Community-Led Monitoring

ANALYZING THE PROCUREMENT OF TB DRUGS

IN THE KYRGYZ REPUBLIC, REPUBLIC OF MOLDOVA, REPUBLIC OF TAJIKISTAN AND UKRAINE IN 2022-2023

2024

Author's team

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Disclaimer

The information presented in this report has been obtained from publicly available sources, official responses from government institutions of the Kyrgyz Republic, the Republic of Moldova, Tajikistan, and Ukraine; international organizations; as well as through interviews conducted with representatives of the aforementioned entities.

The conclusions and recommendations contained in this review reflect the views of the authors and may not necessarily align with the opinions of other stakeholders.

The English translation of the report is technical.

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Table of contents

List of figures

List of tables

Terms and abbreviations used

BC+	Samples with positive microbiological results
WHO	World Health Organisation
CG	Clinical Guidelines
MP	Medicinal products, pharmaceuticals
DS-TB	Drug-sensitive tuberculosis
DR-TB	Drug-resistant tuberculosis
MBT	Mycobacterium tuberculosis
MoH	Ministry of Health
MDR-TB	Multidrug-resistant tuberculosis
INN	International nonproprietary name
ATD	Anti-TB drugs
Pre-XDR-TB	Multidrug-resistant (MDR-TB) or rifampicin-resistant (RR-TB) tuberculosis, with additional resistance to fluoroquinolones (levofloxacin and moxifloxacin)
ATT	Anti-tuberculosis therapy
RR-TB	Rifampicin-resistant tuberculosis
SRA	Stringent regulatory authority
TB	Tuberculosis
DST	Drug sensitivity test
TN	Trade name
TOR	Terms of Reference
XDR-TB	Extensively drug-resistant tuberculosis

Introduction and methodology

The aim of this paper is to organise and conduct a community-led monitoring (CLM) to undertake a comprehensive analysis of procurement of short-term TB treatment regimens to examine the current situation and existing gaps in order to draw conclusions about the design and direction of TB drug procurement interventions.

Objectives and Activities:

1. Assessment of the epidemiological situation of tuberculosis in the country for 2022–2023, with details on DR-TB, MDR-TB and XDR-TB.
2. Study of the country's legislation in the field of TB treatment: identification of web-based legal information resources, analysis of laws and by-laws (regulations, orders, etc.) in the field of TB; availability of TB control programmes; detailed review of monitoring programmes; identification of procuring entities (TB treatment); identification of budgetary resources for procurement of TB drugs.
3. Comparative analyses of national TB treatment guidelines with those of international regulatory bodies.
4. Study of existing international programmes and projects for procurement of TB drugs in the country, including funding and procurement volumes, indicating INN (international non-proprietary name of drugs), quantity of drugs to be procured, cost, manufacturer (if applicable).
5. Study of the country's legislation on public procurement mechanisms, including existing restricted lists and registration of medicines. Including on the supply of medicines, including the rules ensuring that medicines can be imported and distributed into the country without registration.
6. Monitoring of public procurement to identify the entire list of TB drugs purchased at the expense of the state budget, both directly by health care organisations (including MoH) and through procurement organisations.
7. Sharing lessons learnt and good practices.
8. Collecting data on the number of people in need of short-term TB treatment regimens, aggregated by TB type, and the actual number of people receiving short-term TB treatment regimens, aggregated by TB type.

Data sources and methods of data collection:

- Conducting a desk review.
- Review of the country's legislation on public procurement mechanism.
- A review of the country's legislation on tuberculosis treatment.
- Conducting interviews with statistical unit specialists and NTP drug management specialists.

REVIEW OF EPIDEMIOLOGICAL INDICATORS FOR TB

The Kyrgyz Republic, Republic of Moldova, Republic of Tajikistan and Ukraine are among the countries with a high burden of tuberculosis and multidrug-resistant tuberculosis (MDR-TB). The COVID-19 pandemic exacerbated the epidemiological situation by significantly reducing access to TB diagnosis and treatment, which was particularly reflected in high MDR-TB levels. Despite this, countries continue to take action to control TB, using international programmes such as the Global Fund and USAID to improve diagnosis and ensure regular supplies of TB drugs.

Epidemiological indicators on TB in the Kyrgyz Republic

As part of the Tuberculosis-I – Tuberculosis-V programmes in the Kyrgyz Republic, significant progress has been made in reducing tuberculosis morbidity and mortality. The programme has played a key role in improving the TB epidemiological situation (Figure 1).

Despite the progress made, the country still faces serious challenges such as migration, late detection and restructuring of the single payer system (SPF), resulting in less attention to TB at the primary health care level and increasing drug resistance. In 2023, the incidence (new cases and relapses) in the Kyrgyz Republic was 4 674 people – 58.9 per 100 000 population, which is **9%** (443 people) **less** than in 2022 – 5 117 people 65.5 per 100 000 population. The incidence rate among children decreased to a rate of 11.9 per 100 000 population in 2023, compared to a rate of 14.5 in 2022, while the incidence rate among adolescents increased from 29.8 per 100 000 population in 2022 to 41.2 per 100 000 population in 2023. [1, 2].

The number of people with MDR-TB in 2023 was 461, down 17.8% from 561 in 2022. There is also a decrease among people with MDR-TB, with 626 cases in 2023, down 76 people (10.8%) from 702 in 2022.

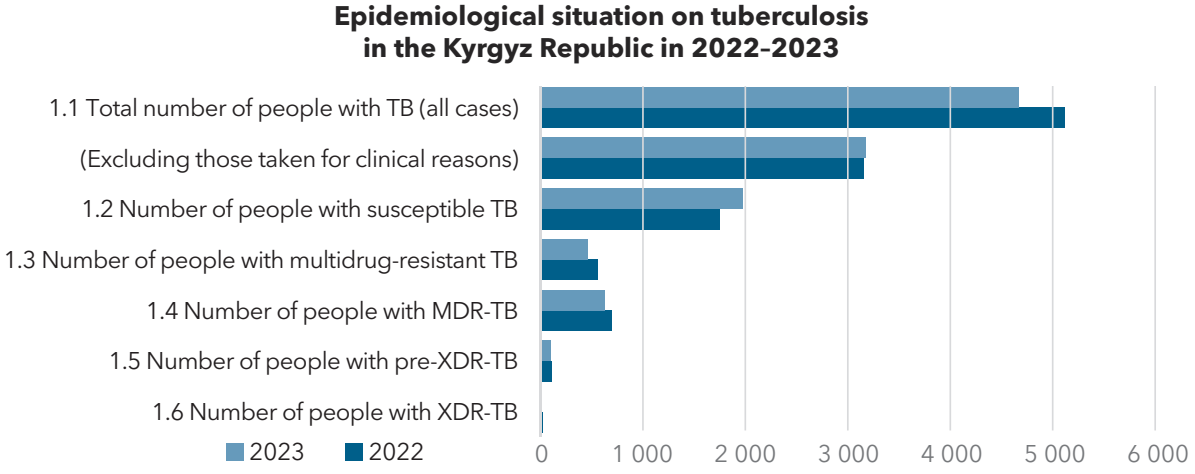

Figure. 1. **Epidemiological situation on tuberculosis in the Kyrgyz Republic**

Thus, both the XDR-TB rate in 2023 was 14 people, 7 people (33.3%) less than in 2022 when there were 21. And the pre-XDR-TB rate in 2023 was 103 people, 11 people (9.6%) less than in 2022 when there were 114 people. The TB mortality rate in 2023 was 2.6 per 100 000 population – 180 people, 4 more than in 2022 when the rate was 2.5 per 100 000 population (176 people) [1, 2].

In 2022–2023, despite the recovery of the health system after COVID-19, the Kyrgyz Republic, like all participating countries, is lagging behind the UN High Level Meeting targets for TB. With donor support, the national TB control programme in the Kyrgyz Republic is actively using GeneXpert molecular genetic tests, improving access to molecular genetic tests by expanding the GeneXpert network and improving the sample transport system. Individual countries are implementing genomic sequencing and digital solutions for population X-ray screening and data transfer. These measures have led to a 9% decrease in the total number of TB cases detected (from 5 117 in 2022 to 4 674 in 2023), with an increase in the number of sensitive TB cases detected. On the other hand, the increased focus on drug-resistant TB and the introduction of new drugs in the Kyrgyz Republic is contributing to an 18% and 33% decrease in the prevalence of multidrug-resistant and extensively drug-resistant TB cases, respectively. This is due to more effective treatment through the introduction of new drugs and short-term treatment regimens, as well as hospitalisation of those with bacteriologically positive smears at the initial stage of treatment, which helps to reduce the prevalence of resistant TB in the general population.

Epidemiological indicators for TB in the Republic of Molodova

> The current National TB Control Programme for 2022–2025 has been developed and approved in accordance with national legislation, as well as the provisions of other national and international TB documents. The NTP and the National Clinical Protocols are strategic documents that formulate TB guidelines.

