessment cards and monitoring visits of MHIF, there are no special surveys on this issue.

According to DPSME, as of 2023, 25 medication items and 271 health commodity items for family planning were registered in Kyrgyzstan. Between 2020 – 6 months of 2023, 680 pharmaceutical items were imported in the amount of 294,9 million KGS, and heath commodities for the amount of 13,9 million KGS, which were intended for retail sales. There are no open data on contraceptive consumers from retail sales sector.

RH is one of key aspects at the center of attention of MoH of KR, with use of Program 2030 indicators aligned with SDGs through analysis of routine data of EHC, tailored surveys, references of the board, etc. Keeping contraceptive records at PHC level is monitored[13] and reflected in summary tables on population health as open data of MoH of KR. Currently, EHC launches digital outpatient card with subsequent integration with other existing health information systems which will enable a simultaneous access to all record keeping and reporting forms from FAP level and an effective forecasting and planning of contraceptive supplies for WRA from MSRG.

Consequently, decline in contraceptive provision rates are caused by a few factors: high cost of available contraception, limited contraceptive choice in the list of ADP MHIF, lack of FP units, shortage

11 http://foms.kg/doppaket/

12 Order of the Ministry of Health of the Kyrgyz Republic #279 dated 14 March 2023.

13 Order of MoH of KR #740 "On approval of primary medical records and quarterly statistical reporting on record keeping of contraceptives flow and use" as of 08.06.2019.

of healthcare workforce at PHC level[14]: and in FDG, the situation with staffing level is worse (for 2022, availability of doctors at PHC level in KR comprised **80,8%** at PHC level and **78,5%** in FDG; availability of nursing staff at PHC level and FDG was equivalent to **90,1%** and **91,1%** respectively; and inadequacy in their governing documents on FP and RH: lack of developed job descriptions for Coordinators, regulation on FP unit, whereas there clinical guidelines and clinical protocols are available.

REVIEW OF INTERNATIONAL GUIDELINES ON REPRODUCTIVE HEALTH

SDGs are comprehensive universal set of 17 goals and indicators until 2030 aimed at enhancing the quality of life in the population and promoting socio-economic development and environmental sustainability of states.

SDG 3 reflects readiness of all countries towards achieving universal health coverage (UHC) by 2030. This implies that all people and communities in any geographical location should have access to quality healthcare services they need: health promotion, prevention, treatment, rehabilitation or palliative care, ensuring that the use of these services does not expose the users to financial hardship. Sustainable Development Goal 3 encompasses 13 targets and 28 indicators for measuring progress towards reaching the goals such as: reducing maternal mortality; ensuring universal access to sexual and reproductive health-care services, including for family planning, and education; achieving universal health coverage.

Implementation of SDG 3.8 is targeted at achieving universal health coverage, including access to safe, effective, quality and affordable essential medicines and vaccines for all. Kyrgyzstan periodically measures the progress towards attaining SDGs against each target area, but lack of tool for monitoring of access to medicines including contraceptives does not contribute to effectiveness of pharmaceutical provision programs in the context of limited health budget[15].

In 2023, UN Women and NSC of KR published a statistical compendium, which provided the following data: Coverage of women of reproductive age by modern family planning methods is an essential element of sexual and reproductive health (SDG 3.7.1.). As per MICS data, in 2018, the share of women using such methods has fallen to **67,4%** (**68,7%** – in 2014). Most of all, contraceptives are used by women aged 30-34 years old (**76,2%**) and 35- 39 years old (**74,5%**), having higher education (**74,3%**) and high welfare level (71,4 % in richest quintile). Adolescent pregnancy and motherhood is an acute health and social issue. In 2021, 29,7 births per 1000 women aged 15-19 were registered in the republic, whereas in 2015, there were 42,3 births. In urban areas, this rate was higher than the average republican level (37,5 births), and lower rate was registered in rural areas (26,4 births)".

In 2021, WHO issued updated guidelines, which covered a wide range of FP issues and is intended for use by healthcare workers in countries with limited resources. Four sections of this guideline: "Medical eligibility criteria for contraceptive use", "Selected practice recommendations for contraceptive use", "Family planning: a global handbook for providers" and

14 Population health and activities of healthcare organizations of KR for 2022.

15 Access to medicines, vaccines and health technology. WHO. 2018.

"Decision making tool for family planning clients and providers: technical guide" represent four cornerstones of WHO initiative on FP.

Particular value of this guideline is that recommendations encompass the most relevant age and sex groups with various sexual and reproductive health needs (adolescents; married and unmarried; men's health; man's care about female partner's health; couples; women approaching menopause; persons with disabilities, etc.).

REVIEW OF NATIONAL REGULATORY DOCUMENTS ON REPRODUCTIVE HEALTH (AFTER 2021)

A vital component of regulatory practice is ensuring the right of individuals to health[16], to fatherhood and motherhood, and to reproductive health[17]. Reproductive rights are integral part of human rights, which should be a priority for advocacy of sexual and reproductive health issues including guaranteed provision of family planning services with awareness raising and educating for all population groups with a focus on MSRG.

Normative legal acts of the Kyrgyz Republic on RH acknowledge reproductive rights of citizens as essential part of human rights, which rest on the recognition of the basic right to decide freely and responsibly the number, timing and spacing of their children, to have reliable and complete information on status and protection of their reproductive health, and right for choice and use of contraception methods.

Regarding RH sphere, analysis of regulatory framework in the context of various survey studies have been repeatedly conducted; therefore, this research focused on key regulatory documents that were amended or updated after 2020.

In Program 2026[18], section on mother and child healthcare contains planned activities on implementation of "Umai-Ene" project, aimed at improvement of RH, preparation to motherhood and newborn care, with indicator "Coverage of 50 % of young mothers, reduction of maternal and child mortality by 3 %".

RH and FP issues are underrepresented in **Program on development of the health care system until 2030 "Healthy Person - Prosperous Country"**, and in preventive activities on the population and at PHC level there is no detailed elaboration of FP and RH challenges, and respectively, no active measures are taken to address these issues. The set of 22 indicators include indicators for reproductive health of population (maternal, infant, child mortality; reduction of unmet need for contraceptives) and ensuring access to quality, effective, safe and affordable essential medicines[19].

Key law of healthcare system – Law of KR #6 dated 9 January 2005 "On protection of public health in the Kyrgyz Republic" is currently in the process of legal inventory[20] and preparation of new draft law which is designed to significantly change and be aimed at protecting health rights and interests of the population. 11 laws of

16 Articles 26, 34 of Constitution of the KR

17 Family Code of the KR dated 02.06.2003, article 2, law "On public health care in the KR", law of KR "On reproductive rights of citizens and guarantees for their realization".

18 National Development Program of the Kyrgyz Republic until 2026. Decree of the President of KR #435 as of 12.10.2021. Resolution of Cabinet of Minister of KR #352 as of 25.12.2021.

19 Resolution of Government of KR # 600 dated 20.12.2018.

20 Decree of President of KR #26 dated 8.02.2021 "On inventory of legislation of the Kyrgyz Republic".

health system (including law of KR "On reproductive rights of citizens of KR) are integrated into a single law, which will allow avoiding duplication, declarativity and improving legislative and regulatory compliance practices. It should be noted that provisions of this draft law do not differ from the existing laws, and, consequently, barriers and risks remain (and possibly, increase the existing gaps).

Hence, for instance, **the existing law of KR "On reproductive rights of citizens and guarantees for their realization"** was adopted in 2015, was revised 2 times – in 2016 and 2019. The 2016 revision of this law assumes delegating to local bodies the authorities on development and financing territorial programs on protection of reproductive rights of citizens; coordination and oversight of activities implemented by public educational establishments, state organizations for healthcare and social protection, and non-governmental organizations in the sphere of promotion of reproductive health of population. The revision of 2019 included revisiting competencies of the Government of KR and MoH of KR as state authorized agency, and Article 7 became invalid.

Competency of authorized state agency on healthcare and protection of reproductive rights of population of the Kyrgyz Republic: Thus, currently, in terms of legislation, MoH of KR does not have competencies in the sphere of reproductive health. In draft law, this gap remains. Moreover, authorities of Cabinet of Ministers of the Kyrgyz Republic on protection of population health (Article 8), also do not have clauses on RH issues.

Whereas authorities of local state administrations and local self-governance bodies on protection of population health (Article 9) have a clause 13) "coordination and oversight of activities implemented by public educational establishments, state organizations for healthcare and social protection, and non-governmental organizations in the sphere of promotion of reproductive health of population".

In line with this law, "sexual and reproductive health intervention (including abortions) in relation to a person under 16 years old, except for purposes of informing and counselling, is undertaken based on consent of minor child and his/her legally authorized representative", whereas Child Code recognizes a minor child as an individual under the age of 18 years old[21]. This provision causes an increased vulnerability in terms of reproductive health in age groups of 16-18 year-olds[22]. A separate Article 17 defines the right to contraceptive use, according to which citizens have the right to contraceptive choice and access to a wide range of safe, effective and acceptable contraception methods, their use and the right not to use them[23].

Draft law "On public health care in the KR" (at the time of survey preparation, it was revised 2 times by Jogorku Kenesh)[24] uses major terms related to RH such as "contraception, family planning, reproductive health, reproductive rights, etc."[25]. It should be noted that the terms are editorially different from the terms of the Family Code.[26]

21 Child Code #100 dated 10.07.2012, article 5

22 Assessment of sexual, reproductive, maternal, newborn, child and adolescent health (SRMNCAH) in the context of universal health coverage. Copenhagen: WHO Regional Office for Europe; 2020 License: CC BY-NC-SA 3.0 IGO.

23 Law of KR "On reproductive rights of citizens and guarantees for their realization"

24 http://kenesh.kg/ru/draftlaw/634571/show , was adopted in 2nd reading.

25 Draft law "On public health care in the KR". Article 3. Key concepts and definitions used in this law.

26 Family Code. Article 2. Key concepts used in this Code.

Main focus areas of public policy include RH issues on "shaping a conscientious attitude of men and women towards birth of healthy and desired children through forming an equal parental responsibility for their birth, prevention of early and unintended pregnancies; creating favorable environment for ensuring equal opportunities for women and men, including underage for realization of their sexual and reproductive rights"[27].

Chapter IV. Rights and responsibilities of citizens on health protection

Among other rights of citizens in terms of health protection, Article 56 outlines reproductive rights of citizens as "comprehensive and accessible sexual and reproductive health services as integral part of health protection". Reproductive rights encompass:

- "control and decide freely and responsibly the number, timing and spacing of children including use of modern birth control methods";
- "access to the existing safe technology on protection of reproductive health including contraception, family planning, termination of pregnancy, diagnosis and treatment of infertility and sexually transmitted infections including HIV";
- "use of artificial insemination methods: insemination, implantation and extracorporeal fertilization";
- "right to parenthood using surrogate motherhood" and other rights related to donation of germ cells in artificial insemination and surrogate motherhood;
- "irrespective of their marital status, women are entitled to independent contraceptive choice, including safe abortion option";
- "voluntary surgical contraception".

This article uses different definitions of age of citizens eligible to be germ cell donors as "adults" (clause 7) and as "having reached marriage age" pertaining to voluntary surgical contraception (clause 9). Whereas, Family Code interprets both notions as persons reaching the age of 18 years old[28].

In addition, in clause 9, there is no clarification on age of women eligible for safe abortion, which can affect the right to safe abortion for adolescent girls.

Chapter VII of this draft law is devoted to RH objectives and principles amongst other priority areas, including continuity throughout the entire life cycle of preventive measures, intersectoral nature of efforts with a focus on self-responsibility and participation of local communities and local-self governance bodies. Importantly, the future law will stipulate "legality, mercy, humanity, respect, observance of human rights and freedoms, confidentiality of information in the framework of medical care ... in realization of sexual and reproductive rights, and at all stages of arranging protection of sexual and reproductive health".

Paragraph 4 "Reproductive health of population and mother and child healthcare" elaborate on the issues of reproductive health of population and maternal and child healthcare.

Article 103. Assisted reproductive methods and technology outline in clause 11) that "Procedures and conditions for using assisted reproductive technology, contraindications and limitations for their use and donation of germ cells are approved by the Cabinet of Ministers of the Kyrgyz Republic and are carried out

27 Draft law "On public health care in the KR". Article 6. Public policy on health protection.

28 Family Code of the KR, article 14 "Marriageable age", articles 2 and 51, 59 "adults"

by healthcare organizations licensed to perform this type of medical procedures". Consequently, state HCO cannot use this reproductive technology as only private medical practice is licensed[29].

Article 104. Contraceptive use in clause 2 excludes social grounds for participation of population in subsidized sexual and reproductive health programs.

Article 105 of the draft law repeats the previous gaps related to situations of increased vulnerability with reproductive health in age group of 16-18 years old, including all methods of contraception and not only abortions. Moreover, this draft law does not outline the right of legally authorized representatives of persons with disabilities to contraceptive use in the best health interest.

RH and FP issues included as additional aspects, are presented in a comparative table (refer to Annex 1).

State guaranteed benefits package program regulating the entitlements of Kyrgyz citizens to medical services (hereinafter referred to as SGBP) is a national program for implementation of minimum state guarantees/standards on healthcare to attain UHC and is approved by CM of KR.

At present, a new version of SGBP is approved by Cabinet of Minister of KR[30]. Revision of SGBP is aimed at reorientation towards full coverage of target vulnerable groups by health services considering main function of MHIF as strategic purchaser of health services.

Such reorientation will enable:

- improving guaranteed access of citizens to subsidized health services and medicines in healthcare facilities in MHI system;
- achieving improved health outcomes in socially vulnerable groups and population insured in the frame of MHI;
- guaranteeing high quality of medical care and high satisfaction of population with health system;
- strengthening public trust in health system in general.

Apart from that, new SGBP has a clear breakdown of scope, types and conditions for provision of health services for citizens of the Kyrgyz Republic, foreign nationals and stateless persons in the Kyrgyz Republic; working citizens and members of their families of Eurasian Economic Union member states. It is vital to ensure expanding and detailed elaboration on packages of preventive services and essential package of health services at PHC level for target populations (children, adolescents, women with normal and pathological pregnancies, patients with NCD).

In a separate chapter on provision of medicines and vaccines, there are no significant changes, and earlier outlined subsidies for pharmaceutical supply have remained unchanged.

In line with State guaranteed benefits package program, subsidized medicine provision has been implemented since 2000 for insured citizens based on Additional Drug Package of Mandatory Health Insurance (ADP MHI) through pharmacy network. Algorithm for electronic prescription of subsidized medicines and their receipt with a partial reimbursement of cost from MHIF was

29 Law of KR #195 as of 19.10.2013 "On licensing and authorization system in the Kyrgyz Republic", Article 15. Types of activities subject to licensing, clause 7

30 Resolution of Cabinet of Ministers of the Kyrgyz Republic #493 as of 21.09.2023

identified. List of pharmaceuticals in the frame of ADP MHI is created based on Essential Medicines List (EML).

Since 2015, five contraceptives (Tri-Regol, Rigevidon, Regulon (removed from formulary in 2018), Depo-Provera, Intrauterina contraception) were added into formulary of medicines subject to reimbursement in line with additional drug package of MHI and state guaranteed benefits package program at outpatient level. Limited choice of contraceptives in the existing EML needs to be expanded. Currently, three types of contraceptives are included into ADP MHI.