The incidence (all cases) TB in 2023 was 72.2 per 100 000 population (2 168 people), compared to 71.6 in 2022 (2 353 people). (2 168 people) compared to 71.6 in 2022 (2 353 people). The incidence rate of DR-TB in 2023 was 11.8 per 100 000 population. (compared to 16.3 in 2022) The proportion of people with DR-TB was 21.43% (508 people) in 2022 out of the total registered, with a decrease of 0.39% from 2022 (21.67% or 510 people). [11, 12]

Based on the data presented, significant progress has been made in diagnostic test coverage in the Republic of Molodova: up to 94% of people with TB have been tested with GeneXpert. And 93% of BC+ people with pulmonary TB have undergone DST to ATDs, of which 86% had DST to the new ATDs. This coverage in TB diagnosis indicates that actually all people with TB had access to testing, and with full access to first- and second-line drugs, virtually all those in need were taken on treatment. Thus, the Republic of Molodova has relatively stable TB incidence rates: there was a decrease in TB incidence of 0.6 per 100 000 population in 2023 (72.2) compared to 2022. There was a decrease in DR-TB incidence from 16.3 per 100 000 population in 2022 to 11.8 per 100 000 population in 2022.

However, an 11.5% increase in TB among children and adolescents from 23 in 2022 to 26 in 2023 should be noted. This may be due to improved contact management: out of an average of 13 901 contacts, 13 303 (95.7%) were examined by clinical and paraclinical methods.

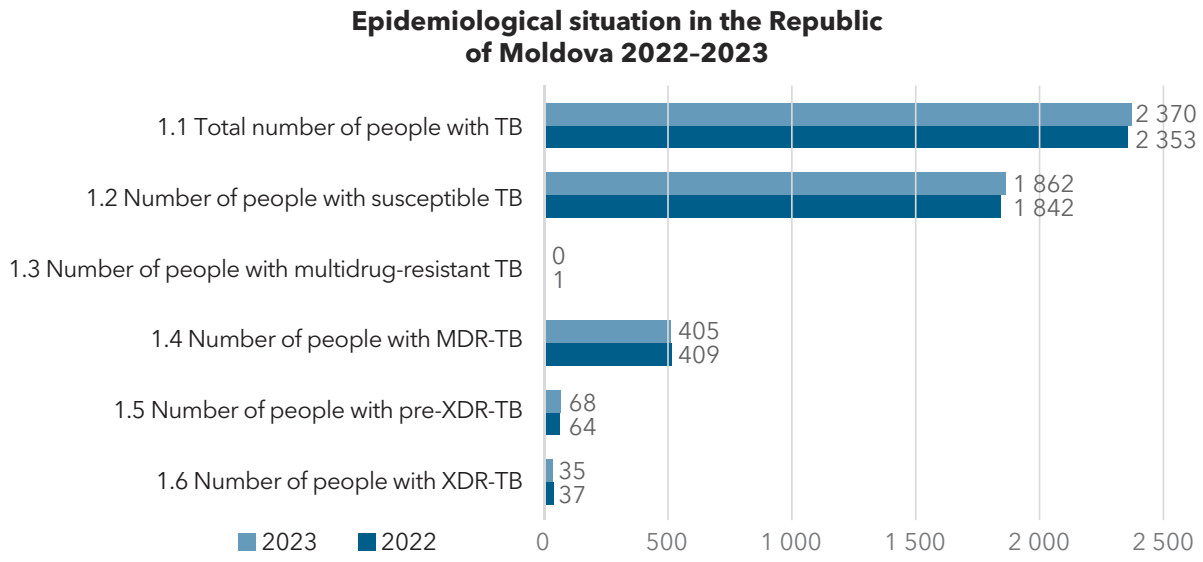

Figure 2. **Epidemiological situation in the Republic of Moldova**

The increase in the number of individuals with XDR-TB by 6% from 64 in 2022 to 68 in 2023 is alarming. With good coverage of diagnostic tests and DST, and appropriate contact management, this may indicate a lack of effectiveness of DST treatment in the 2020 and 2021 cohorts, and it may also be a consequence of the widespread use of fluoroquinolones during the COVID-19 pandemic.

Epidemiological indicators on TB in the Republic of Tajikistan

In Tajikistan, there is an increase in TB incidence in 2023 by 2.7%, compared to 2022, which is a positive trend over the last post-COVID 2020–2023 period, when TB incidence rates fell sharply in 2020 compared to 2019 by 31.2% and remained at the same level until 2022. The total number of people with TB registered in 2022 is 4 421 and in 2023 – 4 540. This indicates that the country's health service is recovering from the COVID-19 pandemic and returning to routine TB interventions. [48, 49]

The total number of people with drug-sensitive TB in 2022 was 3 935; in 2023, there is a 3.4% increase to 4 068. In addition, there has been an increase in the detection of cases of DR-TB with a 2.7% increase in the 6 months of 2024 compared to the same period in 2023.

The number of people with multidrug-resistant TB (MDR-TB) is 37 in 2022 and 30 in 2023. There was a 10.7% decrease in the number of people with MDR-TB in 2023 – 276 compared to 309 in 2022. 2024 decreased by another 18% compared to the same period in 2023.

The number of people with extensively drug resistant (XDR-TB) in 2023 constituted 15 people increased by 25% compared to 2022 where this number was 12 people. There was also an increase in the number of people with pre-XDR-TB in 2023, 86 people, a 9% increase from 2022 where this number was 79 people. This may be due to the massive use of fluoroquinolones (Lfx, Mfx) and repurposed TB drugs (Lzd) during the COVID-19 pandemic or the effectiveness of treatment for people with MDR-TB.

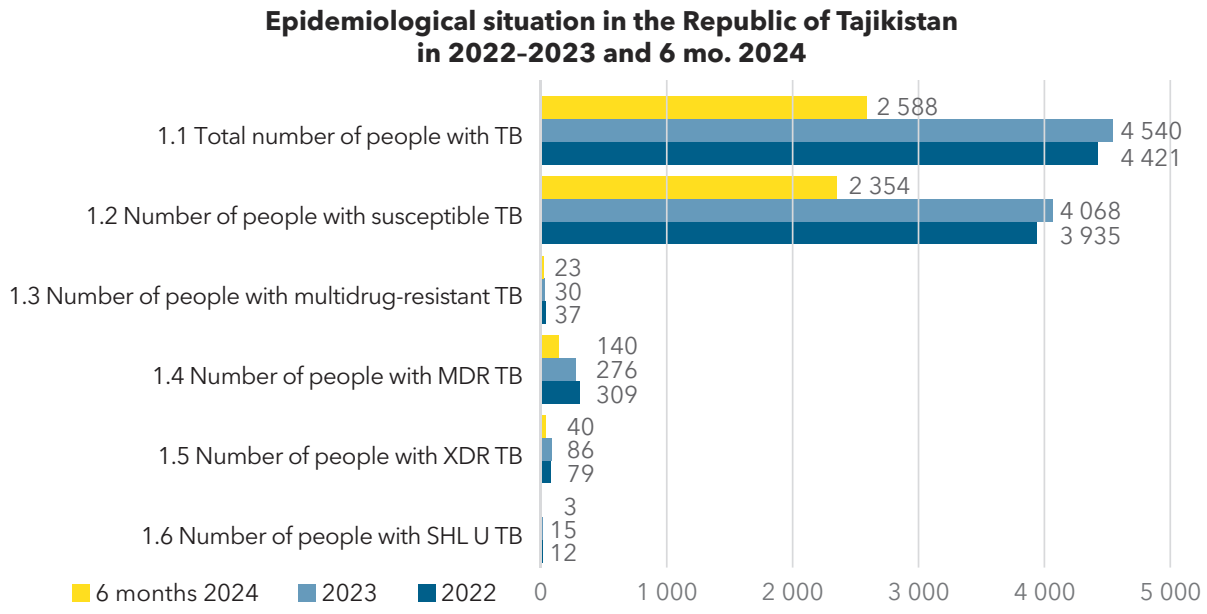

Figure 3. **Epidemiological situation in the Republic of Tajikistan**

TB in children and adolescents of the first-time TB cases in 2022 was 386 and 403 in 2023, an increase of 4.4% is observed. This may be due to improved performance of health care staff in timely detection of new TB cases among children and adolescents. At the same time, 44 children and adolescents with DR-TB were registered in 2022 and 9% fewer (40) in 2023. The downward trend of DR-TB cases among children and adolescents continues according to data from 6 months of 2024: 61% less compared to the same period in 2023.

In Tajikistan, gaps related to inadequate treatment coverage remain due to diagnostic issues, such as access to rapid molecular genetic tests (XDR-TB) and coverage of DST, as well as insufficient communication between laboratory and physicians.

Epidemiological indicators on TB in Ukraine

In 2022, the total number of people with TB is 19 566, and in 2023 it will be 7.3% higher (20 991). The main factor that has led to an increase in the number of people with TB is military aggression by the Russian Federation.

In 2022, 14587 people with susceptible TB were registered, in 2023 – 10% more (16 007 people). As a percentage of the total number of TB cases, the situation with sensitive forms of TB in 2022–2023 remained without significant changes, with about 75% of all TB cases being sensitive.

In 2022, 61 people **with multidrug-resistant TB**, were registered; in 2023, 31% more (80 people). There was no significant trend for polyresistant forms of TB: 0.3% and 0.4% in 2022 and 2023, respectively, as a percentage of the total number of TB cases registered in the respective years. [53, 54, 55].

In 2023, there is a 0.5% increase in MDR-TB cases to 3 924 compared to 3 909 in 2022.

In 2022, 29 people with XDR-TB are registered; in 2023, 48% fewer (15 people). The number of XDR-TB cases as a percentage of total TB cases is decreasing: 0.15% in 2022 and 0.07% in 2023.

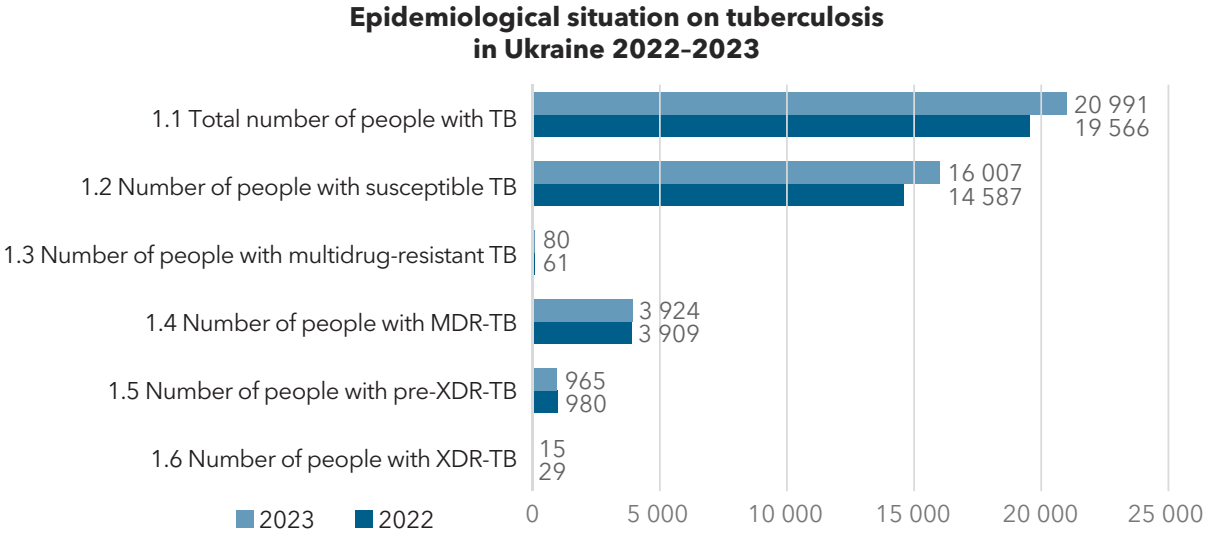

Figure 4. **Epidemiological situation on tuberculosis in Ukraine**

There are 980 people with pre-XDR-TB in 2022 and 2% fewer in 2023 (965 people). The number of pre-XDR cases as a percentage of the total number of people with TB is also decreasing, with 5% in 2022 and 4.6% in 2023.

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In 2022, 4 827 people with pulmonary TB without bacteriological excretion are registered; In 2023 the number of registered people was 4 855. As a percentage of the total number of pulmonary TB cases, there is a decrease in the number of cases without bacteriological excretion: in 2022, pulmonary TB without bacteriological excretion accounted for 28.5% of cases, in 2023 – 26.9%.

In 2022, 12 102 people with bacteriological pulmonary tuberculosis were registered; in 2023, there will be 9% more (13 227 people). There is an increase in the number of bacteriological TB cases, both in absolute numbers and as a percentage of the total number of pulmonary TB cases: in 2022, this indicator was 71.5%, and in 2023 – 73.1%.

General conclusions on epidemiology:

1. ***Long-term impact of the COVID-19 pandemic:*** *The pandemic had a significant negative impact on health systems in all countries under review, resulting in a 30% decline in TB case detection in 2020 compared to the previous period. While there has been a partial recovery, meeting detection targets remains a challenge. Additional efforts are needed to restore early detection and treatment services for tuberculosis.*
2. ***Progress in diagnosis and treatment:*** *All countries are showing significant improvements in the use of molecular genetic tests (e.g. GeneXpert, Molbio, etc.), as well as increased*

access to new short-term treatment regimens such as BPaL. These measures are contributing to improved diagnostic accuracy and treatment efficacy for both sensitive and drug-resistant forms of TB, which is already evident in the decline of resistant forms of the disease.

3. ***Decrease in the prevalence of resistant TB:*** *In Kyrgyzstan and Tajikistan, there has been a significant decrease in the number of cases of multidrug and extensively drug-resistant TB. This is due to the introduction of new drugs and short-term treatment regimens, which has a positive impact on the control of resistant TB. It is important to continue these efforts and increase access to new treatment regimens in other countries.*
4. ***Increased incidence among adolescents:*** *Kyrgyzstan and Moldova have reported an increase in TB incidence among adolescents. This may be due to improved diagnosis in these age groups, but the need to strengthen preventive measures and early TB detection programmes among young people is highlighted. Additional attention is required to address barriers to accessing health care in these age groups.*
5. ***Impact of migration and war:*** *In Ukraine, against the backdrop of full-scale war, there has been an increase in TB cases due to deteriorating social conditions, migration and reduced access to health services. This underscores the need for special programmes to help ensure access to TB diagnosis and treatment in such difficult circumstances.*
6. ***Need for monitoring and experience sharing:*** *In all four countries, further monitoring of the epidemiological situation is required to make timely adjustments to TB interventions. Involvement of civil society and private health providers can be an additional support to improve TB case detection and support treatment of people with TB. Sharing experiences and good practices between countries can help to better respond to existing challenges and improve treatment outcomes.*

SAFETY LAWS AND REGULATIONS

Legislation and regulations play a critical role in establishing a structured approach to TB elimination, including the procurement of essential medicines. Each country – the Kyrgyz Republic, Republic of Moldova, Republic of Tajikistan and Ukraine – has unique legal mechanisms in place to improve access to treatment, provide quality medicines and support national programmes aimed at TB control and prevention.

Laws and regulations on TB in the Kyrgyz Republic:

1. The main provisions for providing citizens with TB care, the powers of health care organisations, the rights and benefits of people with TB, and the provision of medicines are included in the law "On Health Protection of Citizens in the Kyrgyz Republic" No. 14 of 12 January 2024.
   https://cbd.minjust.gov.kg/4-5260/edition/1939/ru [3].
2. The Public Health Act of 12 January 2024 contains more detailed regulations on prevention, provision of health care and procurement of medicines.
   https://cbd.minjust.gov.kg/4-5301/edition/3727/ru [4].
3. The programme of the Cabinet of Ministers of the Kyrgyz Republic "Tuberculosis-VI" for 2023–2026 is aimed at stabilising the TB situation, eliminating the consequences of COVID-19 and strengthening the role of the Ministry of Health.
   https://cbd.minjust.gov.kg/53-324/edition/1233942/ru [5].
4. Law No. 13 "On Circulation of Medicines" of 12 January 2024 regulates the registration, storage and dispensing of medicines.
   https://cbd.minjust.gov.kg/4-5251/edition/1638/ru [6].
5. Cabinet Resolution No. 246 of 30 April 2022 regulates the procurement of medicines through international organisations.
   https://cbd.minjust.gov.kg/7-21590/edition/1167439/ru [7].
6. First-line drugs are procured through the government procurement portal.
   http://zakupki.gov.kg/popp/view/services/statistics/report_new_module1.xhtml [8].

It is planned to increase the state budget expenditure on procurement of medicines from 22% in 2024 to 26% in 2026. To ensure the best value for money and quality assurance, all drugs will be procured through international platforms.

Laws and regulations on TB in the Republic of Moldova

The provision of TB diagnosis and treatment services in the Republic of Moldova is regulated by a number of legal and regulatory documents:

1. Law on Health Protection no. No. 411-XIII of 28 March 1995. https://www.legis.md/cautare/getResults?doc_id=65554&lang=ru [13].
2. Law no. 153-XVI of 4 July 2008 on the control and prevention of tuberculosis. https://www.legis.md/cautare/getResults?doc_id=106894&lang=ru [16].
3. Law no. 10-XVI of 3 February 2009 on state supervision in the field of health care. https://faolex.fao.org/docs/pdf/mol178582.pdf [14].
4. Law No. 263 of 27.10.2005 on the rights and responsibilities of the patient. According to this law, the patient has the right to free medical care to the extent provided for by law. https://www.legis.md/cautare/getResults?doc_id=129085&lang=ru [21].
5. Resolution of the Government of RM No. 1387 of 10.12.2007 on the approval of the Unified Programme of Compulsory Medical Insurance. https://www.legis.md/cautare/getResults?doc_id=111759&lang=ru [22].
6. National Tuberculosis Control Programme (NTCP) 2022–2025. https://balti.md/wp-content/uploads/2022/12/cmb-reshenie-19.18-din-22.12.2022-ru.pdf [23].
7. Clinical protocol "Tuberculosis in adults" [24] [24].
8. Clinical protocol "Tuberculosis in children" [25] [25].
9. Guidelines "Organisation and conduct of systematic tuberculosis screening and prevention" [26].

Laws and regulations on TB in the Republic of Tajikistan:

1. The main provisions of health care for tuberculosis are reflected in the Law of the Republic of Tajikistan "On Public Health Protection". https://faolex.fao.org/docs/pdf/taj62600.pdf [47].
2. Health Code of the Republic of Tajikistan, Chapter 23: Protection of the Population from Tuberculosis No. 1 413 of 30 May 2017. https://continent-online.com/Document/?doc_id=38514256#pos=33;-21 [49].
3. Law of the RT "On Medicines, Medical Goods and Pharmaceutical Activities", enacted by Presidential Decree No. 1 893 of 19 July 2022. https://base.spinform.ru/show_doc.fwx?rgn=142296 [50].
4. The National Tuberculosis Treatment Guidelines and the National Essential Drug List (EML) regulate the choice of drugs. The latest update is Order No. 600 of the Ministry of Health and Social Protection of the Republic of Tajikistan dated 15 August 2022.
5. TB drugs are procured through the State Procurement Portal of the Republic of Tajikistan. https://eprocurement.gov.tj [51].