Order of the MoH of KR # 784 dated 16.07.2019 "On approval of record keeping and reporting documentation on publicly funded contraceptives" aims at improving record keeping of the flow and use of contraceptives, planning the demand of WRA and medical and social risk group for family planning (in total 20 categories including 16 – on medical grounds). For the moment, expansion of MSRG is under consideration, mainly on medical grounds in accordance with structure of clinical causes of maternal mortality. Nonetheless, regular expansion of MSRG categories may result in inefficiencies in budget spending and support of welfare mentality of people.

As per this order, some changes were made to "Reference book of population category codes" which serves as the basis for electronic database of "registered population", which collects data from PHC level healthcare facilities on a quarterly basis. At this stage, EHC undertakes activities on transfer of database "registered population" in online mode based on electronic health record.

For effective implementation of commitments in line with Kyrgyzstan's partnership with "FP2030" and satisfying the demand of WRA from medical and social risk group for contraceptives, Ministry of Health of KR developed **Program of seven-year plan** on gradual increase in public-sector funding to satisfy demand for family planning of women from groups of high medical and social risks of maternal mortality until 2030, which identified the following focus areas:

- increasing the use of publicly funded contraceptives by women of reproductive age from the group of high medical and social risk of maternal mortality;
- strengthening digital mechanisms for forecasting the funding needs and oversight of contraceptive procurement and monitoring of budget execution;
- allocating budgetary resources for family planning, giving priority to contraceptive procurement, to cover minimum 60% of WRA from the group of high medical and social risk of maternal mortality in 2026, and 70% in 2030, with monitoring of budget line for FP commodities in accordance with the approved budget and timeline;
- ensuring mutual accountability between the Ministry of Health (MoH), Family Planning Advisory Council (FPAC) and other stakeholders. [31]

National Costed Implementation Plan (CIP) for 2020-2024 for family planning is one of program documents reflecting country's needs in reproductive health services aimed at consolidation of country efforts and partners' investments in family planning programs and promoting the role of public sector.

31 Order of MoH of KR #1142 dated 22.09. 2023 "On approval of Program of seven-year plan on public-sector funded procurement of contraceptives in the frame of implementing 5 new commitments of the Ministry of Health of the Kyrgyz Republic on FP2030".

Hence, at present, a number of active measures are undertaken in the sphere of RH and FP with the aim of optimization of regulatory framework and refinement of mechanisms and tools for organizational and methodological support. Nevertheless, identified gaps and risks can weaken the efficiency of measures on RH and FP. In this connection, the below recommendations were suggested (refer to the table).

Identified barriers	Recomendations
A rapid situational assessment of reproductive health in the KR demonstrates alarming increase in abortion rates and abortion-related mortality for 2022 compared with 2020-2021 rates	Analysis of abortion rates and abortion-related mortality for 2022 with rapid response measures to minimize the causes
Number of WRA using contraceptives declines from year to year, and as per data of EHC, does not exceed 14% of the total number of WRA. Probably, actual data shows even lower rates.	Regular information campaigns among WRA with input of resources from local state administrations and local-self-governance and local communities on RH issues Google – surveys of WRA Introduction of Family Planning Unit to the staffing table of PHC
Share of subsidized ADP MHI in contraceptive provision is insignificant and there is no trend towards expanding the list and quantities. Inaccessibility for youth and other groups of uninsured population	• increase the amount of reimbursement for contraceptives • monitor prescriptions of ADP MHI for contraceptives • monitor separately the MSRG and WRA under the age of 18 • include condoms to the list of ADP MH and • indicator of Program 2030 "Share of population that is aware of subsidized pharmaceutical programs (SDG 3.8.2)" – to conduct a survey Increase coverage of population with MHI (this is the best way)
New draft regulatory acts keep the same gaps in provision of SRH programs hindering the progress towards implementing country's commitments in line with FP2030	Discuss identified gaps and prepare a comparative table for making amendments to normative and regulatory acts
Program 2030 has no active actions and measures on challenging RH and FP issues taking into account MSRG and uninsured young population There are no measures at population level with participation of local communities, community leaders and LSG. There are no measures at PHC level	New version of Program 2030 to be supplemented with active actions on RH and FP. Add indicator on provision of contraceptives through MHI programs Re-establish FP units at PHC level
A weak fragmented contraceptive supply chain	Add clauses on creating supply chain in general including contraceptive SC, into a 7-year plan of Program 2030

Logistics issues related to contraceptive supply chain are covered in the next section on supply chain management.

ANALYTICAL REVIEW OF REGULATORY DOCUMENTS AND INTERNATIONAL GUIDELINES ON REPRODUCTIVE HEALTH AND SUPPLY CHAIN MANAGEMENT OF PHARMACEUTICALS AND HEALTH COMMODITIES

Analysis focuses on regulatory framework for management of national supply chain of medicines and health commodities including contraceptives. It was important to get insight into the following: the extent to which international and national documents are aligned and normatively secured considering the fact that management of publicly funded national supply chain should have a sustainable institutional nature and serve as powerful contribution to effective implementation of health programs.

The below analytical review of the existing regulatory acts covers the laws of the KR, resolutions of Cabinet of Ministers of KR, strategic and national health programs, international guidelines and agreements, and analytical surveys.

Review of structured the following way:

- national normative acts on reproductive health and supply chain management of pharmaceuticals and health commodities including normative regulatory acts regulating activities of key SCM structures
- EAEU decisions and agreements in the sphere of pharmaceutical supply
- international guidelines on supply chain management of medicines and health products.

National Development Program of the Kyrgyz Republic until 2026[32] defined priorities of immediate prospects for country's development in the context of increased restrictions for interaction with external world and narrowed access to resources (which is important in the context of SCM). Program 2026 envisages shifting the focus in healthcare – from combatting diseases and their consequences to supporting healthy lifestyle based on prevention of diseases, involvement of people in their own health and care, shaping responsible attitude towards their own health and health of others. To implement Program 2026, there was developed an Activity Plan[33] , which contains more than 800 events covering all sectors of socio-economic development of the country with a focus on anti-crisis measures.

Elements of SCM were included into the set of anti-crisis response measures related to COVID-19 consequences, such as establishing a sufficient stock of personal protective equipment, medicines and medical commodities; ensuring a full automatization of record keeping of medicines circulation and the entire activities of DPSME; arranging an inventory of supply chains and stock of essential pharmaceuticals and medical equipment; optimization registration of supply of medicines and medical commodities, their labelling in national system for traceability of medicines and health products, implementation of inventory control in healthcare facilities; development of mobile application for population to ensure their access to information on

32 Decree of the President of the Kyrgyz Republic #435 dated 12.10. 2021.

33 Decree of CM of KR #352 as of 25.12.2021 "On approval of Activity Plan of Cabinet of Minister of the Kyrgyz Republic on implementation of National Development Program of the Kyrgyz Republic until 2026"»

quality and prices for medicines and health commodities; revision of system for registration and evaluation of quality of medicines and health commodities; revision of procedures for formation of prices for pharmaceuticals from EML. The outlined clause of the Plan are key activity areas of DPSME.

Resolution of Government of KR #600 dated 20.12.2018 "On Program of the Government of the Kyrgyz Republic on public health protection and healthcare system development for 2019-2030 "Healthy person, Prosperous country" is a fourth strategic document defining key areas for further development of healthcare system and protection of population health. Benchmarks for this program are SDGs (indicators of Program 2030 are harmonized with SDG indicators)[34].

The program defines the following priority areas:

- Public health;
- Advancing Primary Health Care;
- Enhancing and rationalizing hospital system;
- Development of emergency medical care;
- Laboratory services;
- Medicines and health commodities;
- Strategic management in healthcare;
- Human resources for health;
- Development of electronic health care;
- Development of funding system;
- Program implementation management.

The difference of Program 2030 from previous reforms is mechanism for provision of external financial support with consideration of achieving results both by health organizations and by the system in general (e.g. Primary Health Care Quality Improvement Program).

MoH of KR holds annual review sessions of Program 2030 jointly with participants of external funding, but intermediate reports of the Program were not reviewed by board of management of MoH – as highest level agency of health care system, and previously, a customized website of Program 2030 was functioning (now is not functioning).

Currently, there is an intermediate mid-term assessment of attaining the goals of Program 2030 for subsequent adjustment of activity plan and indicators taking into account the latest strategic documents such as Decree of the President of KR dated 9.02.2021 "On immediate measures for advancing healthcare and enhancing the quality of life and health of population in the Kyrgyz Republic" and Program for country's development until 2026 (which was also endorsed in 2021).

In Program 2030, the aspect of pharmaceutical supply encompasses 3 key objectives: (1) improving the regulation and management of circulation of pharmaceuticals and heath commodities, (2) creating the system for regulating the prices for essential medicines and medical products to reduce population's out-of-pocket payments for medicines, (3) increasing effectiveness of public selection, procurement and use of medicines and health commodities along with improving management of pharmaceuticals in healthcare organizations[35].

Indicators pertain to major trends in health status of population and are harmonized with SDG indicators (maternal,

34 https://www.gov.kg/files/news/froala/4400f6708100e3632e3cfaf0857942cdcc08f79f.pdf

35 http://cbd.minjust.gov.kg/act/view/ru-ru/12976?cl=ru-ru

infant and child mortality rates; rates of premature mortality from NCD, etc.).

The second group of indicators are related to health system strengthening (availability of human resources in HCO; introduction of information technology, etc.). The third group is associated with financial risk protection of population when accessing the needed healthcare services including SGBP.

Indicators for pharmaceutical provision relate to the level of access to quality, effective, safe and affordable essential medicines (SDG 3.8.1; 3.8.2), namely:

- Proportion of generic medicines registered in countries with strict regulatory requirements of the total quantity of registered generic medicines;
- Proportion of dispensed medicines under genetic names in the frame of subsidized programs;
- Proportion of population that is aware of subsidized medicine programs;
- Level of reducing the rate for reimbursable medicines in the frame of subsidized programs from the list of essential medicines.

Moreover, indicators matrix covers other indirect indicators of pharmaceutical supply, which reflect affordability of medicines: increased level of direct expenses for treatment of inpatient patients including for medicines; increased financing of subsidized medicines program at outpatient level; reduced share of populations' out-of-pocket payments for healthcare in total health spending; share of health expenditures of the total budget of households in the first two quintiles; share of public expenditure for healthcare of general government expenditures; proportion of households whose out-of-pocket payments exceed **40%** of their paying capacity; population's out-of-pocket payments for medicines.

To address the issue of high level of out-of-pocket payment for medicines by patients, Cabinet of Ministers has established new rules for regulating prices for medicines in the Kyrgyz Republic[36], which regulate medicines from EML and those that are permitted for medical use in the country as per established procedures. These rules do not apply to: locally manufactured medicines; narcotic and psychotropic substances subject to control in the Kyrgyz Republic; non-prescription medicines; and medicines, which cost below 100 KGS.

However, at PHC level there is a widespread use of unethical marketing practice – prescription of more expensive medicines. This leads to irregular intake of medicines for control of NCD, thereby limiting access to medicines. Other barriers include transportation distance and geographical remoteness for patients with NCD, pregnant women and under 5 children who have to obtain MHI electronic prescription from family doctors or other specialist doctors (cardiologist, endocrinologist, oncologist).

At inpatient level, the perennial problem of informal payments mainly relates to health commodities for clinical diagnostic services. As per survey data, **20%** of hospital patients purchased medicines. Drug package of SGBP and ADP MHI do not have a significant impact on the reduction of financial burden of private expenditure for medicines. In spite of SGBP update, there is no expansion of the list of medicines and quantities of medicines and health commodities including contraceptives. Similarly, there is no introduction of new

36 Decree of CM of KR #292 as of 31.05.2023 "On approval of rules for regulating prices for medicines in the Kyrgyz Republic".

mechanisms for enhancing access to quality, safe and effective medicines and medical products.

It ought to be noted that Program 2026 and Program 2030 are two strategic programs containing clauses on creating SCM mechanisms and tools.

Recomendations for new version of Program 2030:

1. Commence forming an organized supply chain of pharmaceuticals and health commodities to ensure appropriate quality, efficacy and safety of medicines and health commodities

1.1. Create a permanent Working Group under MoH of KR to launch supply chain

1.2. Take measures to boost the capacity of employees of MoH, MHIF, CHDMT (Center for health development and medical technology (CHDMT), NIPF (national institute for public health), DPSME and Kyrgyzfarmatsiya SE on M&E in SCM, forecasting, public procurement, program budgeting, health technology assessment (HTA) in order to establish a group of high-level specialists

1.3. Add indicators on supply chain and prevention of unethical marketing of medicines to accreditation standards and licensure requirements and key performance indicators of healthcare organizations

1.4. Design the methodology for comprehensive assessment of evidence-based clinical and economic/(pharmacoeconomic) efficacy and safety of health technology to reduce unreasonable consumption of medicines by population and rational selection of pharmaceuticals and health commodities to be procured

1.5. Arrange survey of national market of medicines including contraceptives by international experts to satisfy the needs of population and identify the role of public sector in regulation of the market for pharmaceuticals through introduction of integrated supply chain

Analysis of draw law "On public health care in the Kyrgyz Republic" in the context of supply chain management of medicines and health commodities

This draft law integrates the provision of the existing 11 laws of health care system; moreover, provisions and articles (34) of some laws on population health become inoperative. The following laws are integrated into a new draft law:

1. Law of the Kyrgyz Republic "On public health care in the Kyrgyz Republic";
2. Law of the Kyrgyz Republic "On narcotic drugs, psychotropic substances and precursors (related to treatment);
3. Law of the Kyrgyz Republic "On psychiatric care and guaranteeing the rights of persons receiving such care";
4. Law of the Kyrgyz Republic "On oncological assistance to the population";
5. Law of the Kyrgyz Republic "On transplantation of human organs and (or) tissues";
6. Law of the Kyrgyz Republic "On healthcare organizations in the Kyrgyz Republic";
7. Law of the Kyrgyz Republic "On

diabetes mellitus in the Kyrgyz Republic";
8. Law of the Kyrgyz Republic "On donation of blood and its components";
9. Law of the Kyrgyz Republic "On protection of breastfeeding and regulating the marketing of milk substitutes";
10. Law of the Kyrgyz Republic "On status of the health worker";
11. Law of the Kyrgyz Republic "On reproductive rights of population and guarantees for their implementation".

The draft law used the norms of the existing laws without their expansion; in some cases, the outlined norms have been clarified, and duplication provisions of each law were removed.

The following terms were added to the draft law:

Existing law	Draft law
Pharmaceutical activity is or several interconnected activity processes pertaining to production, preparation, wholesale and retail sales, dispensing medicines and health commodities including import, export, storage, labelling, distribution, use and destruction of medicines and health products	143) Pharmaceutical activity are types of activities in the sphere of circulation of medicines and health commodities on production, wholesale sale (distribution), retail sales, preparation and dispensing medicines and/or health commodities related to import, export, procurement, labelling, transportation, storage, distribution (dispensing), use and destruction/disposal of medicines and health products
	144) pharmaceutical service is activity of entities in the sphere of circulation of medicines and health commodities related to pharmaceutical provision of population at outpatient level in the frame of State guaranteed benefits package program and/or system for mandatory health insurance

Existing law	Draft law
Analysis **The definition of the term in new Law on pharmaceutical activity is expanded and supplemented as per complete cycle of circulation of medicines and medical products. The term "pharmaceutical service" requires revision and clarification.** **In accordance with survey of International Pharmaceutical Federation, there are 44 pharmaceutical services, and the most common are:** **• clinical services aimed at adherence to appropriate use of medicines and prevention of side effects;** **• product-oriented services;** **• sale of medicines and consultation;** **• primary medical care – participation of pharmacists in consultations for vaccination and antibiotic resistance awareness;** **• undertaking screening tests in pharmacy;** **• substance abuse treatment programs;** **• consultations on emergency contraception (Main pharmaceutical services: experience of developed countries | Schotizhevnik PHARMACY) ;** **Hence, a pharmaceutical service is a service provided to the population and healthcare organizations by legal and physical entities involved in pharmaceutical activity and having relevant license and by public bodies exercising regulatory oversight and control of pharmaceutical activity.** **Pharmaceutical service is provided by a qualified specialist who bears responsibility for the provided pharmaceutical service.** **Overall, pharmaceutical services can be divided into:** **informational;** **consultative;** **product-related.** **https://con-pharm.ru/** **In addition, Article 65 outlines the term "medication service".**	

Key objectives and principles of public policy on public health protection do not specify the function and role of state medicine policy as important integral part of general policy.

Article 10 defining the competencies of MoH, contains the following main tasks of MoH: "10) ensuring quality assurance, safety and effectiveness of medicines and health commodities", without mentioning formation of sustainable supply chain of medicines and health commodities which ensure a positive contribution to national public health programs through: • Increasing program impact; • Enhancing the quality and accessibility of services; • Improving cost effectiveness and efficiency, and rational use of limited resources[37].

16) creating national stockpile of anti-diabetic medications (mainly, insulin) with the means to deliver their 6-months' supply, purchase of reagents to diagnose and control blood sugar levels in patients with diabetes mellitus. Meanwhile, creating the stock of medicines and health supplies for crisis and emergency situations is not mentioned in the text of this Law.

Description of the rights of citizens and specific groups of population (children

37 John Snow Inc.(JSI), 2020. The supply chain Managers Handbook. A practical guide to the management of health commodities. Arlington, Virginia: John Snow Inc. (JSI).

("underage" is specifically outlined!!), women, elder people, persons with disabilities, NCD patients and persons diagnosed with communicable diseases, mentioned the right to pharmaceutical provision (Articles 59- 64). Article 65 on the rights of patients during medical care provision elaborates on the right to medication services among others (not pharmaceutical services).

Article 67 outlines the rights of patients to reliable information from health workers, among others: "5) on the procedures for taking medications and possible side effects".

In Article 72, patient responsibility was supplemented with the norm to "provide a health care provider with information on their health including contraindications for medications".

In 2021, the Kyrgyz Republic adopted a range of decrees of the President of the Kyrgyz Republic such as strategic tools for stabilizing socio-economic situation of the country that was exposed to severe shocks related to COVID-19 consequences. The pandemic showed that in the context of potential and long-term emergencies and crises, the country should be prepared for effective and rapid response to emergencies[38], which requires creating sustainable and agile supply chain of commodities and services, which is particularly important for medicines and health commodities too. Crisis situations easily damage fragile and unsustainable supply chains of medicines and health supplies, diverting significant funds for unplanned and poorly thought-out investments (artificial pulmonary ventilation, oxygen concentrators during COVID-19).

38 Central Asia Regional Economic Cooperation (CAREC) 2030

Decree of the President of the KR #23 dated 8.02.2021 "On immediate measures for advancing healthcare and enhancing the quality of life and health of population in the Kyrgyz Republic" specify developing health system and improving quality of population health including in the sphere of medicines circulation as the government priority. This regulatory document informs subsequent normative legal acts to create a legal framework on supply chain management of pharmaceuticals and health commodities, forming a strategic stockpile of medicines and health supplies, electronic regulation and management of medicines and medical products, and creating conditions for setting up pharmaceutical factories for local manufacturing of medicines and health products.

An active law of the KR #165 dated 2.08.2017 "On circulation of medicines" is under legal inventory[39]. Revision of this law is targeted at large scale and quality change through strengthening rights and interests of a citizen and legal entities in the sphere of circulation of pharmaceuticals.

Specified changes pertain to 3 spheres of circulation of medicines:

1. harmonization with new developments in the sphere of public procurement and EAEU requirements to ensure the system for quality, safety and effectiveness of medicines, including import and export of pharmaceuticals;
2. taking into account enhancement of the system for state regulation and introduction of electronic management in the process of a full cycle of circulation of pharmaceuticals and health supplies;
3. strengthening issues related to provision of the country with medicines during

39 Decree of the President of the Kyrgyz Republic #26 dated 8.02.2021 "On inventory of legislation of the Kyrgyz Republic".

emergencies including the threat of the lack and stock-out of medicines.

There was a significant change to conceptual structure in the draft law and 3 groups of concepts were introduced:

- harmonization of concepts used in EAEU acts (active pharmaceutical substance, safety of medicine, quality of medicines, production of medicines, country of the regions of International Council for harmonization of technical requirements to registration of medicines for medical use, falsified medicines);
- ensuring a common understanding and approach to terms in the sphere of circulation of drugs at all levels and by all participants of processes, for instance, "pharmacy-based preparation of medicines, starting materials used for producing medicines, wholesale sales (distribution) of medicines, retail sales of medicines, pharmaceutical activity, pharmaceutical organization";
- provision of the country with medicines during emergencies including the threat of the lack and stock-out of medicines (strategic essential medicines, socially significant diseases). Despite introduced amendments, supply chain management issues are not fully considered. Recommended updates are presented in comparative table (refer to Annex 2).

The law of the KR #166 dated 2.08.2017 "On circulation of medicines" is also under inventory, and new draft law envisages adherence of legislation in the sphere of circulation of medicines and health products to the principles of justice and partnership, rationale and effectiveness and ensuring the access of population to quality and safe health commodities.

The structure of the draft law takes into account the stages of circulation of medicines, and contains new provisions considering enhancement of the system for public regulation and introduction of electronic management, and issues of providing the country with medicines in the context of emergencies, issues of harmonizing national legislation with EAEU acts. In February 2023, period for registration of medicines and medical equipment as per national procedures was extended until 31 December 2025 in the frame of EAEU. Deadline extension will enable EAEU member states to improve the system for registration of medical supplies including clinical centers and testing laboratories, which is required for transition to unified registration of health commodities (note: at discussion of draft laws on medicines and health supplies, representatives of pharmacological companies shared their opinion about deadline extension). Despite introduced amendments, supply chain management issues are not fully considered. Recommended updates are presented in comparative table (refer to Annex 2).

Law of KR #7 "On public procurement" was adopted on 14.04.2022 and is designed for effective and economical use of public finance through regulating the relationship associated with ensuring functioning of procurement organizations. Public procurement principles are as follows: 1) optimization of public procurement processes via creating a unified system for public procurement and building public trust towards it; 2) implementing the rights and legally protected interests of public procurement participants; 3) openness, impartiality, publicity and transparency at public procurement; 4) purchasing innovating and high-tech goods, works and services.

Law of KR "On amendments to certain legislative acts of the Kyrgyz Republic on public procurement" dated 29.06.2023 envisages simplification of public procurement procedures, optimization and shortening the duration of public procurement procedures and making amendments to the range of laws of KR (13). Moreover, complicated and unimplemented mechanisms for public procurement were removed and revised; procedures for changing the procurement plan were shortened; and the scope of using single sourcing method was expanded. In addition, authorized state agency on public procurement (MoF of KR) have the function of providing written explanations on use of legislation on public procurement.

In the adopted law, restricted tendering in public procurement became invalid, and public procurement of goods, works and services will be carried out through the following methods:1) unlimited; 2) request for quotation; 3) single source.

In health care, single source method can be applied for purchase of medicines and health commodities not only through organizations (agencies) established by the United Nations, but also via special procurement organizations working in the frame of the United Nations programs in the sphere of heath care (including their operational components), which entered into the agreements (memorandum) with Cabinet of Ministers. The procedures of such public procurement are established by the decision of Cabinet of Ministers. However, the methods of long-term supply of contraceptives to the country with a combination of optimal price and quality of goods through international organizations have not been defined.

Law of KR #67 dated 22.05.2004 "On technical regulations in the Kyrgyz Republic" stipulates adoption of technical regulations on protection of human life and health.

Technical regulation #646 as of 25.09.2012 "On safe storage of medicines in pharmaceutical organizations and sanitary conditions of pharmaceutical organizations".

Technical regulation #137 dated 06.04.2011 "On safety of medicines for medical use".

Specified technical regulations are valid and are periodically updated.

Law of the KR #195 dated 19.10.2013 "On licensing and authorization system in the Kyrgyz Republic" states that medical activity and pharmaceutical activity are subject to licensure; manufacture and sale of vaccines and serums in specialized enterprises in the field of veterinary medicine. The turnover of narcotic drugs, psychotropic substances and precursors is regulated within the framework of separate licensing requirements for this type of activity.

In 2021, the new Criminal Code of the Kyrgyz Republic and the Code on Violations of the Kyrgyz Republic were adopted, which establish new levels of administrative and criminal liability for violations in the field of circulation of medicines.

Code on Violations of the Kyrgyz Republic #128 dated 28.10.2021 (e.g. Article 76 'Price gouging for sale of medicines and medical products during an emergency, state of emergency or martial law'; Article 77 'Violation of the order, requirements, and rules established in the

field of circulation of medicines and health supplies)'.

Criminal Code of the Kyrgyz Republic #127 dated 28.10.2021 (e.g. Article 294 "Illegal production and sale of medicines). Moreover, amendments are currently being made to the Code on Violations, the Criminal Code, as well as to the law on licensing and authorization system to strengthen liability. The draft law on amendments to the above-mentioned normative regulatory acts is under approval by the ministries'.

ANALYSIS OF STATUTORY FUNCTIONS AND RESPONSIBILITIES OF KEY STRUCTURES IN THE SPHERE OF PHARMACEUTICAL SUPPLY

The Ministry of Health of the Kyrgyz Republic manages the health system and develops health policy directions and measures to regulate the health system, including medicines provision and draft regulations of the health system.

The Mandatory Health Insurance Fund (MHIF) under the Ministry of Health consolidates government finance at the central level for strategic procurement of services from healthcare organizations.

Ministry of Health of the Kyrgyz Republic[40] is in charge of implementing key objectives on development and implementation of public policy including objectives related to enhancing accessibility of quality, effective and safe medicines and health commodities. In accordance with its mandate, MoH has 4 types of key functions, each of them reflects provisions of pharmaceutical public policy:

- functions of sector-specific policy: "designs and implements national, state and targeted programs on health protection and promotion, state guaranteed benefits programs, monitors and evaluates their implementation; shapes and implements public policy in the field of circulation of medicines and health supplies to provide the population and healthcare organizations with quality, effective and safe medicines and medical products;"
- regulatory function: "develops and introduces quality assurance and safety management system for medical and pharmaceutical services; arranges registration of medical and pharmaceutical personnel, issues adjudication for import and export of goods; issues licenses.... for pharmaceutical activities";
- coordination, control and oversight function: "coordinates activities on provision of medicines to the population and healthcare organizations of the Kyrgyz Republic and interaction with local pharmaceutical industry in the field of production and provision of medicines to the population and healthcare organizations, creating a List of Essential Medicines; ensures control over the rational use of medicines by healthcare organizations regardless of the source of procurement; determines the state social contracting and coordinates activities in the field of training and retraining of medical and pharmaceutical personnel, regardless of the forms and ownership and departmental subordination; provides support in the development of local production of pharmaceuticals and medical products;".

40 Decree of CM of #249 dated 15.11.2021 "On Ministry of Health of the Kyrgyz Republic".

service provision function: "undertakes activities on improving population health, involving civil society, mass media, and community organizations for starting a healthy lifestyle and increasing citizens' responsibility for their own health and health of other people;"

support function: "provides measures to improve infrastructure, facilities and resources of healthcare organizations; arranges keeping financial records for the receipt and use of resources irrespective of the source of funding, humanitarian aid, grants and loans provided to the healthcare sector, and ensures accounting and financial reporting on their use in the healthcare system; ensures development and support of Health Information and Communication Technologies; and determines the needs and carries out tender-based centralized procurement of goods, works, and services;". Department for Organization of Treatment and Prevention Care and Medicines Policy (Department of Quality of Medical Services and Medicines Policy) is directly involved in implementing the outlined functions[41] by developing pharmaceutical policy, which is implemented by subordinate structures of the Ministry of Health, according to the tasks assigned to them.

Ministry of Health procures vaccines and medicines for patients with diabetes mellitus, diabetes insipidus and hemophilia in line with Centralized Events (CE) and the High Technology Fund (HTF).

Subordinate agencies of the Ministry of Health (2 departments, one SE and 37 republican institutions) are independent legal entities directly reporting to the relevant deputy ministers and departments of the Ministry of Health. Directors of some of them are appointed by the Chairperson of the Cabinet of Ministers based on recommendations of the Ministry of Health, while others are appointed by the Minister.

Department of pharmaceutical supply and medical equipment (DPSME) is a national regulatory authority in the field of pharmaceutical products (including vaccines) and medical products; for control of the legal turnover of controlled narcotic drugs, psychotropic substances and their precursors; for regulation of activities in the sphere of circulation of medicines and health commodities within the framework of the Eurasian Economic Union. DPSME is run by a director appointed by the Chairperson of the Cabinet of Ministers based on recommendations of the Minister of Health.

Main tasks of DPSME are:

1. implementation of the state policy on providing the population and therapeutic health organizations of the republic with medicines, medical products and medical equipment;
2. organization of a management and control system for providing the population with safe, effective and quality medicines, medical products, medical devices, therapeutic nutrition and cosmetics;
3. identification of areas of activities and arranging the scientific research to improve methods of management and control and standardization of medicines.

As per the legislation of the Kyrgyz Republic in the sphere of circulation of medicines, procured health products should be registered in the Kyrgyz

41 https://med.kg/ministry/structure/222

Republic or included in a tailored list of medical products, which have permission for temporary import without registration. For sale of medicines and medical commodities, there are procedures for assessing the quality and issuing a decision on the quality of medicines and medical commodities for a specific series/ batch intended for distribution across healthcare facilities.

DPSME is responsible for issuing marketing permits, quality control and post-marketing supervision of medicines and medical products. Moreover, it carries out quality control of medicines[42]: each batch (lot) of pharmaceutical imported into the country or manufactured in the country, undergoes a quality assessment to establish compliance of quality with regulatory requirements. For this purpose, there was established the procedure for ensuring the traceability of medicines which are produced, imported and sold on the territory of the Kyrgyz Republic; for participants in the drug turnover and their functions, the procedure for their registration, ways of information exchange, the procedure for providing and requirements for using codes of e-labeling for medicines, and the procedure for providing information for EDB (electronic database) of medicines and health products.

Cabinet of Ministers of the KR has approved relevant resolutions (Resolution of CM of KR #53 dated 9.02.2023 "On introduction of traceability system of medicines in the Kyrgyz Republic", Resolution of CM of KR #136 dated 7.03.2023 "On registration, confirmation of registration and amendments to the registration dossier of medicines for medical use").

These regulations enable optimizing the state registration of pharmaceuticals and health commodities based on the principles of Good Regulatory Practices, including the procedure for accelerated registration of generic drugs registered in the ICH and PIC/S member countries.

DPSME performs the following functions: registration of medicines and health commodities, quality assessment, licensing, pharmacovigilance, promotion and advertising of medicines and medical products, pharmaceutical inspection, DPSME laboratories, Department for the control of legal drug turnover, regulation of prices for medicines, Department of good pharmaceutical practices. The required divisions have been formed in the structure of DPSME in line with specified functions.