Tajikistan's drug regulatory legislation is not regularly updated and does not include mechanisms for accelerated registration of certain categories of medicines, such as those prequalified by the World Health Organisation (WHO) and those registered in countries with strong regulatory authorities. In addition, the country does not participate in the WHO Collaborative Registration Procedure and there are no regulators supporting this initiative, which limits access to internationally recognised medicines.

Due to the fact that few TB drugs are registered in the country, the choice of drugs is very limited and the country procures unregistered drugs, as well as drugs that are not WHO prequalified and/or registered in countries with strong regulatory authorities. Procurement of drugs using state budget funds is carried out within the framework of the Law on Public Procurement of Goods, Works and Services No. 168 of 03.03.2006.

Laws and regulations on TB in Ukraine:

1. Law of Ukraine "On Medicinal Products". This law regulates the procedure for importing unregistered medicines into Ukraine for the implementation of state programmes. Medicines can be supplied within the framework of centralised procurement, which is carried out at the expense of the state or local budget. Important attention is paid to the control of safety and effectiveness of medicines. https://base.spinform.ru/show_doc.fwx?rgn=143115 [53].
2. Cabinet of Ministers Resolution No. 1 082 of 2020. This normative act defines the procedure for public procurement, including medicines, which is also applicable to TB drugs. (https://phc.org.ua/sites/default/files/users/user90/National_response_HIV_TB_VH_SMT_war_2023_UKR.pdf, as well as https://phc.org.ua/kontrolzakhvoryuvan/tuberkuloz/statistika-z-tb/analitichno-statistichni-materiali-z-tb) [54].
3. International procurement through UNDP and other organisations. Since 2014, procurement of medicines, including TB drugs, has been outsourced to international organisations. This step has significantly increased the transparency of the process and allowed to save significant amounts of money by reducing drug prices. Procurement is carried out on international platforms, taking into account the standards of WHO and other recognised regulatory bodies. https://phc.org.ua/kontrol-zakhvoryuvan/tuberkuloz/statistika-z-tb/analitichno-statistichni-materiali-z-tb, http://www.drlz.com.ua/ibp/ddsite.nsf/all/shlist?opendocument [56].

General conclusions on laws and regulations:

TB procurement legislation in the Kyrgyz Republic, the Republic of Moldova, the Republic of Tajikistan and Ukraine plays a key role in ensuring that people with TB have the medicines they need. The main objectives of legal mechanisms are to improve access to quality medicines, support national TB programmes and comply with international standards in procurement.

- ***The Kyrgyz Republic is** actively updating the legislative framework to improve public procurement of TB drugs, including cooperation with international organisations to ensure the availability of quality drugs.*
- ***The Republic of Moldova** implements clinical protocols and insurance programmes that aim to provide free treatment to people with TB, and supports the active fight against drug-resistant TB.*

- *In **Tajikistan** there are a number of problems with updated legislation, lack of accelerated registration of medicines and inefficient procurement procedures, resulting in limited access to medicines, especially for DR-TB. Donor assistance has so far covered the needs, but an increased share of public funding is required in the future.*
- *In **Ukraine** despite significant support from international organisations and the existence of a regulatory framework for procurement, there are short-term shortages of certain drugs, which requires increased monitoring and forecasting of needs within the framework of national programmes.*

COMPARATIVE ANALYSES OF NATIONAL RECOMMENDATIONS

All countries rely on the WHO recommendations, but each country adapts them according to its national health system, epidemiological situation and resources. As indicated in the WHO recommendations for people with MDR-TB all countries have adopted **BPaLM** (Bedaquiline, Pretomanid, Linezolid, Moxifloxacin) and **BPaL** (Bedaquiline, Pretomanid, Linezolid) as the first regimen of choice for people resistant to fluoroquinolones, also an important aspect of the analysis are the modified short treatment regimens for DR-TB recommended by WHO operational research for people who are not resistant to fluoroquinolones and aminoglycosides: **4–6 Mfx (Lfx) Km (Am) Pto Cfz Z Hhd E / 5 Mfx** (or **Lfx**) **Cfz Z E** (4–6 months Moxifloxacin (Levofloxacin), Kanamycin (Amikacin), Prothionamide, Clofazemine, Pyrazinamide, Isoniazid (high dose), Etambutol/ 5 months Moxifloxacin, Clofazemine, Pyrazinamide, Etambutol). Special attention is paid to the organisation of treatment, monitoring of safety and efficacy of therapy, and integration of new drugs into the clinical protocols of each country.

Analysis of national recommendations in the Kyrgyz Republic

The 2023 Clinical Guidelines for the Diagnosis and Treatment of Drug-Resistant Tuberculosis and Clinical Protocol for the Diagnosis and Treatment of Drug-Resistant Tuberculosis are based on the WHO Consolidated Guidelines on Tuberculosis, **Module 4: Treatment**. The basic principles of treatment, management tactics, drug dosages, duration of treatment, eligibility and exclusion criteria, and active monitoring and management of treatment safety are well reflected in the national clinical guidelines and protocol and are consistent with those in the WHO consolidated guidelines. It should also be noted that there are some generalisations and adaptations in the national guideline and protocol that do not change the overall meaning of the recommendations. It should also be noted that the national guideline and protocol include the introduction of a modified short-term treatment regimen for DR-TB (mSTR) recommended by WHO in operational research.

Analysis of national recommendations in the Republic of Modlova

National clinical protocols are strategic documents that articulate TB guidelines. As of 2024, these documents address and prescribe aspects of the introduction of new drugs or regimens that involve: justifying the introduction of a new drug or regimen at the country level; updating clinical guidelines, including through (1) information on inclusion and exclusion criteria for people with TB; and (2) optimal use of the new TB drug and choice of concomitant drugs; case management; treatment monitoring (record-keeping and reporting; monitoring and evaluation; pharmacovigilance and ethical review; and (3) the use of the new TB drug and choice of concomitant drugs. TB treatment is based on the National Clinical Protocols (NCPs) for TB for adults and children and health standards developed in accordance with WHO recommendations and approved by the Ministry of Health. All first- and second-line anti-TB drugs are available in the country.

Analysis of national recommendations in the Republic of Tajikistan

Drug selection for TB treatment in Tajikistan is based on the National Guidelines for the Treatment of Drug-Sensitive (DR-TB) and Drug-Resistant Tuberculosis (DR-TB) and TB infection. These documents are based on World Health Organisation recommendations and are regularly revised to reflect the latest international standards.

The National List of Essential Medicines (NLM), which is updated by the Ministry of Health and Social Protection of the Population of the Republic of Tajikistan (MoHSDP), plays a key role in drug selection. The latest version of the List, approved by Order No. 600 of the Ministry of Health and Social Protection of the Republic of Tajikistan dated 15 August 2022, includes all TB drugs recommended by WHO, including Pretomanid.

The updated sections of the TB and DR-TB management guidelines are fully compliant with the latest WHO 2022 recommendations, ensuring that international treatment standards are applied in Tajikistan. This ensures effective and safe treatment of people with TB that meets the modertn requirements of global medicine.

Analysis of national recommendations in Ukraine

Ukraine was one of the first countries in Eastern Europe and Central Asia to introduce new WHO recommendations into national clinical protocols. Thus, Ukraine is actively introducing short regimens for the treatment of drug-resistant tuberculosis, which are recommended by WHO. On 19 January 2023, the Standard of Medical Care "Tuberculosis" was approved, which stipulates the use of BPaL and BPaLM regimens for the treatment of people with drug-resistant TB.

Overall conclusions on national guidelines

All four countries, the Kyrgyz Republic, the Republic of Moldova, the Republic of Tajikistan and Ukraine, have successfully integrated international WHO recommendations into their national guidelines and protocols, ensuring effective and safe tuberculosis treatment. In the Republic of Tajikistan, the guidelines have been revised to reflect the latest WHO recommendations and submitted to the Ministry of Health for approval. In the remaining countries, adapted national guidelines have also incorporated WHO updates on short-term TB treatment regimens and have been approved by the relevant authorities.

STUDY OF EXISTING INTERNATIONAL PROGRAMMES

International programmes aimed at eliminating TB play an important role in providing countries with TB drugs and supporting the introduction of innovative diagnostic and treatment methods. Due to limited national resources, many countries with high TB burdens rely on donor support, especially for TB drugs and clinical and operational research.

Existing international programmes in Kyrgyz Republic

The Global Fund has been the main donor to the TB programme, procuring second-line TB drugs over the past few years. It should be noted that the list of drugs procured through the Global Fund includes only drugs provided through the GDF – Global Drug Facility, where almost all TB drugs have WHO requalification, which guarantees high quality of TB drugs.

In 2021–2022 in the Kyrgyz Republic, the National Centre for Phthisiatry together with the KNCV office in the Kyrgyz Republic implemented the international project LIFT TB with the financial support of TB Alliance/KOICA, according to which the country received 50 courses of pretomanid as part of humanitarian aid, providing early access to treatment in the framework of an operational trial.

The Global Fund procured TB drugs in 2022 with a final contract amount of 2 619 501 USD with an initial tender amount of 2 619 501 USD, which may indicate that there was no competition with a single supplier at a fixed price.

And in 2023, TB drugs were procured through the Global Fund with a final contract amount of 1 265 195 USD against the initial tender amount of 1 265 195 USD.

Existing international programmes in the Republic of Moldova

The Global Fund finances public procurement. IP UCIMP DS (Romanian: Implementing Partner "Unitatea de Coordonare, Implementare și Monitorizare a Proiectelor în Domeniul Sănătății") The Unit for Coordination, Implementation and Monitoring of Health Projects is the main recipient of the GF and, at the same time, the contracting authority for drugs and medical products procured through the Global Drug Facility. Donor funds earmarked for the procurement of medicines belong to the state budget and while never being deposited into the government's account. The Global Drug Facility of the Stop TB Partnership is an integrated procurement and supply chain mechanism providing a package of services that combines strategic procurement of TB drugs and market coordination with technical assistance and capacity building for TB programmes.

In the period 2016–2022, two international multicentre clinical trials were implemented in Moldova to evaluate the safety and efficacy of different doses and durations of medication

and regimens of innovative and repositioned TB drugs: the first study STREAM 2, which sought to gather evidence on the efficacy, safety and cost-effectiveness of more easily tolerated MDR-TB treatment regimens, including a 9-month oral regimen containing Bdq. This study was conducted in 13 research centres (sites) in 7 countries – Ethiopia, Georgia, India, Moldova, Mongolia, South Africa, Georgia and Uganda. There were 588 participants enrolled worldwide, including 63 participants from Moldova; and the second partially blinded ZeNix phase 3 study, which aimed to provide evidence for the safety and efficacy of different doses and durations of BPaL in treatment regimens of 6–9 months for participants with XDR-TB and pre-XDR-TB or participants with MDR-TB treatment intolerance. The study was conducted at 7 sites in 4 countries – Georgia, Moldova, the Russian Federation and the Republic of South Africa. A total of 180 participants were enrolled, 10 of them in Moldova.

An operational multi-country prospective cohort study to evaluate the efficacy and safety of mSTR for the treatment of fluoroquinolone-sensitive and rifampicin-resistant pulmonary TB with short-term 9-month oral modified regimens containing Bdq, Dlm, Lnz and Cfm/CS was implemented in Moldova 2020–2023. The study was conducted in 13 countries in the WHO European Region. A total of 2 813 participants were enrolled, of whom 294 in Moldova were enrolled between 2022 and 2023. Until 2024, BPAL was implemented in Modova only in the context of a clinical trial (ZeNix).

Existing international programmes in the Republic of Tajikistan

Over the decades from 2004 to 2018 NTP of RT has been continuously supplied with quality TB drugs through external funding from GF grants, grants from the Global Drug Facility (GDF) (drugs for DR-TB and paediatric dispersible drugs for DR-TB), and partially through USAID, MSF and Stop TB/TB REACH projects. Procurement of these drugs was mainly through GDF, except for drugs procured by MSF. As of 2018 the procurement of most TB drugs for DR-TB treatment is financed by the Global Fund and procured by the UNDP Principal Recipient through GDF.

At the moment, the Republic of Tajikistan is fully stocked with second-line TB drugs through donor assistance for 2024–2025, which allows the NTP to successfully treat people with DR-TB on all existing regimens, providing equal access to short treatment regimens across the country. However, from 2024 onwards, funding from the Global Fund will be gradually reduced in line with commitments made by the government to increase its share of procurement of these drugs. The Government of Tajikistan, as part of its financial commitments, has committed to annual financing of procurement of drugs for DR-TB, covering 100% of the need. The Government has also decided to start financing drugs for DR-TB treatment, with the condition of gradual increase of the state's contribution to the procurement of these drugs (in 2024 – 15%, 2025 – 20%, 2026 – 25%). There is a slight increase in state funding for procurement of 1st-line TB drugs (from 7 to 12% during 2020–2023), despite the overall low level of public spending on health care.

Existing international programmes in Ukraine

From 2022, Ukraine is fully dependent on international donor assistance to finance procurement of TB drugs. In 2022–2023, funding was provided by the Global Fund, as well as USAID and the charity organisation TBPeopleUkraine. The drugs were procured directly from the Global Drug Facility and were WHO prequalified. Only the supply from TBPeopleUkraine was made on an emergency basis without the requirement of WHO prequalification due to an acute shortage of ethambutol 400 mg in the country.

In 2024, supplies are mainly USAID-funded and also procured through GDF.

During 2022–2024 the procuring organisation is the Centre for Public Health of the Ministry of Health of Ukraine.

Overall conclusions on international programmes

1. ***Key donors:*** *In all four countries, the key donor is the Global Fund, which finances procurement of TB drugs through the Global Drug Facility. USAID also provides significant support, especially in Ukraine and Tajikistan.*
2. ***Procurement of drugs:*** *All countries are heavily dependent on international donors to meet the need for second-line drugs. Drugs procured through the GDF are WHO prequalified, which guarantees their quality. However, under conditions of shortages, as in the case of Ukraine, and weak regulatory frameworks, as in Tajikistan, unqualified TB drugs may be procured.*
3. ***Introduction of new treatment regimens through research:*** *The Kyrgyz Republic, Republic of Moldova and Republic of Tajikistan have been actively involved in international research and implementation of new treatment regimens, including short regimens for drug-resistant TB using bedaquiline, delamanid and pretomanid. For example, the Kyrgyz Republic successfully implemented the LIFT TB project, and the Republic of Moldova conducted the STREAM 2 and ZeNix trials to test new approaches to MDR-TB treatment.*
4. ***Funding and donor dependence:*** *In all countries, except for some cases in Moldova, most funding for TB programmes comes from external sources. Ukraine is fully dependent on donor funding for TB drugs from 2022 onwards.*
5. ***Future prospects:*** *International support is driving significant improvements in TB treatment, but programme sustainability requires strengthening national health systems and reducing donor dependence. Country strategies should include integrating new treatment regimens and ensuring stability of supply even in crises.*

STUDYING LEGISLATION ON PUBLIC PROCUREMENT

Public procurement of TB medicines is regulated by legislation to ensure quality, accessibility and transparency of procured medicines. Each country has its own unique procedures governing procurement under government health programmes.

Public Procurement Legislation in the Kyrgyz Republic

State procurement of TB drugs, as well as other medicines purchased in the health care system of the Kyrgyz Republic, is carried out in accordance with the "Procedure for centralised supply of medicines and medical devices by the state enterprise "Kyrgyzpharmacia" under the Ministry of Health of the Kyrgyz Republic", approved by the Cabinet of Ministers Resolution No. 601 of 15.11.23 in order to ensure centralised supply of medicines and medical devices, in accordance with the Decree of the President of the Kyrgyz Republic. The Cabinet of Ministers of the Kyrgyz Republic approved the Procedure for centralised supply of medicines and medical devices by the State Enterprise "Kyrgyzpharmacy" under the Ministry of Health of the Kyrgyz Republic. It is also established that the State Enterprise Kyrgyzpharmacy under the Ministry of Health of the Kyrgyz Republic is a supplier of medicines and medical goods for state and municipal health care organisations according to the List of medicines and medical devices centrally purchased by the Ministry of Health of the Kyrgyz Republic. The State Enterprise Kyrgyzpharmacy, when concluding contracts for the supply of medicines and medical devices, is entitled to take into account overhead costs associated with transportation, loading, registration, quality control, storage, delivery and a markup of up to 5 per cent of the contract amount. State and municipal health care organisations make payment for the supplied medicines and medical goods to the state enterprise "Kyrgyzpharmacy" at the expense of funds provided in the budget of the organisations for the relevant year. Also, public procurement may be carried out in accordance with the Procedure for public procurement of medicines and medical devices through organizations (representative offices) established by the United Nations, approved by Resolution of the Cabinet of Ministers of the Kyrgyz Republic No. 246 of 30 April 2022.

All first- and second-line anti-TB drugs are included in the updated national list of essential medicines and medical goods on 6 August 2024 signed by the Chairman of the Cabinet of Ministers of the Kyrgyz Republic Akylbek Zhaparov. Chairman of the Cabinet of Ministers of the Kyrgyz Republic Akylbek Zhaparov on 6 August 2024. [9]

Almost all first- and second-line TB drugs (except **Bedaquiline, Delamanid and Rifampentine** – which are purchased with donor funds and imported by UNDP under humanitarian aid regulations) are registered with the Department of Drugs and Medical Technology https://www.pharm.kg/ru/register_of_mi/ [10] Both adult and paediatric doses of first- and second-line TB drugs have been registered. TB drugs from different manufacturers are registered in the Kyrgyz Republic.