National List of essential medicines and health products was approved by the Resolution of the Government of the Kyrgyz Republic #254 as of 6.06.2018 "On approval of national Essential Medicines Lists". This EML required revision.

Ministry of Economy and Commerce of the Kyrgyz Republic is a key state regulatory authority[43], and among the main tasks for designing government economic policy, MEC is assigned with the tasks of "formation of tax and customs policy; increasing the effectiveness of state regulation in the sphere of industry and improving legal and regulatory framework in the field of macroeconomic, trade, antimonopoly (except for the fuel and energy sector), customs tariff, licensing, foreign economic, tax, customs policy and

42 Resolution of CM of KR #53 dated 9.02.2023 "On introduction of traceability system of medicines in the Kyrgyz Republic".

43 https://mineconom.gov.kg/ru/ministry/regulation

administration of insurance payments; technical regulation, standardization and metrology;".

The functions of the sectoral policy of MEC encompass development of a unified state tax and customs policy; joint efforts with the EAEU on harmonization and improvement of customs legislation of the EAEU, and on the harmonization and improvement of legislation pertaining to technical regulation; business regulation policy in the licensing and authorization and control and supervisory spheres, on simplification and optimization of the procedure for obtaining licenses and permits; the unified state antimonopoly policy with enhancement of legislation on consumer protection, advertising, improvement of the procedure for the formation and application of prices (tariffs);

regulatory functions: intersectoral coordination of the activities of state bodies in the sphere of technical regulation; regulating the activities of conformity assessment bodies; issuance of permits (license/permit/adjudication) for the export/import/transit of specific goods and services; creating and maintaining the national part of the Unified register of issued certificates of conformity and registered declarations of conformity of the EAEU; forming the list of products subject to mandatory conformity assessment; authorizes bodies to assess (confirm) compliance with the requirements of technical regulations; etc.

Ministry of Finance of the Kyrgyz Republic[44] is the central executive authority responsible for the development and implementation of state policy on public financial management; internal audit, accounting and financial reporting of general government sector; budget crediting; public procurement, etc.

The MoF finances healthcare organizations through MHIF and partially some HCO through the MoH that are not included in the MHI system, for instance, public health programs, medical education, rehabilitation centers, centralized events, and the High Technology Fund.

Apart from the state budget for medicines, which contribute to the provision of medicines in the public sector, there are other funding systems (international donors, charitable contributions and direct household expenditures for medicines).

The ongoing reforms in the sphere of public finance management in healthcare are aimed at improving the rationality and efficiency of public spending through introduction of programmatic budgeting in line with Program 2030.

Mandatory Health Insurance Fund (MHIF) is a single payer covering the state guaranteed medical services, and a separate law defines its budget. In spite of transferring MHIF to MoH of KR, its budget is separate from the budget of MoH of KR.

MHIF consolidates funds from the state budget (MoF), MHI funds, co-payments from patients and other funds (e.g. from external donors) and allocates them to healthcare organizations. The purpose of subsidized medicines provision through MHI funds is ensuing accessibility and affordability of pharmaceuticals and medical products for patients at outpatient level.

44 http://cbd.minjust.gov.kg/act/view/ru-ru/158728?ysclid=llq2nvzg9c335004966

The main principles are 1) mandatory prescription of medicines, 2) approval of the list of medicines according to INN and the amount of compensation depending on the dosage form, and 3) co-payment by the patient for medication.

The role of MHIF in providing the population with essential medicines is to administer 2 programs of subsidized treatment in an outpatient setting:

- as per SGBP for free treatment of socially significant diseases (patients with diabetes mellitus, diabetes insipidus, hemophilia and TB; and for patients with paranoia, schizophrenia, affective disorders, epilepsy, bronchial asthma and patients with late stages of cancer).
- as per ADP MHI, which allows insured citizens to procure medicines through the system of electronic prescriptions from family doctors, with partial reimbursement of the cost of medicines, including contraceptives.

The insured population, MHIF, outpatient HCO, a network of retail pharmacies (more than 180 in the country) participate in subsidized medicine provision. The list of medicines and the amount of compensation, the procedure for the release of subsidized pharmaceutical products is regulated by agreements between pharmacies and MHIF.

In hospitals, patients are provided with medicines as direct expenses of healthcare facilities, funded by MHIF in the Single Payer system. All medicines should adhere to provision of Clinical protocols/ Clinical guidelines, in the framework of Essential Medicines (EML). It is allowed to procure additional medicines and health commodities at up to **20%** of EML, in accordance with the profile and specifics of the hospital. Nevertheless, the number of pharmaceuticals covered by these programs is limited, as is the number of insured citizens; therefore, the level of out-of-pocket payments by patients is high[45].

There are no considerable changes in the new version of the SGBP in comparison with the current version in terms of medicines provision.

The charter of state enterprise "Kyrgyzfarmatsiya" under the Ministry of Health of the Kyrgyz Republic (hereinafter referred to as SE) regulates the activities of SE[46] and defines that the objectives of the activity "are to make a profit, as well as the implementation of state programs and socially oriented projects of the Cabinet of Ministers of the Kyrgyz Republic, enhanced satisfaction of the needs of state medical organizations and other consumers for services on supply of medicines and health products."

As per the Charter, the functions of the SE encompass entering into agreements for supply of medicines and medical equipment; storage and transportation of medicines; centralized direct supplies of medicines to meet the needs of state healthcare centers; wholesale and retail supplies of medicines; import of pharmaceuticals in line with the established procedure; export and import of medicines; wholesale and retail sale of medicines and production of medicines; pharmacy-based preparation of medicines; the sale of

45 Moldoisaeva S., Kaliev M., Sydykova A., Muratalieva E., Ismailov M., Madureira Lima J., Rachel B. Kyrgyzstan: review of the healthcare system. "Health system review: a time for change". 2022; 24(3): i-152

46 Resolution of CM of KR #176 dated 30.03.2023

narcotic, psychotropic substances and their precursors in accordance with the established procedure. SE can perform the function of a representative and/or distributor of factories and manufacturers of medicines and related products. Functions such as

– "selects manufacturers and distributors of medicines;
– provides medicines to state health centers in line with order of authorized state bodies;
– assists with creation of an emergency supply (reserve) of the most common medicines" necessitate an anti-corruption analysis of this regulatory act.

Subject to reservation "within its competence", SE develops measures to ensure effective implementation of state policy on corruption prevention; designs draft normative legal acts on implementation of anti-corruption policy in the field of circulation of medicines; develops and implements projects on public-private partnership, etc. Whereas, the outlined measures should relate to the SE's own activities, but not to the industry as a whole.

There are some editorial inaccuracies:

– in terms of the competence of the MoH of KR on amendments and approval? of SE Charter (clause 11, sub clause 1);
– in terms of participation in SE (membership) of associations in the form of associations, unions, foundations that are non-profit or commercial organizations in agreement with MoH of KR (not required by the Civil Code) (clause 19, paragraph 11);
– on development and approval of "sectoral performance indicators of the financial and economic activities of the Enterprise" (MoH); "approval of key performance indicators of the Head of the Enterprise and his/her deputy" (State Property Management Fund/ SPMF).

It ought to be mentioned that the SE should operate based on a 3-year strategic development plan (business plan), which is described in Chapter 6. Financial and economic activities, accounting and reporting. According to the Charter: "The strategic development plan should contain:

1. formulation of the goals and main areas of activities of the Enterprise;
2. description of the industry and market, characteristics of the goods (works, services) produced by the Enterprise;
3. justification of the need for the presence of the state in the market of goods (works, services) produced by the Enterprise;
4. assessment of the financial and property status of the Enterprise;
5. plan for production of goods (works, services);
6. organizational plan;
7. financial plan;
8. risk analysis.".

As per the Charter, MoH approves this development plan; and the role of SPMF is not defined. Hence, the tasks and functions of key bodies in the context of the SCM lack detailed provisions on the SCM, and it is scattered/unsystematically indicated in the functions of the DPSME. Upon adoption of amendments to the laws, the next step is to review the above-mentioned provisions of state bodies and their structures.

The Resolution of Government of the KR# 376 dated July 8, 2014, approving the Program of the Government of the

Kyrgyz Republic for the development of the sphere of circulation of medicines in the Kyrgyz Republic for 2014-2020, was adopted with the purpose of developing pharmaceutical sector of the country, in continuation of the previous program of the National Medicines Policy (2007-2010). This Program was an essential part of the country's health program, in the format a detailed activity plan for development of pharmaceutical sector.

As part of implementation of this Program, significant efforts were made to improve the legislation in the sphere of circulation of medicines; to introduce a National database of medicines and a codifier of medicines in the electronic public procurement system; as well as to enhance mechanisms for regulating the market of medicines in the framework of the country's integration into the Eurasian Economic Union.

At the end of 2021, with the support of the WHO Country Office in the Kyrgyz Republic, this Program underwent an external evaluation by specialists of "Legal Alliance" legal company. The recommendations of this review regarding the improvement of regulatory control of pharmaceutical sector are reflected in new draft laws on the circulation of medicines and health commodities; in the adopted resolutions of the Cabinet of Ministers of the KR on registration and quality assessment. It should be mentioned that in spite of a detailed and systematic review of the Program, and accordingly of individual links in the logistics of the supply chain of medicines and health supplies, there is no analysis and recommendation on strengthening/ creating a strong sustainable supply chain of pharmaceuticals and medical products as a unified process and system[47].

RELEVANT EAEU SOLUTIONS AND AGREEMENTS ON PHARMACEUTICAL SUPPLY

In the frame of Kyrgyzstan's participation in the implementation of the Strategic Directions for Development of Eurasian Economic Integration until 2025, upon completion of the formation of a common market with guarantees of quality and safety of goods, considering the formation of the digital space of the EAEU, the country actively transitions to the rules for regulating the circulation of pharmaceuticals and health products[48] in line with the regulatory requirements of the EAEU, which are focused on strengthening control (unlike the European regulatory model envisaging strengthening the monitoring functions of regulators while increasing the responsibility of manufacturers). The pharmaceutical sector is one of the first where a common market was established within the framework of the EAEU.

Kyrgyzstan's membership in the EAEU requires adaptation from the national regulatory system to the ever-increasing requirements of the EEC. The slogan "Think globally, act locally" is relevant.

Registration process of medicines can be divided into 3 main stages: 1) the last (before July 1, 2021), when national registration procedures were applied; 2) the current stage (from July 1, 2021 to December 31, 2025), which is the period

47 Report on the results of the analysis of the implementation of the Program of the Government of the Kyrgyz Republic for the development of the sphere of circulation of medicines in the Kyrgyz Republic for 2014-2020. The period of the analysis - 12.11.2021-30.12.2021

48 Decision of the Council of the Eurasian Economic Commission #78 as of 03.11.2016.

of transition from the use of national registration procedures to the EAEU procedures; and 3) the future stage (from January 1, 2026 onwards) when the EAEU registration procedures will be in effect.

The full transition to the rules for regulating the circulation of medicines within the EAEU should be finalized by December 31, 2025. This significantly increases the burden on DPSME and complicates regulatory mechanisms in the sphere of circulation of medicines and medical products, and requires ongoing improvement of the capacity of employees.

DPSME participates in optimization of regulatory support for medicines turnover to align national standards in accordance with decisions in the EAEU. This process concerns:

- general requirements to the safety and efficacy of pharmaceuticals and medical products (96 documents regulating the circulation of pharmaceuticals and medical products in the EAEU). [49]
- rules for the classification of health commodities, their registration, testing for safety, quality and effectiveness;
- rules for registration and examination of medicines, labeling requirements, rules for maintaining nomenclature lists of medicines and good manufacturing and distribution practices in relation to medicines.

INTERNATIONAL EXPERIENCE ON INTEGRATED SUPPLY CHAIN OF PHARMACEUTICALS AND HEALTH COMMODITIES IN PUBLIC HEALTH

Public health supply chain of medicines and health commodities is an extensive and complex network of systems, components and processes that collectively serve the purposes of manufacturing, distributing and ensuring access of patients to medicines and medical products while maintaining their quality and effectiveness at various stages of the supply chain.

For achieving better health outcomes, it is required to have a sustainable supply chain of medicines and health commodities. Despite the fact that many Governments in low- and middle-income countries have increased funding and improved the system for procurement of medicines and health products for treatment of patients, investments in broader supply chains that deliver these goods to the end users (patients) are often delayed. As a result, even if products are available in central warehouses, HCO may experience shortages, or the shelf life of products in warehouses may expire due to the lack of an integrated supply chain management system, including financing and trained personnel. Therefore, investments in the supply chain and their strengthening are just as important as procurement of pharmaceuticals and health commodities.

Countries should integrate supply chain management in their strategic plans and financing schemes. Investment in the creation of integrated and sustainable systems for supply of medicines and health products managed by qualified and effective personnel, is necessary for

49 https://eec.eaeunion.org/comission/department/deptexreg/formirovanie-obshchikh-rynkov/

ensuring coverage of health services in stable and unstable times.

Many countries have several parallel logistics systems for selecting, procuring, and distributing different types of supplies to clients/patients. Often health programs - family planning, reproductive health, malaria control, TB control, or HIV and AIDS - each manage and distribute supplies for their programs. These programs are called disease-specific programs (sometimes called vertical programs) and, historically, have often had separate standard operating procedures and distribution channels and may be managed by separate management units at the central level.

Procuring, storing, or delivering all of these products in the exact same way does not make sense and will not achieve **100%** availability. At the same time, it is important to attain efficiencies in the supply chain whenever possible, so that efforts are not duplicated and available resources can be used to their fullest.

All operations/actions performed in the logistics cycle (e.g. product selection, procurement, warehousing and distribution) are all steps in an interconnected process. Data on consumption of products is necessary for quantification to procure the right quantities of products. Likewise, product selection can have an impact on warehousing and distribution, as the attributes of products can influence warehouse and transportation requirements.

It is crucial to closely interact with employees performing various operations/ actions at different levels of the system (central, regional, district, health facilities level) in the supply chain. When reporting and ordering processes are provided, this contributes to the correct forecasting of the demand for pharmaceuticals and health products. Partners across programs, organizations, and sectors must work together in a coordinated way. When international donors harmonize the data they require from national supply chain managers, it allows busy health system staff to streamline their information systems and focus on other important task.

Consequently, an integrated approach to supply chain management takes a whole system perspective, rather than looking at separate activity, such as a LMIS or warehousing; or separate programs, such as HIV and AIDS or malaria; or separate levels, such as central or regional. Integration results in a more cost-effective, agile, and reliable supply chain, yielding lower stock out rates, reduced costs, and better order fulfillment rates.

Countries typically move through an evolution process to achieve an integrated public health supply chain. While every country and supply chain is different, the path to integration generally goes through three sequential phases as illustrated in Figure 1.

Zooming out to supply chain management more broadly, an integrated supply chain has seamless links among the various actors, levels, and functions within a given supply chain to maximize customer/patient service, to ensure that clients/patients have access to quality health care services, medicines and health supplies wherever and whenever they are needed. Thus, an integrated supply chain is a cost-effective, operational and reliable system that unites all participants involved in the management of medical products into a unified supply chain

management organization. Integration leverages resources from all parts of the supply chain and enables rational implementation of innovations and new technologies to improve the system.[50]

50 John Snow Inc.(JSI), 2020. The supply chain Managers Handbook. A practical guide to the management of health commodities.