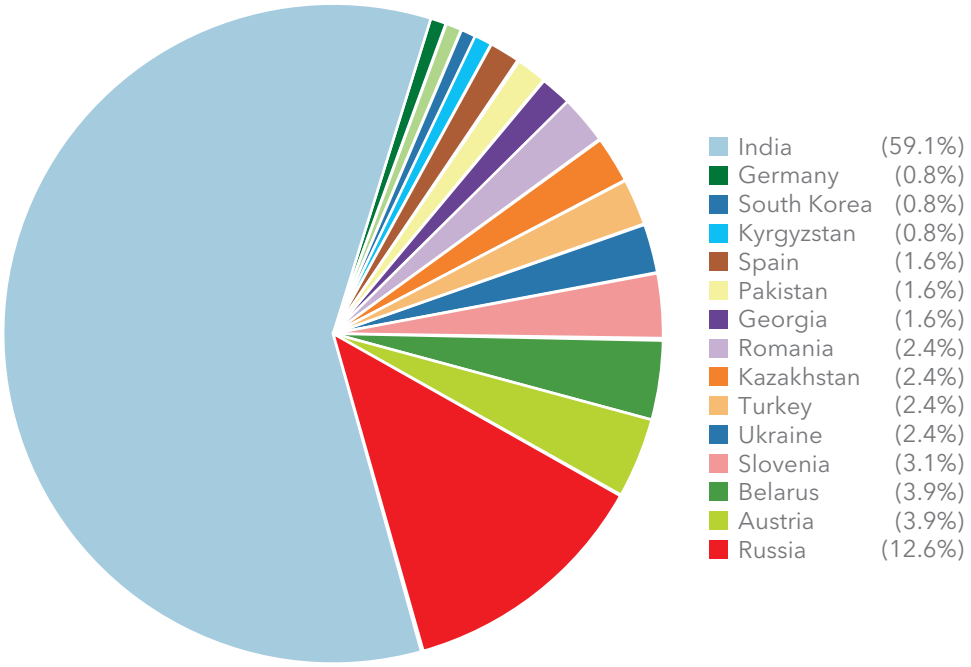

Figure 5. **Percentage of registrations by country of production in the Kyrgyz Republic**

Registration certificate holders are mainly (59%) Indian companies: Macleods, Lupin, Simpeks, Aigo, Zota, Simpeks, Scotish and Mylan. The Russian pharmaceutical company Pharmasintez takes the second place (13%). The third place have taken Austrian company Lek and Belarus-based Belmedpreparaty (4% each).

To a lesser extent, companies from Slovenia (3.1%) – Novo mesto, Ukraine (2.4%) – Yuria Farm and Borschagovsky CPP, Turkey (2.4%) – Deva Holding A.S. and Dr. Sertus Ilac Sanayi ve Ticaret Limited Sirketi, Turkey/Kazakhstan (2.4%) – Nobel, Romania (2.4%) – World Medesin are represented.

A small block of registration certificate holders are from Georgia (1.6%) – Aversi, Pakistan (1.6%) – CCL Pharmaceuticals, Spain (1.6%) – GM Pharmaceuticals.

Less than 1% each of the registration certificate holders are from South Korea – DONG, Germany – PenSeph Pharma GmbH, Greece – Libytec.

It is important to note that the holder of 0.8% – one registration certificate for Levofloxacin 500 mg dosage – is the domestic company Pharma Noor.

Import and distribution of medicines in the country is carried out in accordance with the regulation on the procedure for the reception and distribution of humanitarian aid in the Kyrgyz Republic, approved by the Resolution of the Government of the Kyrgyz Republic № 43 of 1 February 2016 https://cbd.minjust.gov.kg/7-21590/edition/1167439/ru. According to this document, humanitarian goods imported into the territory of the Kyrgyz Republic are exempt from taxes, customs duties and fees for actions related to the release of goods.

Legislation on public procurement in the Republic of Moldova

Public procurement in health care from budgetary funds in Moldova is regulated by the following legal and regulatory documents:

1. Law No. 131 of 03.07.2015 on public procurement [31].
2. In 2016. Government Decree No. 1128 of 10.10.2016 established the Agency for Centralised Public Procurement in Healthcare (hereinafter CAPCS) [33].
3. MoH Order No. 859/2020 of 22.09.2020 on the organisation of public procurement of medicines, medical devices and other medical devices [34].
4. Law No. 102 of 09.06.2017 on medical devices. This law establishes the rules for the market launch and operation of medical devices, the procedure for the control and supervision of medical devices, as well as the procedure for the supervision of activities for the sale and distribution of medical devices and the provision of related services [35].
5. Government Decision No. 665 of 27.05.2016 on approval of the Regulation on public procurement of small value. This regulation establishes legal grounds for public procurement of goods, works and services of small value [36].
6. Government Decree No. 666 of 27.05.2016 on approval of the Regulation on the procurement of goods and services by request for quotations [37].
7. Government Decision No. 667 of 27.05.2016 on approval of the Regulation on the activities of the working group on procurement. This Resolution establishes the functions, duties and rights of the working group on procurement, as well as the procedure for its establishment and functioning [38].
8. Government Decision No. 668 of 27.05.2016 on the approval of the Regulation on the implementation of public procurement through a negotiated procedure [39].
9. Government Decision No. 45 of 24.01.2008 on the approval of the Regulation on the procedure for compiling the List of Prohibited Economic Operators and keeping their records. This Resolution establishes the procedure for compiling the List of Prohibited Economic Operators and keeping their records [40].

Government procurement of TB drugs is financed by the Global Fund (GF) and regulated by the following documents:

10. The State Institution "Unit for Coordination, Implementation and Monitoring of Health Projects" (hereinafter IP UCIMP DS) was established by the Government Decision of the Republic of Moldova No. 391 of 19 April 2 000 and is an autonomous, non-profit, self-governing organisation operating in accordance with the national legislation in force and external donor procedures. IP UCIMP DS is the principal recipient of GF and, at the same time, the purchaser of medicines, other medical products and medical devices procured through the mechanisms of the Global Drug Facility of the Stop TB Partnership GDF). Donor funds earmarked for the procurement of medicines belong to the state budget and have never been received into the de facto account of the state.
11. The GDF is an integrated procurement and supply mechanism providing a unique package of services that combines strategic TB procurement and market coordination with technical assistance and capacity building for TB programmes.

The Ministry of Health centrally procures medicines for national programmes through a secure and sustainable CAPCS mechanism. Procurement is conducted through public tenders in accordance with the technical requirements and criteria of the National

Programmes and international recommendations. Bids are submitted through the SIA RSAP electronic system (MTender) and are evaluated based on the tender documents. Once the winners are selected, tripartite contracts are concluded between the supplier, CAPCS and the beneficiary institution (e.g. Institute of Phthisiopulmonology and National Penitentiary Administration). Goods are delivered according to schedule, after which CAPCS monitors the timeliness and compliance of deliveries with the terms of the contract.

In Moldova, medicines, including TB drugs, are subject to 8% VAT. There are no exceptions for medicines purchased at the expense of the state budget. CAPCS applies the INCOTERMS DDP requirement, which obliges suppliers to deliver goods directly to the beneficiaries – the Institute of Phthisiopulmonology or the National Administration of Penitentiaries. UCIMP DS is exempted from payments and customs duties on importation of medicines by the IP UCIMP Government Decree, but incurs costs for delays in customs clearance and for the transport of goods. Additional costs for medicines through GDF, such as procurement commission and transport costs, are up to 18.5 per cent and are not included in the prices of medicines.

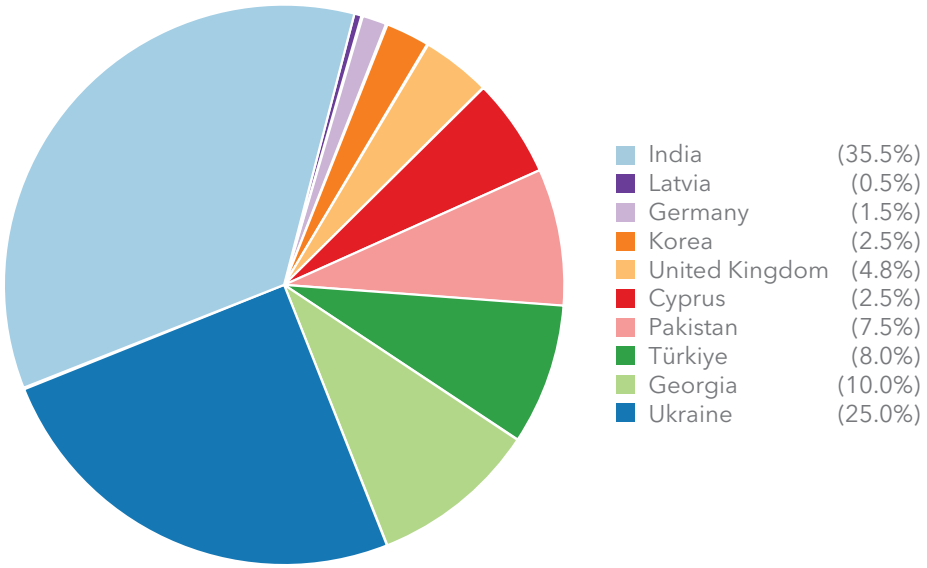

Figure 6. **Percentage of registrations by country of production in the Republic of Moldova**

As of 30.07.2024 out of 11 drugs (INN) used for treatment of resistant forms of TB, Amikacinum; Amoxicillinum + Acidum clavulanicum; Bedaquilinum; Clofaziminum; Cycloserinum; Delamanidum; Imipenemum+Cilastatinum; Levofloxacinum; Linezolidum; Moxifloxacinum; Natrii para-aminosalicylas; Pretomanidum; Prothionamidum are registered. Currently, Bedaquilinum, Delamanidum and Prothionamidum are not on the list of registered medicinal products in the Republic of Moldova.

Public Procurement Legislation in the Republic of Tajikistan

Procurement of TB drugs at the expense of the state budget for treatment of DR-TB and TB prevention is carried out on the local market through national competitive procedures, where, according to the legislation of Tajikistan, the main criterion for selection of drugs is the lowest price.

The country has regulatory legal acts governing relations in the area of drug circulation, quality control, and the provision of medicines and medical products to the population. The legislative document regulating the legal framework of state policy in the sphere of circulation of medicines, medical products and pharmaceutical activities is the Law of the RT "On Medicines, Medical Products and Pharmaceutical Activities", enacted by Presidential Decree No. 1893 of 19.07.2022 [50]. In connection with the updating of this Law, the MoHSHSW of Tajikistan, together with the State Supervision Service for Health Care and Social Protection of the Population (SSHSDPP), is currently in the process of developing relevant by-laws.

At the time of publication of this material, there is no separate document regulating the procurement of medicines and medical products, describing the rules of organisation and conduct of procurement taking into account the peculiarities of this product category (e.g. mandatory WHO prequalification for TB drugs). There are no regulations on simplified registration of WHO prequalified medicines and medicines registered with SROs.

There are some problems related to local procurement in the country. The current legislation of the Republic of Tajikistan does not provide procedures for procurement of medicines and medical products through international organisations such as the UN. This limits access to quality medicines, especially when there are no registered analogues in the country. The absence of such a procedure makes it difficult to procure internationally certified medicines, which may negatively affect the provision of necessary medicines to patients.

Table 1

Registration status of TB drugs in the Republic of Tajikistan used for DR-TB treatment as of March 2024

INN of the drug	Dosage/ packaging	Date of issue of the registration certificate	Registration deadline date	Manufacturer
Levofloxacin (Levofloxacin)	250 mg No. 100	Pending submission of the registration dossier		Macleods
Moxifloxacin (Moxifloxacin)	400 mg No. 100	Pending submission of the registration dossier		Macleods
Bedaquiline (Bedaquiline)	100 mg No. 188	Pending submission of the registration dossier		Macleods
Linezolid (Linezolid)	600 mg No. 100	15.03.2024	14.03.2029	LUPIN LIMITED
Clofazimine (Clofazimine)	100 mg No. 100	Pending submission of the registration dossier		Macleods
Cycloserine (Cycloserine)	250 mg No. 100	No registration		
Delamanid	50 mg No. 672	No registration		
Pyrazinamide (Pyrazinamide)	400 mg No. 672	Pending submission of the registration dossier		Macleods
Pretomanid	200 mg No. 26	21.06.2021	20.06.2026	Mylan Lab. Lim.
Imipenem/Cilastatin (Imipenem/Cilastatin	500 mg/500 mg No. 10	No registration		
Amoxicillin + Clavulanic acid (Amoxicillin+Clavulanic acid)	500 mg/125 mg No. 100	No registration		
Levofloxacin (Levofloxacin)	100 mg No. 100	No registration		
Bedaquiline (Bedaquiline)	20 mg No. 60	No registration		
Linezolid (Linezolidum)	150 mg No. 100	No registration		
Clofazimine (Clofazimine)	50 mg No. 100	No registration		
Cycloserine (Cycloserine)	125 mg No. 100	No registration		
Delamanid	25 mg No. 48	No registration		

Macleods Pharmaceutical Company is preparing dossiers for filing for registration for the following drugs: Levofloxacin 250 mg No. 100, Moxifloxacin 400 mg No. 100, Bedaquiline 100 mg No. 188, Clofazimine 100 mg No. 100, Pyrazinamide 400 mg No. 672.

Linezolid 600 mg No. 100 by the manufacturer LUPIN LIMITED is registered in the Republic of Tajikistan since 15.03.2024, registration expiry date – 14.03.2029.

Pretomanid 200 mg No. 26 manufacturer Mylan Laboratories Limited is registered in the Republic of Tajikistan since 21.06.2021, registration expiry date – 20.06.2026.

Other drugs for treatment of drug-resistant tuberculosis are not registered in the Republic of Tajikistan: Cycloserine 250 mg No. 100, Delamanid 50 mg No. 672 and 25 mg No. 48, Imipenem/Cilastatin 500 mg/500 No. 10, Amoxicillin + Clavulanic acid 500 mg/125 mg No. 100, Levofloxacin 100 No. 100, Bedaquiline 20 mg No. 60, Linezolid 150 mg No. 100, Clofazimine 50 mg No. 100, Cycloserine 125 mg No. 100. However, thanks to donor support, the country is provided with these drugs.

The selection of drugs for TB treatment is based on the National Guidelines for the treatment of DS-TB, DR-TB, treatment of TB infection, as well as National List of Essential Medicines (SOLS), which is regularly reviewed by the MoHSD of RT. The last update of the List was made in 2022 Order of the MoHSHSD of RT No. 600 of 15.08.2022 , as a result of which all TB drugs recommended by WHO, including Pretomanid, were included. [52]

Until 2022, there are no registered TB drugs of guaranteed quality on the country's market due to the lack of interest of suppliers and manufacturers in Tajikistan's relatively limited market. In addition, registration fees are quite high. Tajikistan has not joined the WHO Collaborative Registration Procedure, which provides for accelerated registration of WHO pre-qualified medicines. Thanks to technical assistance from the USAID-funded PQM+ Programme, implemented by USP, in 2022–2024 14 TB drugs were registered, of which 13 are 1st-line ATDs and 1 is a 2nd-line PTP. Rifampicin 150 75 mg, Rifampicin 150 mg/Isoniazid 75 mg/Etambutol 275 mg/Pyrazinamide 400 mg, Etambutol 400, Rifampentine 300 mg/Isoniazid 300 mg, Rifampicin 75 50 mg (soluble), Isoniazid 100 mg, Etambutol 100 mg, Rifampicin 75 mg/Izoniazid 50 mg/Pyrazinamide 150 (soluble), Isoniazid 300 mg, Rifampicin 150 mg/Izoniazid 75 mg/Etambutol 275 , Rifampentin 300 . Also 5 TB drugs of 2 lines: Levofloxacin 250, Moxifloxacin 400 mg, Bedaquiline 100 mg, Clofazemine 100 mg and Pyrazinamide 400 mg are at the stage of submission of dossiers for registration to the regulatory authorities of the country. The timeframe for registration depends on the completeness and quality of the documents (TB dossiers) submitted to the regulatory authorities. In general, the timeframe for registration can take a period of 3 to 6 months. [49].

Public Procurement Legislation – in Ukraine

During 2022–2024, the procurement organisation is the Centre for Public Health of the Ministry of Health of Ukraine. Despite the fact that the country has stable sources of funding and there are practically no delays in the supply of medicines, however, in 2023 and 2024 there are shortages of certain medicines. In 2023, there was a shortage of Ethambutol, which was promptly closed with the help of TBPeopleUkraine funds. In 2024, there was a shortage of Pyrazinamide, Etambutol, Rifampicin, Rifapentine, as well as a short-term shortage of Pretomanid in some regions of Ukraine during August 2024, which was closed in early September. As of September 2024, Ukraine is stocked with drugs to treat drug-resistant TB, but there are not enough drugs to treat susceptible TB [55].

In Ukraine, most of the drugs that are used to treat various forms of tuberculosis, including drug-resistant tuberculosis, are registered. Also, most drugs have several registration certificate holders (for example: Isoniazid, Moxifloxacin, Levofloxacin, Rifampicin and others).

However, there are drugs that are not registered in Ukraine and are used under special authorisation documents from the Ministry of Health of Ukraine. Such drugs include the paediatric form of Clofazimine (50 mg), the paediatric form of Linezolid (150 mg), the paediatric form of Delamanid (25 mg), Rifabutin, Rifapentin (150 mg and 300 mg), the combination drug Rifapentin/Izoniazid (300 mg/300). [56]

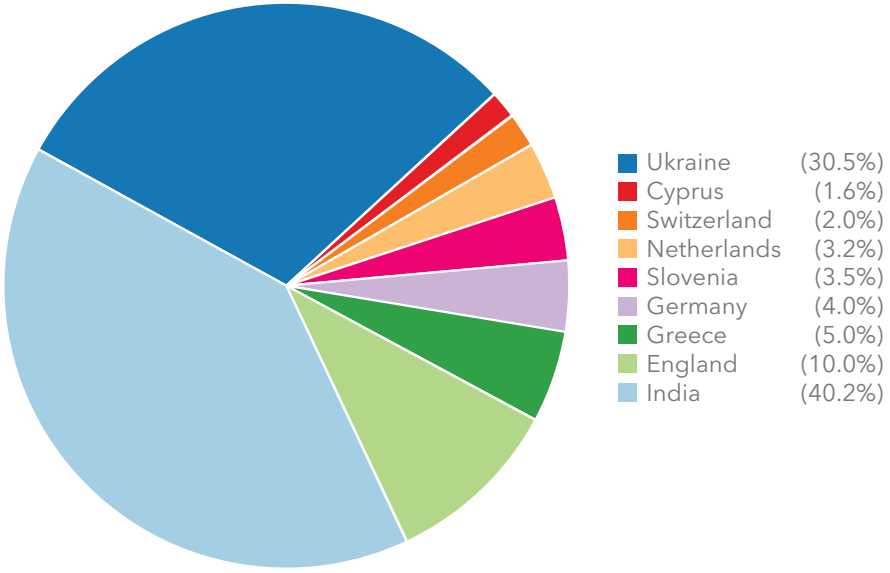

Figure 7. **Percentage of registrations by country of production in Ukraine**

Most drugs have indefinite registration, but such drugs as Bedaquiline, Delamanid and the combination drug Rifampicin/Izoniazid/Pyrazinamide have registrations that expire within 11 months. In general, Ukraine is able to purchase and supply all TB drugs necessary for the treatment of various forms of TB and in any dosages. But there is a risk of limiting the supply of drugs not registered in Ukraine in case of changes in the position of the Ministry of Health of Ukraine. There are also restrictions from donors. The Global Fund does not recommend using their financial resources to purchase drugs that are not WHO-qualified.