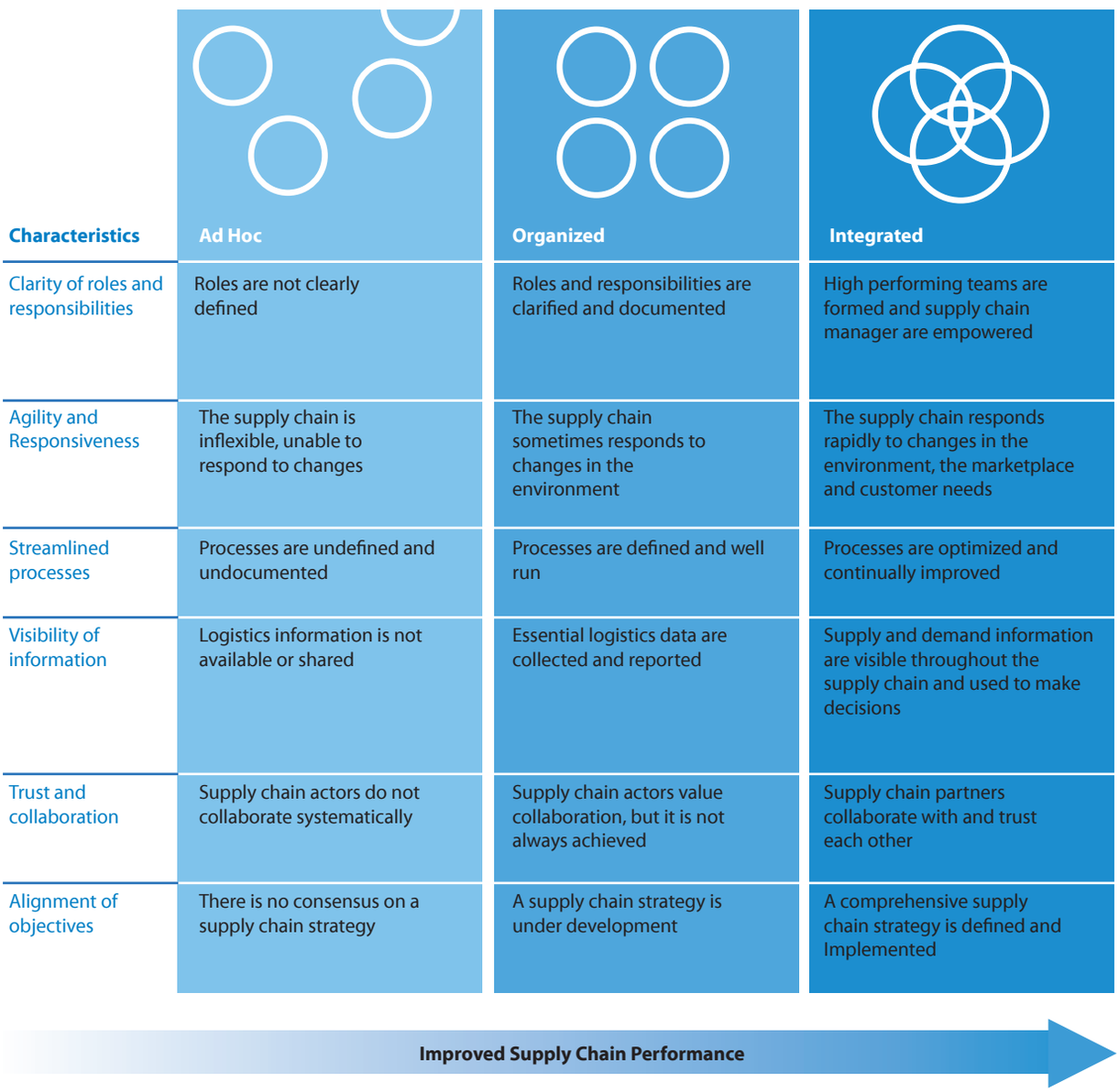

Figure 1. Supply chain evolution

Ad hoc phase: Stakeholders have little common understanding of what the supply chain looks like and have no formal procedures for its operation, leading to fragmented supply chain efforts across various entities in the system.

Organized phase: Standard supply chain systems, including MIS (management information system), are designed and implemented, roles and procedures for basic logistics functions are clarified, and sufficient financial and human resources are mobilized to operate the system.

Integrated phase: People, functions, levels, and entities of the supply chain are linked and managed under an interconnected supply chain organization. Supply chain managers are empowered and understand how to collect and use information to map the system and streamline processes, use resources more effectively and efficiently, monitor and improve performance, and align various supply chain partners to achieve common goals.

The supply chain managers should understand where their supply chain exists on the evolution continuum, and identify how to move the supply chain along this continuum, towards integration. Analysis can be conducted - whether singularly focused or multidimensional - to identify supply chain performance drivers and bottlenecks, and formulate actionable solutions.

In the frame of exercise based on Supply Chain Compass conducted in the Eastern Europe and Central Asia region – Kyrgyzstan and Uzbekistan (2020), it was found that in Kyrgyzstan, the supply chain overall is moving from the ad hoc to the organized phase, with various areas in need of support to strengthen supply chain maturity. The processes for forecasting and planning supplies, product selection and procurement, warehousing and inventory management are at the most organized stage. In Uzbekistan, the level of integration of supply chain was assessed as achieving the highest level and all stages are in the organized phase. Several functions have a relatively high level of process development but lack comprehensive and cohesive strategies that link them together.

ANALYSIS OF CURRENT SITUATION IN PHARMACEUTICAL SUPPLY CHAIN MANAGEMENT OF KR TO IDENTIFY GAPS IN EXISTING NATIONAL MECHANISMS OF SUPPLY CHAIN MANAGEMENT (SCM) INCLUDING LOGISTICS MANAGEMENT INFORMATION SYSTEM (LMIS):

Logistics cycle of health commodities

The structure of report on the analysis of the current situation in supply chain management considers various stages of the logistics cycle of medicines and health products on the territory of the Kyrgyz Republic. It aims to identify aspects related to quality assurance at each stage, comparison of current practices with international best practices, and developing short-term, medium-term, and long-term recommendations. The supply chains of pharmaceuticals and health commodities consist of well-defined stages.

The HCO personnel involved in the logistics cycle should be aware of all the problems that exist at each stage of the supply chain. A full and comprehensive understanding of these issues will contribute to a more efficient operation, greater transparency and reliability of the supply chain.

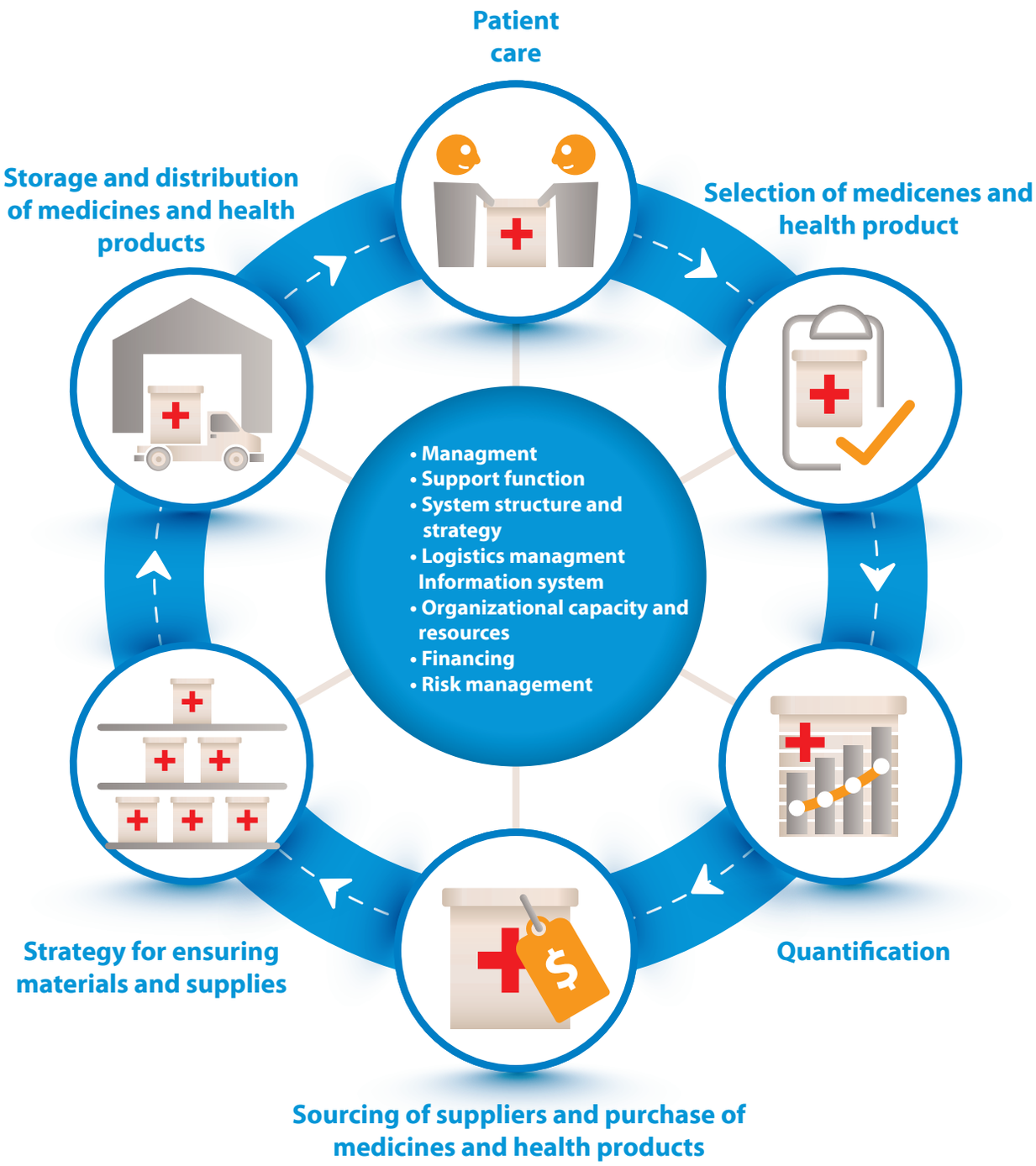

Figure 1. Logistics cycle of pharmaceuticals and health commodities in the Kyrgyz Republic

Key types of activities in the logistics cycle encompass:

1. Selection of medicine/product (medicines and health commodities): availability of medicines and health products of guaranteed quality (GMP) on the market, compliance with standard treatment guidelines.
2. Quantification and budget planning: data collection and quality, access to market prices.
3. Selection of sources and procurement: availability of medicines and health commodities of guaranteed quality (regulatory system), procurement processes and procedures, quality of technical specifications, customs and import restrictions, procurement legislation.
4. Inventory management strategy: warehouse management systems, data quality and data management.
5. Acceptance, warehousing and distribution: quality control testing, physical storage, standard operating procedures, distribution volumes.
6. Customer service: patient data and post-marketing surveillance (PMS), analysis of consumption data, pharmacovigilance to confirm compliance with safety standards.

The logistics cycle center consists of management functions that support the operational components:

1. Logistics Management Information System (LMIS)
2. Personnel involved in supply chain
3. Financing
4. Performance management.

Key questions of assessment and its results

Strategic planning and implementation management

In Program of the Government of the Kyrgyz Republic on public health protection and healthcare system development for 2019-2030 "Healthy person, Prosperous country"[51] and vertical health programs such as Reproductive health[52], Immunoprophylaxis[53], Tuberculosis[54], HIV/AIDS[55] proper functioning of supply chain of pharmaceuticals and medical products is considered as an essential component of ensuring adequate access to medicines and health products.

In the framework of these vertical health programs, the issues of strengthening the supply chain are included as priorities, and the approaches to addressing them are the most rational from the perspective of view of organizing the supply chain of pharmaceuticals and medical commodities. The supply chain of vertical programs, as far as possible, is integrated into the existing health care system and is an

51 On Program of the Government of the Kyrgyz Republic on public health protection and healthcare system development for 2019-2030 "Healthy person, Prosperous country", Resolution of GKR #600 dated 20.12.2018 http://cbd.minjust.gov.kg/act/view/ru-ru/12975?cl=ru-ru

52 Program of seven-year plan on gradual increase in public-sector funding to satisfy demand for family planning of women from groups of high medical and social risks of maternal mortality until 2030.

53 "On approval of the Immunoprophylaxis program for 2020-2024, Resolution of the Government of the Kyrgyz Republic" #609 dated December 16, 2020, http://cbd.minjust.gov.kg/act/view/ru-ru/94223

54 The program of the Cabinet of Ministers of the Kyrgyz Republic "Tuberculosis-VI" for 2023-2026, Resolution of the Cabinet of Ministers of the Kyrgyz Republic #118 dated March 3, 2023.

55 The program of the Government of the Kyrgyz Republic on overcoming HIV infection in the Kyrgyz Republic for 2017-2021, Resolution of the Government of the Kyrgyz Republic #852 dated December 30, 2017, http://cbd.minjust.gov.kg/act/view/ru-ru/11589

example of an integrated approach[56], considering medicines and health products as important part of medical care.

56 "On approval of Standard Operating Procedures (SOPs) for the delivery and dispensing antiretroviral (ARV) drugs in healthcare organizations and at community level", Order of MoH of KR #622 dated August 14, 2020.

Interventions of vertical programs

Program	Intervention
Tuberculosis	Developed and approved "Practical guide to the management of anti-tuberculosis drugs" (Order of the MoH of KR #449 dated 20.04.2021) is developed and approved Based on this document, the Procedures for managing a pharmacy and conducting quality control of medicines in public health organizations have been developed and approved (Order of the MoH of KR # 523 dated 04.05.2023) These Procedures are intended for employees of health organizations' pharmacies and cover all pharmacy management operations, from receipt of medical supplies and to final delivery to patients. It encompasses the basic principles of Good Storage Practice, Good Pharmacy Practice and quality control applicable to any organization with stocks of medicines and health commodities, including ATD (anti-tuberculosis drugs), in any supply chain (medical supplies) Analysis of the assessment of the rationality of the use of medicines and spending of budgetary funds for medicines provision in National Center for Phthisiology according to the ABC/VEN methodology is carried out
HIV/AIDS	SOP for the delivery and dispensing of antiretroviral (ARV) drugs in healthcare organizations and on community level was developed and approved
Immunoprophylaxis	Resolution of the Government of the Kyrgyz Republic #609 dated December 16, 2020 approved a new Program "Immunoprophylaxis" for 2020-2024 SOPs on effective vaccine management in healthcare organizations of the Kyrgyz Republic have been introduced
Reproductive health	A document has been adopted reflecting all components of contraceptive supply chain "Program of seven-year plan on gradual increase in public-sector funding to satisfy demand for family planning of women from groups of high medical and social risks of maternal mortality until 2030". (Order of MoH of KR #1142 as of September 22, 2023 "On Approval of the Program of the seven-year Plan for publicly funded contraceptives procurement in the frame of implementing five new commitments of the Ministry of Health of the Kyrgyz Republic under FP2030") Contraceptives are added in ADP MHI of MHIF The allocation of funding for procurement of contraceptives for socially vulnerable groups of women has been advocated, and the process is sustainable

Strategic planning of supply chains is the foundation for interaction of internal and external economic processes, factors and phenomena to determine the most promising areas of supply chain activity, ensuring its efficiency and effectiveness.

Currently, a unified Strategic plan for the development of the supply chain of medicines and health commodities in the Kyrgyz Republic has not yet been developed to implement the above program documents.

The healthcare system has approved accounting and reporting forms for medicines and health products, numerous forms are manually maintained directly by medical personnel, some of the forms are part of separate information systems. Theoretically, it is possible to collect data at the central level, but it is time-consuming, and in most cases, it is data on procured or consumed medicines and medical products. With the right design of information systems, it will not be difficult to collect such data at the central level.

The issue of measuring the effectiveness of the functioning of systems is a new task for health system in the KR, since there is a lack of basic reporting forms and methods for collecting information in relation to indicators on the effectiveness of the supply chain of medicines and health commodities.

In the current situation, it is impossible to timely assess the situation pertaining to the availability of medicines and health commodities and prevent failures in the supply chain, assess risks and take measures to mitigate them.

In the structure of the Ministry of Health, it is advisable to create a unit responsible for coordination and monitoring of the availability of pharmaceuticals and health products and evaluating the effectiveness of pharmaceutical supply system as a whole.

The supply chains of pharmaceuticals and medical products are mainly represented by pharmacy warehouses, pharmacies/pharmacy points/pharmacy kiosks of the private sector and a small number of government warehouses and hospital pharmacies. All healthcare organizations (hereinafter referred to as HCO), including FMC/FDG/FAP, store and distribute medicines and health supplies received by them through public procurement or as humanitarian aid.

The main part of medicines and health products is procured by HCO independently from private suppliers through competitive (tender) procedures. A small group of medicines and medical commodities is purchased by the Ministry of Health: insulin, contraceptives, tuberculin, vaccines, medicines and health commodities in the frame of High Technology Fund, etc., which are stored in state warehouses (DPSME, Republican Center for Quarantine and Highly Dangerous Infections (RCQ&HDI) and further distributed across HCO. Pharmaceuticals and medical products procured in the frame of vertical programs arrive at the warehouses of DPSME, NCF, RC AIDS, RCI.

Resolution of the Cabinet of Ministers of the Kyrgyz Republic 176 dated March 30, 2023, approved establishment of State Enterprise "Kyrgyzfarmatsiya" (SE) under the Ministry of Health of the Kyrgyz Republic. The purpose of creating a SE, implementing a new approach to providing state health centers and the population of the Kyrgyz Republic with medicines and medical products at an affordable price. Procurement of pharmaceuticals and health commodities should be carried out on a non-competitive basis (without tenders), by direct conclusion of a supply contract with manufacturers of medicines and health products. During the first stage, the SE analyses applications and takes necessary measures for upcoming procurement of medicines and health products for Centralized Events (CE) and High Technology Fund (HTF) for a proper provision of patients with essential medicines and timely disbursement of allocated funds. HCO prepare applications for pharmaceuticals and health commodities for the coming year based on the order of the Ministry of Health of the Kyrgyz Republic #649 dated May 30, 2023. The SE accepts applications, analyzes and takes the necessary procurement actions.

In line with HTF, it is expected to purchase and supply all items according to the application and their distribution plan. As for FMC, procurement and delivery of the following medicines is expected: ARV, anti-tuberculosis drugs, anti-diabetic drugs, influenza vaccine, tuberculin and contraceptives.

Further, it is expected to expand the activities of the SE with full coverage of the provision of medicines and health products for all HCO.

Individual activities, such as support for information systems on medicines and health products, training of specialists, payments to the staff responsible for storage, accounting and distribution of medicines and health supplies, maintenance of warehouses and refrigerators are funded by HCO themselves, which will allow collecting data on the operating costs of servicing the supply chain of a particular HCO and using them to manage resources on their level, if necessary. The collection of such data is currently not required on a routine basis.

Within the framework of centralized procurement at the level of the Ministry of Health or MHIF, there are no separate budget lines for activities on maintenance of supply chain of pharmaceuticals and medical products due to the lack of such a task in the framework of monitoring public expenditures and the lack of information collection tools.

There is a Country Committee[57] on combating HIV/AIDS, tuberculosis and malaria, which aims to ensure coordination and interaction of interested government agencies, as well as non-profit and public organizations in addressing issues related to HIV/AIDS, tuberculosis and malaria. The issues of providing medicines and health products are also included in the activities of this Committee.

There is no such official body dealing with supply chain issues for all pharmaceuticals and health products. It is worth noting the activity of the civil sector (non-governmental and patient organizations) and international organizations, which have a good capacity for cooperation and coordination of stakeholders.

The activities of suppliers providing medicines and medical supplies are regulated by legislation in the sphere of circulation of pharmaceuticals and health products, in the field of circulation of narcotic and psychotropic substances, in the field of public procurement, in the licensing and authorization system, and in the field of inspections of business entities. To carry out pharmaceutical activities in the Kyrgyz Republic, an appropriate license is required from the Ministry of Health of the Kyrgyz Republic. Public procurement of medicines and medical products is carried out on a competitive basis. In addition, starting from 2023, procurement of medicines and health supplies is partially undertaken without competitive procedures, by direct conclusion of an agreement with manufacturers of medicines and health products through Kyrgyzfarmatsiya State Enterprise.

Requirements of the current legislation in the field of circulation of medicines [58] on introduction of Good Pharmacy Practices (GPP - GMP, GDP, GPP, GPP, GSP) in the activities of pharmaceutical organizations is a good prerequisite for strengthening supply chains in the future. The legislation defines a transition period for the implementation of the GPP until December 31, 2025.

There are contradictions and gaps in the legislation of the Kyrgyz Republic that hinder the effective functioning

57 Committee on Combating HIV/AIDS, tuberculosis and malaria under the Coordinating Council for Public Health under the Government of the Kyrgyz Republic, http://hivtbcc.kg/pages/mission.html

58 The Law of the Kyrgyz Republic "On the circulation of medicines", # 165 dated August 2, 2017, http://cbd.minjust.gov.kg/act/view/ru-ru/96634

of state regulation of the circulation of pharmaceuticals and medical products, which puts the lives of citizens at risk. However, the process of improving legislative norms and by-laws is ongoing.

Ключевые рекомендации:

1. **Involve all key stakeholders (Government, donors, non-governmental organizations, private sector, academia) in identifying and prioritizing key supply chain issues to address them:**
   - **Key stakeholders should be organized into a permanent working group/subgroups to coordinate strategy development and further implementation.**
   - **Create a coordinating body for supply chains of pharmaceuticals and health commodities, determine its status and functions, and include representatives of all stakeholders.**
2. **Analyze the overall medicines and health commodities market to meet the needs of clients/patients and strengthen the role of the public sector in oversight of the market in general to satisfy the demand for all essential goods.**
3. **Develop basic implementation and performance monitoring tools:**
   - **Design a strategic plan for the development of supply chains of pharmaceuticals and health supplies.**
   - **Identify key performance indicators (KPIs) for all functions in the supply chain.**
   - **Start the process of strengthening supply chains based on the development of a strategic plan for enhancement of supply chains of medicines and health products to create an integrated inventory and supply management system for pharmaceuticals and medical products.**
   - **Determine the structure for basic reports for monitoring the effectiveness of the supply chain, forms for communicating them to all interested parties (open access publications, public discussions, etc.).**
   - **Undertake an inventory of all approved reporting forms on medicines and health products in the health care system and assess their information capability as information collection tools, and modernize them if necessary.**
   - **Identify effective ways for collecting information (to provide, as far as possible, in the design of IS)**
   - **Implement administrative regulations, standard operating procedures for all components of the supply chain**
4. **Implement a cost collection and estimating system to manage all major supply chain functions..**
   - **Collect and evaluate the cost of managing all major supply chain functions by conducting cost estimates within the supply chains.**
   - **Develop financial monitoring tools to ensure adequate financing of all functions within supply chains and departments at all levels.**

Information Systems Management

The key prerequisite for development of a transparent and accountable healthcare system is creation and implementation of high-quality digital infrastructure and technologies. In this aspect, information systems (hereinafter referred to as IS) are the main management tool enabling systematizing the variety of business processes in the supply chains of medicines and health products and receiving structured information in a timely manner. The correct design of IS for pharmaceuticals and medical products and their integration with the processes of providing health services can significantly enhance the quality of medical care, particularly in cases when the availability of medication is a critically important condition in the treatment of patients or maintaining their health.

In line with digital transformation of the country, outlined in many government decisions, information systems for all regulatory processes should be introduced to transfer the relationship between business and regulatory authorities to a digital format. Overall, activities are underway to digitalize processes

in the healthcare sector, but there is a fragmentation of information systems in health system, when all information is stored in different places, and there is weak operational interaction. Information systems and databases support different data formats, which leads to their insufficiency and low quality.

In the framework of vertical health programs, there is no unified electronic tool for the supply chain of medicines and health supplies. As per the analysis, not all supply chain processes are automated using electronic tools. Existing electronic tools are used fragmentarily (they vary at different levels). Most business processes are duplicated while using both information systems (electronic and paper-based). Use of digital tools does not cover/ covers the level of FDG/FAP.

Due to the insufficient level of automation of the medical care process, a large amount of information is duplicated, and maintenance of information and systems requires considerable time. There is a lack of measures to ensure full protection of information and data. The existing structure of the supply chain also affects the fragmentation of IS and its participants, since there is no proper information interaction between the private and public sectors.

Regarding public health organizations, they use an automated accounting system with a unified software "1C: Accounting". Designed for accounting purposes, it cannot fully replace the information system for managing the logistics of pharmaceuticals and medical products. In some HCO, the management has made attempts to implement "1C: Warehouse/ Pharmacy" to have complete information about the movement of medicines and health commodities inside the hospital, however, the launch of this system will not allow data aggregation and exchange between all HCO, which will prevent from carrying out digitalization measures related to business processes of medicines and health commodities supply. In addition, the use of a single 1C: Accounting software product does not mean that the country has an integrated database of accounting departments of all HCO. This software is used autonomously by each HCO, while integration into a single repository is impossible due to technical limitations.

In case if it is required to track the movement of medicines and medical products within the framework of a specific vertical program (TB, HIV/AIDS, contraceptives, etc.) it is impossible to do this centrally at the level of existing information systems, for example, 1C: Accounting. This situation encourages HCO to appeal to international (donor) organizations supporting individual health programs so that to create their own LMIS to solve specific tasks:

- Reproductive health - "CHANNEL"
- Tuberculosis - "Pharmacy" in the frame of health information system "TB HIS", QuanTB
- HIV/AIDS - within the framework of IS "Electronic monitoring of HIV cases in the Kyrgyz Republic"
- Immunoprophylaxis - within the framework of the Immunization Information System (IIS) (at the implementation stage).

Hence, in the country, each vertical program has implemented/implements LMIS to proper management of supply of medicines and medical products within the scope of its goals and objectives. Logistics Management Information System (LMIS) is a record-keeping and reporting system, whether in paper-based or electronic

format, used to accumulate, analyze, verify and display data (from all levels of the logistics system) that can be used to inform logistics solutions and supply chain management.

LMIS tools include:

- Systems for dispensing medicines and health products or customer/patient service delivery points that track medicines consumption in healthcare organizations.
- Electronic solutions in LMIS (e-LMIS) for reporting, sending requests for pharmaceuticals and medical commodities and their distribution, data visualization and warning users about efficiency problems.
- Warehouse management systems for inventory control.
- Fleet management systems for transportation and loading planning.
- Distribution planning systems for loading and route planning.
- HCO resource planning systems that manage many of these core functions, but also encompass finance, human resources, procurement, and other business functions.
- Development and use of standard treatment guidelines.

Characteristics of information systems on pharmaceuticals and medical commodities for vertical programs:

Program	LMIS	Objective
Reproductive health	Software "CHANNEL" It is installed in RHPC (Republic Health Promotion Center), at warehouse of DPSME and HCO at PHC level. The system was evaluated 59	It covers all stages of the supply chain, from determining the needs and forecasting to the provision of contraceptives to the patient. CHANNEL enables managing any quantities and types of medical commodities, including reproductive health products, essential medicines, vaccines and pharmaceuticals. This is a network software system and can be installed to enter data from several computers connected to a computer network. It allows tracking supplies and inventory levels in healthcare organizations. It provides an opportunity to summarize information across the country. CHANNEL software was tested in FMC #7 in Bishkek. This process was not taken to the next stage due to the lack of financial resources and termination of contraceptives supply by donors.
Tuberculosis	QuanTB	Forecasting the needs and placing a request for the supply of anti-tuberculosis drugs. The prediction is based on actual consumption data, defined as the number of medications given to patients, and statistical data on the incidence rate. NTP (National Tuberculosis Program) was launched in 2016 with support from USAID/KNCV

59 Independent evaluation of Contraceptives Logistics Management System and other related issues, UNFPA

Program	LMIS	Objective
	«Аптека» в рамках «ТБ МИС»[60] It is installed in NCF and in some health facilities for anti-tuberculosis care at provincial level.	It enables automatization of routine actions of medical staff for treatment of patients, forecasting, monitoring and record keeping of stocks of anti-tuberculosis drugs in healthcare organizations. The module provides control and accounting of all stocks of anti-tuberculosis drugs and health commodities (including tuberculin). • shows the balance of anti-tuberculosis drugs in the warehouse of health facility for anti-tuberculosis care in the context of types of financing; • shows/the possibility of entering a request/requests for anti-tuberculosis drugs for each tuberculosis patient from the warehouse of the hospital pharmacy; • shows the movement of anti-tuberculosis drugs inside the warehouse of the facility, and from the facility warehouse to the warehouse of the facility; • enables generating the reports, for example, on the turnover and the balance of anti-tuberculosis drugs; • provides opportunity for interacting with another software; • it is available in Russian language. The above-mentioned information enables ensuring the management and specialists working in the sphere of management of pharmaceuticals and health products and treatment of patients with high-quality information for inventory management, forecasting the demand, procurement planning and distribution of medicines and medical commodities, and ensuring patient safety. The module was introduced 2020 with support of the USAID Cure Tuberculosis project and is integrated with the electronic health record of a TB patient and the clinical module for TB patient surveillance. The tool facilitates summarizing information on medicines and health products throughout the anti-tuberculosis service.
ВИЧ/СПИД	IS "Electronic HIV case tracking in the Kyrgyz Republic61 It was piloted in Bishkek AIDS Center It is planned to scale it up across the country	The program is linked to patients, which allows forecasting the demand, and also provides an opportunity to track the movement of ARV drugs from the moment they are received at the central warehouse of the AIDS Center, their subsequent distribution by regions, and its release to the patient. The program also tracks the duration of the course of treatment from the moment the drug is dispensed to patients and enables identifying non-compliant patients. It enables summarizing data by country in automatic mode.
Immunophy-laxis	DHIS2 platform Development of an online immunization reporting system (as an option of Immunization Information System (IIS), the I-stage to the development of an integrated IIS" 62	At the stage of introduction Objective: To integrate immunization into a unified e-health information system The program is implemented in the framework of the HSS-2 project (health systems strengthening) of the Global Alliance for Vaccines and Immunization (GAVI), Goal 5 "Improving data quality"

60 "On introduction of software products in healthcare organizations for anti-tuberculosis care", Order of MoH of KR # 1078 dated 27.11 2019

61 On the system for Electronic HIV case tracking in the Kyrgyz Republic", order of MoH of KR #192 dated 15.03.2018

62 "On the implementation of DHIS2 platform in the immunization program in the Kyrgyz Republic", order of MoH of KR #105 as of February 19, 2020

The positive thing is that availability of the above-mentioned IS serves as the foundation for transition to an integrated IS model in healthcare, including IS for medicines and health commodities as developers and users of various IS have already gained experience in developing IS, and learnt lessons that will give an impulse to further improvement of systems.

It is required to conduct a relevant assessment to assess the possibility of integrating different LMIS with each other for obtaining a more complete picture of the supply chain. Absence of the possibility of system integration leads to a low capacity for process automation on the system, thus reducing the effectiveness of using IS as an effective tool. Hence, the possibility of integrating the systems with each other and with the EDD of DPSME will provide an opportunity to cover government requirements in the most optimal and rational way in terms of implementing relevant policies and measures.

Each private pharmaceutical and medical organization has its own information system for inventory control and accounting purposes. As practice has shown, these information systems also do not have the technical capability to integrate data on pharmaceuticals and health commodities.

The lack of measures to integrate such disparate IS on medicines and health commodities does not enable a full use of their potential for monitoring the situation and decision-making at the level of the Ministry of Health and MHIF, and o limits the ability of the population to receive timely information.

Despite the fact that medicines and health commodities are an integral part of the provision of medical care, they were not conceptually considered as part of the IS of health system. To eliminate this gap, in 2015, the Government of the KR adopted the Concept of creating an electronic database of medicines and medical devices in the Kyrgyz Republic (hereinafter EDB)[63], which is considered as a transparency tool that ensures traceability of drugs and health products throughout the supply chain, starting from the moment of registration of drugs and health commodities in the country, their import into the country and until their receipt by the patient from a pharmacy or hospital.

Technically, within the framework of the EDB, it is possible to build effective IS for medicines and health supplies with a high potential for automating business processes. The system is based on the use of a unified MD system (Master Data) throughout the country, the 2D DataMatrix matrix code on the packages of medicines and health supplies, and proper interconnectedness and integrability of data between participants in the healthcare system.

The first stage of EDB was implemented in the framework of 'Den Sooluk' National Health Reform Program. Currently, the public procurement portal has implemented integration with the database, which enables all purchasing organizations to carry out public procurement of medicines and health commodities on a unified platform. This facilitates accumulating data across the country for automated comparative monitoring of public procurement in real time. At present, as part of the implementation of the second stage of the EDB project, a drug traceability system has been developed and put into commercial operation.

63 Concept of creating an electronic database of medicines and medical devices in the Kyrgyz Republic, resolution of GKR #743 dated 27.10.2017, http://cbd.minjust.gov.kg/act/view/ru-ru/98122

On March 4, 2023, the Resolution of the Cabinet of Ministers # 53 as of 09.02.2023 "On introduction of a drug traceability system in the Kyrgyz Republic" entered into force. This system is able to track medicines (marked with codes) from entry into the country to the end user in pharmacies and hospitals.

The traceability system of medicines and health products will ensure a higher level of safety for patients, improve quality control of medicines and health supplies, and prevent the sale of falsified and counterfeit pharmaceuticals and medical products.

Since October 2022, DPSME commenced testing a pilot project for import, quality assessment, warehousing and traceability of medicines with participation of five pharmaceutical companies, at the end of which pilot testing was successfully completed. According to resolution of CM of KR "On introduction of a drug traceability system in the Kyrgyz Republic" #53 dated 09.02.2023 and the orders of the MoH of KR for DPSME, medicines traceability in the Kyrgyz Republic is implemented in 4 stages:

The first stage included a list of medicines containing narcotic, psychotropic and superpotent substances, and a list of labeled medicines on a voluntary basis (to be supplemented in the second and third stages); **The second stage** was launched in July 2023 and the list is being supplemented with medicines used within the framework of the High Technology Fund; **The third stage** includes medicines from the EML and will be launched in November 2023.

All other pharmaceuticals must be labeled before 01. 03.2024. As per the latest data, 402 pharmacies operate in the drug traceability system, including 13 warehouses and 222 HCO. There are 149 trade names of medicines, which comprise more than 600,000 packages.

As part of the implementation of the drug traceability system, participants in the drug turnover (individuals or legal entities engaged in pharmaceutical or medical activities on the territory of the Kyrgyz Republic), regardless of their forms of ownership, throughout the republic, were trained to work in the EDB system of medicines and health products. Information on the implementation of the system for the public was provided through the media. Registration of participants in the turnover of medicines in the EDB has been carried out. In the frame of the phased implementation of the IS EDB of DPSME, the process of integration with the IS of State Registration Service, customs, and tax service is underway through the 'Tunduk' State Enterprise (there is a memorandum).

Mobile application. For convenience of the population, a mobile application was developed and is available in Google Play Market: https://play.google.com/store/apps/details?id=com.ndb NDBProductScanner&hl=en&gl=US

The application enable checking medicines included in the DPSME Order # 29 dated 03.03.2023. The verification function allows finding all required information about the drug (manufacturer, importer, expiration date, date of manufacture, batch number, price and status of medicine).

Reproductive health: with support of UNFPA, DPSME and all HCO providing family planning services have installed "CHANNEL" software, which allows managing contraceptives stocks in warehouses. Data on the movement of contraceptives, based on journal entries, are entered into the CHANNEL

software at the pharmacy warehouse and family planning units. The CHANNEL software helps to avoid untimely use of contraceptives (due to expiration), and plan a minimum (three-month), semi-annual and annual stock of contraceptives.

At the same time, the software "1-C: Accounting" was introduced in the financial information system of healthcare, which also keep records of contraceptives along with other medicines and health products. Duplication of information in two software products required their integration. With support of UNFPA, "CHANNEL" software was integrated with the "1-C: Accounting" which would help avoiding duplication of data entry on movement of contraceptives in HCO. The CHANNEL software, integrated with the 1-C: Accounting software, provided information along the entire contraceptives supply chain:

- arrival at the warehouse
- release from the warehouse
- monthly standard release for each type of contraceptives
- minimum and maximum level of contraceptives stock
- checking the probability of a shortage of contraceptives and discrepancies
- monitoring the timely use of contraceptives.

The "CHANNEL" software was tested at FMC 7 in Bishkek. This process was not taken to the next stage due to the lack of financial resources and termination of contraceptive supply by donors. The CHANNEL accounting and reporting system is part of the Contraceptive Logistics Management Information System (C-LMIS). C-LMIS is a system for managing information (record keeping and reporting), and material flows of contraceptives (receipt, movement, expenditure) based on physical and technological aspects, which is designed to ensure optimization of all processes.

Key recommendations

1. Analyze existing Logistics Management Information Systems (LMIS) and identify gaps in data and information for timely decision-making.
2. Analyze the business processes that will be managed using the LMIS.
3. Undertake business process mapping for reporting and data collection.
4. Design data collection and reporting tools for managing data on various components of the supply chain, and for ordering and replenishing the stock of medicines and health commodities
5. Provide authorities and training for technical personnel for regular analysis of supply chain optimization by analyzing logistics data and information to implement business process improvements through ongoing updating of standard operating procedures
6. Finalize integration of IS EBD of DPSME with other IS like the IS of State Registration Service, and customs and tax services of the Kyrgyz Republic.

Human resources

At present, health system does not have a methodology for human resource planning, approved by regulatory acts, which would establish criteria and conditions for long-term planning considering the needs of healthcare system in personnel for the future, the forecast of morbidity of population, demographic trends, geographical distribution of population and other factors.[64]. Issues of capacity building of personnel are resolved through periodic professional development and the requirements of relevant documents (job description, SOP) for implementation of activities: pharmacists, procurement specialists. There is a special course for

64 Program on the protection of public health and the development of the health care system in the Kyrgyz Republic for 2019-2030 "Healthy Person — Prosperous Country", http://cbd.minjust.gov.kg/act/view/ru-ru/12976?cl=ru-ru

middle-level health practitioners on record keeping and storage of medicines and health commodities in KSMIRAT (Kyrgyz State Medical Institute for Retraining and Advanced Training).

A new course on use of EDB for procurement of medicines and health commodities was launched at the Training Center of the Ministry of Finance in partnership with DPSME. Strong and qualified teams are trained within the framework of vertical healthcare programs due to an integrated approach to the functioning of the supply chain.

Interventions in the frame of vertical programs

Program	Intervention
Tuberculosis	NCP (National Center for Phthisiology) has 2 medicine management coordinators and 1 clinical pharmacologist, and a medicine management coordinator at each regional level, who are partially involved in the management of the supply chain of anti-tuberculosis drugs. Specialists have been trained to use SOPs on pharmacy management in HCO and SOPs on pharmaceutical management and use of "QUAN TB" tool
HIV/AIDS	AIDS Republican Center employs two specialists engaged by the UNDP GF project, HIV program Medical Support Manager and national consultant for treatment and care of PLHIV, responsible for forecasting and planning.
Immunoprophylaxis	There are 2 cold chain specialists working at the national level. There are cold chain specialists at the regional and district levels.
Reproductive health	It is planned to train specialists on SCM of contraceptives. It is required to boost the capacity of health workers in HCO on quantification of contraceptives for persons from medical and social risk group, and relevant specialists providing services for transportation and storage of contraceptives.

Key recommendations:

1. **1. Conduct an organizational assessment to determine where the supply chain management unit (i.e., the Logistics Management Unit - LMU) should be located, and identify the respective roles, responsibilities and scope of authority of employees within the existing structure:**
   - **Design a relevant regulatory framework for this structure and identify its vision and mission.**
   - **Address the issue with a structure that can manage the supply chain comprehensively.**
   - **Train the organization's personnel in line with their functions.**
2. **Enhance the capacity of supply chain specialists:**
   - **Define the competence requirements for each position in the supply chain.**
   - **Identify gaps in staff competence and training requirements.**
   - **Evaluate and strengthen training plans for all employees at all levels.**
   - **Develop measures to increase staff efficiency through development and implementation of performance management plans, administrative performance management processes, and performance measurement methods.**
   - **Create employee incentive programs.**
   - **Identify effective methods of stimulation and motivation.**
3. **Collect information on the staffing of the supply chain with required staff for a gradual transition to staffing planning, create a Database on supply chain personnel (the task should be included in Management unit of IS).**

Forecasting and supply planning

Upon selecting of medicines and health commodities it is required to determine the required quantity and cost of each of them. Quantification or forecasting is the process of estimating the quantity and cost of necessary medicines or medical products and determining when they should be procured and delivered to ensure uninterrupted supply. The main method of forecasting the need for pharmaceuticals and health products is the accumulated long-term data on procurement and consumption of medicines and medical commodities in HCO and correlating them with the planned budget. The budget usually cannot cover the entire demand, therefore most HCO carry out a priority cost analysis (VEN/ABC).

The forecast of needs and analysis is carried out manually, with the exception of HCO, which are equipped with automated tools. More advanced forecasting methods and accumulation of consumption data are associated with vertical programs that have patient data, donor/mixed funding, and local LMIS within a specific service (Reproductive health, Tuberculosis, HIV/AIDS, Immunoprophylaxis, etc).

Vertical programs' interventions

Program	Intervention
Tuberculosis	Forecasting the need for anti-tuberculosis drugs is carried out using the "QUAN TB" tool on a quarterly basis at the regional level and semi-annually at the national level. Calculations take into account the actual balances and expected deliveries. In the "QUAN TB" tool, the "dashboard" section shows an urgent and expected order, and an over-stock (surplus stock) of anti-tuberculosis drugs.
HIV/AIDS	Forecasting the need for ARV drugs is undertaken using an Excel spreadsheet once a year at the national level, and more often if required. Calculations take into account the actual balances and expected deliveries. A monthly report is compiled on the remaining stock of ARV drugs and an analysis for each drug to avoid over-stoking or under-stoking.
Immunoprophylaxis	Based on the long-term plan, a target group is identified for forecasting and planning of vaccines supplies and consumables
Reproductive health	At the regional level, LMIS is used to monitor the level of contraceptive stocks in accordance with their type and shelf life, which inform supply forecasting and planning.

In the frame of vertical programs, consumption and inventory data are collected throughout the supply chain and transferred "up the chain" from primary health care centers to the central level. The data collection interval and the tools used at different levels vary. The below table demonstrates the structure and reporting intervals using the example of a TB service:

PHC (family doctors, rural health points)	**Quarterly reports at district level Tool: manually filled out journals/registers**
At district level (Family Medicine Center)	Quarterly reports at provincial level. Tool: manually filled order forms in QuanTB
At regional (provincial) level (provincial tuberculosis care centers)	Quarterly reports at central level. Tool: Quan-TB
At central level	Data are summarized every 6 months. Tool:: Quan-TB

Regardless of the fact that there are guidelines for data collection, tools and reporting structure, data exchange between levels is often complicated, schedules are not followed, data quality is often questionable/insufficient, and the whole process is extremely time-consuming.

Reproductive health: The calculation of the need for contraceptives for WRA from medical and social group is based on:

1. Forecast data on WRA in Kyrgyzstan from UN Data Portal, Population Division.[65]
2. Information on the number of women from risk group for in previous years.
3. Survey of WRA

The following major record keeping and reporting forms were approved by the decree of the MoH of KR #740 as of 08.06.2019 "On approval of primary medical records and quarterly statistical reporting on record keeping of contraceptive commodity flow and use":

- "Register of contraceptive commodity flow" (form #040/u)
- "Register of women of reproductive age from medical and social risk group" (form 040-2/u)
- "Patient card for contraceptive user from medical and social risk group" (form # 040-1/u) and quarterly reporting form
- "Report on contraceptive commodity flow" (form # 12-2).

"Report on contraceptive commodity flow" is a major statistical and accounting document reflecting data on contraceptive commodity flow and use and a key document for timely planning of demand for contraceptives. Summary reports on the regions, HCO of Bishkek and Osh are submitted to the E-Health Center under MoH of KR, where summary information is generated on the expenditure and balances of contraceptives in the republic, taking into account the balances of contraceptives in DPSME warehouse. This information is used for analysis of the situation and planning the demand for contraceptives in the healthcare system. The data of the reports from the level of the health organization are entered and provided to higher authorities in electronic format, through "Report 12-2" software.

Currently, EHC installs an automated information system "Outpatient card" with a subsequent integration with other existing health information systems. This integration will facilitate medical workers' record keeping activities, free up health workers to do other work, improve data quality and enable automatic generation

65 https://population.un.org/dataportal/countryProfiles/types/1/topics/5/coreThemes/1/locations/417?classId=reg&palette=Blues&secpalette=alphabet

of all outcome reporting data through "Outpatient card". Simultaneous access to all record keeping and reporting forms from the level of FAP, provides Managers of health care organizations/ Service Coordinators with an opportunity to forecast and plan contraceptive commodities for WRA from medical and social risk groups.

Budget planning

Typically, the required annual state budget for procurement of pharmaceuticals and health products is calculated by multiplying the required number of medicines and medical commodities obtained using a forecasting and quantitative assessment tool by the estimated cost of one unit of goods/ products. Such costs are often lower than the actual market prices. Moreover, these prices tend to fluctuate over a long procurement process, hindering achievement of optimal cost goals.

Besides development of a more realistic budget planning methodology, consideration should be given to including the costs of mandatory quality control tests at various levels of the supply chain into a separate budget line (Order of MoH of KR #523 dated 04.05.2023 "The procedure for conducting quality control of medicines in public health organizations"). There is also an additional link to the section, the costs of warehousing and distribution are not currently budgeted, which causes difficulties at all levels of the supply chain.

It will be beneficial to evaluate the current budget planning methodology and make recommendations for its further improvement and the inclusion of a variable cost component.

Key recommendations:

1. **Review the existing forecasting methodology and standardize it based on proven results.**
2. **Automate processes and tools for manual forecasting and supply planning (if required). Ensure the accuracy, timeliness and completeness of the data (if the data is collected manually, the organization must automate the data collection process).**
3. **Develop and implement KPIs for monitoring processes (i.e. accuracy of forecasting, accuracy of supply planning, etc.).**
4. **Train relevant personnel to track and use cost measurement tools and other supply chain indicators to monitor and enhance efficiency.**
5. **Plan and convene coordination meetings to identify, verify and support the results of quantification.**
6. **Involve relevant supply chain officials/activists from various system levels and organizations in activities on quantification and promotion of data to obtain accurate, updated forecasts and financing to satisfy the demand.**
7. **Analyze the financing deficit based on the results of quantification and financing obligations, and plan supplies every six months or quarterly in conjunction with the update of quantitative indicators.**

Selection and procurement of medicines and health commodities

Selection of medicines and health products is based on the most appropriate treatment regimens in the framework of national or international clinical guideline/ clinical protocols in line with National Essential Medicines List. The National Essential Medicines List (hereinafter referred to as Lists) is approved by the Cabinet of Ministers of the KR to ensure priority health needs, increase access to effective types of medical care and rational use of public funds.

Legislation in the sphere of medicines circulation[66] and health products[67] envisages approval of Lists which are designed to meet priority health needs for disease prevention and treatment.

Lists[68] should be periodically revisited (supplemented/expanded) and approved in order to contribute to improving access to effective types of medical care and the rational use of public funds. The frequency of revision is at least once every 2 years. Nonetheless, the analysis showed that since 2018, the Lists have not been updated and there are no medicines and health products for some types of diseases.

The public HCO for procurement of medicines and medical devices prepare hospital lists of pharmaceuticals and health commodities, which should be part of medicines and medical products from the approved List. It is allowed to include into hospital list of pharmaceuticals and health commodities those items that are not part of the lists, but not more than **10%** of the provided funds should be spent on them. This norm is stipulated in the Program of state guaranteed benefits package of KR[69].

Procurement is carried out in accordance with the legislation of the Kyrgyz Republic on public procurement [70] through electronic public procurement portal[71] and also by the method of direct conclusion of agreement with manufacturers.

In the Kyrgyz Republic, the following organizations procure medicines and health products:

a) HCO - Public procurement for MHI (through EPC portal)

b) Kyrgyzfarmatsiya SE - Public procurement under MHI without conducting competitive procedures (tender), by the method of direct conclusion of an agreement with manufacturers.

c) Organizations established by the United Nations and/or other international procurement organizations – Donor-funded procurement (GF/UNDP, UNFPA, UNICEF, etc.).

According to the legislation of the Kyrgyz Republic in the field of circulation of medicines, procured goods must be registered in the Kyrgyz Republic or must be included in a tailored list of medicines and health products allowed to be imported without registration. The system provides for quality assessment procedures for sale of medicines[72] and issuing an opinion on the quality of medicines and health products for a specific series/batch, which are provided to HCO upon delivery.

Despite numerous efforts taken in this direction, the legislation, procurement processes, IS, etc. require further improvement.

66 The Law of the Kyrgyz Republic "On circulation of medicines" #165 dated August 2, 2017, http://cbd.minjust.gov.kg/act/view/ru-ru/96634

67 The Law of the Kyrgyz Republic "On circulation of medical devices" # 166 dated August 2, 2017, http://cbd.minjust.gov.kg/act/view/ru-ru/111673/20?cl=ru-ru

68 On approval of national essential medicines and health products lists, Resolution of the Government of the Kyrgyz Republic #274 dated June 6, 2018, http://cbd.minjust.gov.kg/act/view/ru-ru/11924

69 State guaranteed benefits package program #790 dated 20.11.2015, http://cbd.minjust.gov.kg/act/view/ru-ru/98211?cl=ru-ru

70 The Law of the Kyrgyz Republic "On Public Procurement" #27 dated April 14, 2022, http://cbd.minjust.gov.kg/act/view/ru-ru/111125

71 http://zakupki.gov.kg/popp/

72 The procedure for evaluating the quality of medicines, Decree of the Government of the Kyrgyz Republic # 312 dated July 5, 2018, http://cbd.minjust.gov.kg/act/view/ru-ru/11980

The procedure for assessing the quality and safety of medical devices, Resolution of the Government of the Kyrgyz Republic #313 dated July 5, 2018, http://cbd.minjust.gov.kg/act/view/ru-ru/11983?cl=ru-ru

Interventions in line with vertical programs

Program	Intervention
Tuberculosis	Forms a list of anti-tuberculosis drugs to be procured, prepares technical specification and submits a request for purchase of anti-tuberculosis drugs of I line to Kyrgyzfarmatsiya SE. The latter carries out the supply of anti-TB drugs to the central warehouse of the NCP according to the application. Procurement of anti-TB drugs of II line is carried out according to the procedures of the Global Fund to Fight Tuberculosis, HIV (through GDF).
HIV/AIDS	Procurement of ARV drugs is carried out according to the procedures of the Global Fund to Fight Tuberculosis, HIV (through GDF). Since 2018, several items of ARV drugs have been procured from the budget of the AIDS Republican Center in line with current legislation through public procurement portal according to the legislation of the Kyrgyz Republic. From 2023, ARV drugs previously purchased by AIDS RC, will be purchased and delivered by Kyrgyzfarmatsiya SE.
Immunoprophylaxis	Procurement of immunobiological products is undertaken from state budget, as well as through GAVI and UNICEF
Reproductive health	Procurement is based on forecasts of needs using clear criteria and information about past consumption, using information from CHANNEL and provided by Republican Medical Information Center (RMIC)

Ключевые рекомендации

1. Regular revision and update of EML and clinical protocols.
2. Development of a monitoring and evaluation component to ensure the completeness, relevance and consistent use of all technical specifications for procurement.
3. Development, introduction and use KPIs for monitoring processes.
4. Revision of the current legislation on procurement of medicines:
   - consideration of the implementation of long-term contracts that can provide significant price reductions and sustainability of medicines and health commodities provision.
   - introduction of procurement methods through global suppliers, joint procurement mechanisms with other countries enabling getting high-quality goods at reasonable prices.
   - improvement of mechanisms for framework agreements for medicines and medical products procurement.
5. Improving procurement transparency - consider the possibility of providing publicly available price monitoring data
6. Introducing inventory control in HCO as part of EDB launch (the task should be included in the unit - IS Management) – all stages of the supply chain should interact in IS.

Warehouse management and inventory management

Stocks of pharmaceuticals and health supplies play a crucial role in achieving the goals of the supply chain. The decision to reserve the stock gives enables HCO to balance supply and demand. A coordinated inventory management strategy will establish measures determining which drugs should be reserved, the quantities of medicines to be reserved, and their storage location. It will also ensure that inventory management solutions are documented, and consistently applied throughout the system.

Proper condition of warehouses and their space are one of the important components determining the capacity for storing the required stock of pharmaceuticals and medical supplies and their effective distribution. This affects the safety of goods, the frequency of ordering goods, optimization of the delivery

schedule, savings in transportation costs, and other indicators in the supply chain.

The rules for storing drugs and health products are regulated by the relevant normative legal acts[73] and the Order of MoH of KR23 and are used in the design of warehouses. The minimum spaces and the composition of the premises of pharmaceutical organizations are also defined, which are used as licensing requirements[74]. The existing normative legal acts have not yet been aligned with the provisions of EAEU GDP and WHO GMP recommendations.

73 On approval of the Technical Regulations "On the safe storage of medicines in pharmaceutical and healthcare companies and the sanitary regime of pharmaceutical organizations", Decree of the Government of KR # 646 dated September 25, 2012, http://www.pharm.kg/ru/legislation

74 On approval of the Technical Regulations "On the safety of medicines for medical use", Resolution of the Government of KR # 137 dated April 6, 2011

The warehouses of private suppliers are additionally inspected by DPSME manufacturing plants when concluding annual contracts, and many warehouses are being upgraded to transition to GDP. If necessary, private sector warehouses are used to store medicines and health products (outsourcing).

Great focus is placed at the development of warehouse infrastructure within the framework of vertical programs for their proper functioning. For instance, SOPS for vaccines warehousing and storage have been developed at district and central levels, and the issue of evaluating DPSME storage and distribution systems is currently being worked out: vaccines[75].

75 "Improving the vaccine storage and distribution system at the national level in Kyrgyzstan", WHO mission Recommendations, March 2020

Interventions in line with vertical programs

Program	Intervention
Tuberculosis	The National Center for Phthisiology does not have enough facilities to store the required stock of medicines and health supplies. The existing pharmacy warehouse does not meet international standards for storage of medicines and medical commodities. Anti-TB drugs of II line procured by GF are stored separately at warehouse rented by GF/UNDP. Anti-TB drugs of I line and for totally drug resistant TB are kept at two warehouses, which are also located at the premises of NCP. The pharmacy warehouse management process is carried out manually, and is not automated. Specialists are trained according to SOPs on medicines management
HIV/AIDS	AIDS RC does not have two storage facilities, one in AIDS RC for the northern region and one in Osh regional center for AIDS for the southern region. ARV drugs purchased from GF funds are stored separately in a warehouse leased by the GF/UNDP. ARV drugs procured from the budget of the AIDS RC are immediately delivered to the regions and stored in warehouses located at the premises of Center for AIDS. The pharmacy warehouse management process is carried out manually, it is not automated.

Immunoprophylaxis	At national, regional and district levels, there are cold storage rooms and special refrigerators for storing vaccines that meet international standards.
Reproductive health	Contraceptives are delivered to DPSME warehouse, and further distribution to healthcare organizations is carried out according to the distribution plan

The situation in public sector is less clear, where there is insufficient investment in warehouse infrastructure and no information on storage spaces and refrigeration facilities at the central level. Such situation sometimes causes problems with distribution of medicines and medical products supplied through centralized procurement, when the quantity of distributed goods does not correspond to the storage capacity of warehouses. This is particularly important for drugs that require a cold chain (insulin, vaccines).

Issues of utilization of medical[76] and pharmaceutical[77] wastes are regulated by legislation of KR.

Reproductive health: Incoming contraceptives are stored at DPSME warehouse. According to the needs and request of the heads of regional HCO (FP Coordinators), the commission for distribution of contraceptives, established under the Ministry of Health of the KR prepares distribution list for issuance of contraceptives to the level of the region, which is approved by the order of the MoH of KR. Request of the regional FP Coordinators is drawn up considering the average monthly consumption and the level of minimum/maximum stocks of contraceptives for medical and social risk group and LMIS data.

Further, according to the approved distribution plan, DPSME specialists release contraceptives from the warehouse to regional centers for human reproduction and regional FMC. At the regional level, regional centers for human reproduction and regional medicine center commission prepare distribution plan for issuance of contraceptives to FMC, GMPC, according to which specialists from the pharmacy warehouse of regional HCO release contraceptives to FMC, GMPC, in line with their requests and data from the LMIS for women of reproductive age from medical and social risk group. In HCO, commissions for distribution of contraceptives have also been established, which distribute contraceptives to the level of FDG, FAP, taking into account the data LMIS. From the pharmacy warehouse of FMC, CMPC, contraceptives are issued based on a shipping list using the CHANNEL software in FP committee, FDG, FAP. Release of contraceptives is also recorded in medical record of patient using contraceptives, and in "Register of contraceptive commodity flow" (form 040/u) according to the order of the MoH of KR # 170 dated 08.04.2015.

76 "On issues related to the management of medical waste and work with mercury-containing products in healthcare organizations of the Kyrgyz Republic", Resolution of the Government of the Kyrgyz Republic #719 dated December 30, 2019

77 On approval of the Technical Regulations "On the safety of medicines for medical use", Chapter 10, Resolution of the Government of the KR #137 as of April 6, 2011

Ключевые рекомендации

1. **Analyze the existing storage facilities at all levels and determine the conditions, spaces and methods of storage in accordance with the requirements of manufacturers.**
   - **Consider investment opportunities and construction of new warehouses and warehouse maintenance.**
   - **Develop a Maintenance Plan.**
2. **Use the services of contractors for reverse logistics and waste disposal.**
3. **Develop, introduce and use KPIs to monitor the process.**
4. **Revise normative regulatory acts**
   - **Optimize processes for disposal of medicines and health products.**
   - **Harmonize normative regulatory acts for storage of medicinal products with recommendations of WHO GMP and EAEU.**
5. **Optimization of warehouse management**
   - **Create a Database on warehouse infrastructure, warehouse capacity at all levels for management purposes and distribution and supply planning.**
   - **Automate the record keeping of goods in warehouses – all stages of the supply chain must interact in IS.**
   - **Implement monitoring of warehouse record keeping and inventory record keeping based on key performance indicators.**

Transportation

At the centralized level, transportation of medicines and health products is not organized. During public procurement, pharmaceuticals and health products are delivered to the warehouse of DPSME, then, according to distribution plan, HCO independently carry out transportation. The transportation of contraceptives is undertaken out according to the same scheme. Transportation of insulin from DPSME warehouse is carried out by a car with refrigerator of NCI. In cases of a competitive procurement by HCO, transportation of medicines and health commodities is carried out by private pharmaceutical companies (distributors), this condition is included in the supply agreement.

Regarding vertical programs:

For tuberculosis, anti-TB drugs transportation system operates up to the district level throughout the country. Logistical processes have been established, and coordination personnel have been assigned. In 2022, MoH of KR issued Order # 1512 dated 29.12.2022 "On issues of transportation of biomaterials and anti-tuberculosis drugs". According to this order, anti-TB drugs transportation system has been gradually transferred to state financing. Since 2023, MHIF commenced financing the transportation system through regional tuberculosis control centers.

The system of transportation of vaccines and supplies is functioning up to the district level throughout the country. Logistical processes have been established, and coordination personnel have been identified. Specialists are trained on an ongoing basis, transportation procedures are outlined (SOP).

ARV drugs procured from UNDP GF resources, are delivered to regions according to the distribution plan, taking into account balances and needs. ARV drugs purchased from the budget of AIDS RC, are delivered directly by suppliers in line with Terms of Reference. AIDS Republican Center does not have its own transport for delivery.

Key recommendations

1. **Analyze economic efficiency of various transportation systems.**
2. **Consider the potential involvement of private contractors for storage/transportation services for implementation of tasks and emergency supplies.**
3. **In case of using private services, develop a contractor management guide.**
4. **Tools for transportation monitoring base on KPIs:**
   - **Identify relevant measurements/indicators and develop basic tools for performance monitoring.**
   - **Include cost indicators in performance monitoring tools.**

CONCLUSION

Analysis of the current situation with supply chain system for pharmaceuticals and health commodities in the Kyrgyz Republic showed an overall picture of supply chains in the field of public health in the Kyrgyz Republic. The main conclusions and recommendations are presented in the relevant sections of this report and for each key stage of the overall pharmaceuticals and health products supply chain. Accordingly, more detailed information about the recommendations can be found in the relevant sections.

Overall, the supply chain of medicines and health commodities in the Kyrgyz Republic is on the way from an unorganized, situational phase to an organized stage. This means that formal roles and processes in logistics have begun to be defined, procedures for collecting basic logistics data have been established, and supply chain system is at the initial stage of developing a national document on management of a unified national supply chain of pharmaceuticals and health commodities including contraceptives.

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