General conclusions on the study of public procurement law

Procurement regulation: *In all countries reviewed, procurement of TB drugs is governed by legislation that regulates the procurement process, quality control and distribution of medicines. In most cases, authorised government organisations or agencies are responsible for centralised procurement, which ensures transparency and control over the use of budgetary funds.*

Drug: *registration problems: In some countries, such as the Republic of Tajikistan, there are problems with the registration of TB drugs, which limits the choice of drugs on the domestic market. The Kyrgyz Republic, Republic of Moldova and Ukraine also have drugs that are not registered or require special authorisations for importation and use.*

Table 2

List of registered medicines by country in 2022–2023

INN of the drug	Kyrgyz Republic	Republic of Moldova	Republic of Tajikistan	Ukraine
Amikacinum				
Amoxicillinum + Acidum clavulanicum				
Bedaquilinum				
Clofaziminum				50 mg
Cycloserinum				
Delamanidum				25 mg
Ethambutolum				
Imipenemum+Cilastatinum				
Isoniazidum				
Levofloxacinum				
Linezolidum				150 mg
Moxifloxacinum				
Natrii para-aminosalicylas				
Pretomanidum				
Prothionamidum				
Pyrazinamidum				
Rifampicinum				
Rifampicinum + Isoniazidum				
Rifampicinum + Isoniazidum + Pyrazinamidum + Ethambutolum				
Rifapentinum				
Rifapentinum+Isoniazidum				
Rifampicinum + Isoniazidum + Pyrazinamidum				
Rifampicinum + Isoniazidum + Ethambutolum				

registered pending registration registration

Important role of international: *In all countries, donors such as the Global Fund and USAID play a critical role in financing TB drug procurement, especially for drug-resistant TB. In almost all countries studied, the majority of second-line drugs are procured through external funding.*

Trends and Challenges: *In general, each country faces unique challenges. In Tajikistan, there is a lack of funding, resulting in insufficient procurement of medicines. In Ukraine and the Kyrgyz Republic, there is a heavy reliance on donor funds, and in Moldova there are taxation difficulties when procuring through national mechanisms.*

Sustainable TB drug supply requires further efforts to strengthen national procurement mechanisms, increase domestic funding for ATDs procurement, and accelerate registration of new drugs, especially those used in short-term regimens for drug-resistant TB.

MONITORING OF PUBLIC PROCUREMENT

Monitoring of public procurement of TB drugs is a key tool for assessing the efficiency of budget utilisation, transparency and accessibility of essential medicines for the treatment of people with TB.

Monitoring of public procurement in the Kyrgyz Republic

The National Centre of Phthisiology centrally procured anti-TB medicines in 2022 for the amount of 242 875 USD at the initial tender amount of 705 880 USD, and in 2023 the final contract amount was 600 000 USD at the initial tender amount of 705 882 USD to cover the need for anti-TB medicines at the expense of the budget. The list of procured TB drugs includes.

Table 3

Volume and amount of budget purchases of ATDs in the Kyrgyz Republic in 2022–2023

Years	Subject of purchase (INN)	Object of purchase dosage	Number of tablets per purchase	Price USD per 1 tablet.	Amount
2022	Amikacinum + Clavulanic acid	500 mg/125 mg	2 500	2,11	5 275
	Streptomycin	1,0 г	8 000	0,3	2 240
	Ethambutol	400 mg	800 000	0,046	36 800
	Isoniazid	100 mg	150 000	0,016	2 400
	Isoniazid	300 mg	200 000	0,028	5 600
	Rifampicin	150 mg	400 000	0,064	25 600
	Pyrazinamide	500 mg	100 000	0,041	4 100
	Isoniazid + Pyrazinamide + Rifampicin + Ethambutol	75mg + 400 mg + 150 mg + 275 mg	500 000	0,105	52 500
	Rifampicin + Isoniazid + B-6	150 mg + 100 mg + 10 mg	1 600 000	0,066	105 600
	Total for 2022				**240 115**
2023	Pyrazinamide	500 mg	45 000	0,032	1 440
	Imipenem/Cilastatin	500/500 mg	8 000	3,4	27 200
	Rifampicin + Isoniazid	150 mg + 100 mg + 10 mg	1 299 300	0,041	53 271,3
	Ethambutol	400 mg	749 600	0,03	22 488
	Rifampicin	150 mg	599 960	0,069	41 397,24
	Pyrazinamide	500 mg	999 600	0,016	15 993,6
	Moxifloxacin	400 mg	150 000	0,24	36 000
	Cycloserine	250 mg	597 800	0,195	116 571
	Total for 2023				**314 361,1**

In 2022, the listed drugs were provided by the supplier Medservice KJI LLC, except for Amoxicillin + Clavulanic acid provided by Pharm Asia Group LLC and Streptomycin provided by Bi-Ai Company LLC. And in 2023 the procured drugs were provided by SE "Kyrgyzpharmatsiya" except for 42 courses of Pyrazinamide 500 mg. Kaarus OOO and Imepenem/Cilastatin 500 mg/500 mg provided by Medservice KG OOO.

In addition, in 2022, the Principal Recipient UNDP procured TB drugs with Global Fund financing for a contract value of 2 619 501 USD with the same initial tender amount.

Table 4

Volume and amount of ATDs procurement from the Global Fund through UNDP/GDF in the Kyrgyz Republic in 2022

Subject of purchase (INN)	Object of purchase dosage	Number of tablets per purchase	Price USD per 1 tablet.	Amount
Linezolid	150 mg dispersible tablet	26 500	0,273	7 226,00
Pretomanid	200 mg	119 028	2 000	238 056,00
Bedaquiline	100 mg (Sirturo) 188 tab jar	515 120	1,447	745 280,00
Bedaquiline	20 mg 60 tab jar	6 120	0,425	2 604,00
Clofazimine	100 mg 100 cap jar	624 100	0,480	299 425,00
Clofazimine	50 mg	13 400	0,404	5 413,60
Cycloserine	125 mg 100 cap bl	13 200	0,450	5 940,00
Delamanid	25 mg dispersible tab blister, 48 tablets	11 952	1,771	21 165,00
Delamanid	50 mg 672 tab bl	497 952	2,530	1 259 700,00
Ethambutol	100 mg Film coated tablet(s) 100 tabs	19 400	0,067	1 303,56
Levofloxacin	100 mg dispersible,100 tab bl	21 000	0,124	2 606,00
Moxifloxacin	400 mg 100 tab bl	89 100	0,160	14 256,00
Pyrazinamide	150 mg dispersible,100 tab bl	1 000	0,149	149,40
Rifampicin/Isoniazid	75 mg/50 mg/Dispersible tablets	81 396	0,051	4 180,35
Rifampicin/Isoniazid/Pyrazinamide	75 mg/50 mg/150 mg /Dispersible tablets/	39 228	0,064	2 521,80
Vitamin B-6	50 mg (pyridoxine HCl), 100 tab	1 087 000	0,009	9 674,30
Total				**2 619 501,01**

Also in 2023, the Principal Recipient UNDP procured TB drugs with the Global Fund for a contract amount of 1 265 195 USD with the same initial tender amount.

Table 5

Volume and amount of ATDs procurement from the Global Fund through UNDP/GDF in the Kyrgyz Republic in 2023

Subject of purchase (INN)	Object of purchase dosage	Number of tablets per purchase	Price USD per 1 tablet.	Amount
Clofazimine 100 mg 100 cap jar	100 mg 100 cap jar	275 400	0,5	137 700,00
Bedaquiline	100 mg uncoated tablets, pack of 188, HDPE container(s)	61 100	0,940	57 460,00
Bedaquiline	20 mg uncoated tablets, pack of 60, HDPE cont(s)	3 420	0,426	1 455,21
Clofazimine	50 mg film coated tablets, pack of 100, Strip(s)	6 600	0,404	2 666,40
Delamanid	25 mg dispersible tablets, pack of 48, Blister(s)	6 240	1,771	11 050,00
Delamanid	50 mg to be changed from 672 tab bl to 48 tab	372 960	2,530	943 433,40
Ethambutol HCl	100 mg 100 tab bl	8 700	0,036	311,46
Levofloxacin	100 mg dispersible tablets, pack of 100, Blist(s)	32 000	0,123	3 947,00
Linezolid	150 mg dispersible tablets, pack of 100, Strip(s)	1 800	0,273	490,86
Linezolid	600 mg film coated tablet, pack of 100, Blister(s)	153 800	0,170	26 192,14
Pretomanid	200 mg uncoated tablets, pack of 26, HDPE cont(s)	29 822	1,319	39 330,60
Pyrazinamide	150 mg dispersible tablets, pack of 100, Strip(s)	11 200	0,159	1 785,28
Vitamin B6 (Pyridoxine)	50 mg, tablet	1 406 200	0,028	39 373,60
Total				**1 265 195,98**

Monitoring of public procurement in the Republic of Moldova

Analysis of procurements for 2022–2023 was performed based on official data provided by CAPCS and IP UCIMP DS procurement departments. The total amount of procurement of TB drugs for DR-TB treatment in CAPCS procurement for 2 years was 11 882 876.21 MDL. By year, the procurement amount is almost the same: in 2022 – 6 055 871.32 MDL (320 463.9480 USD), in 2023 – 5 827 004.89 MDL (320 801.4874 USD). The total amount of procurement of TB drugs for DR-TB treatment in IP UCIMP DS procurement over 2 years was 674 961.1 USD. By year, the procurement amount almost doubled: in 2022 – 226 790.95 USD, in 2023 – 448 170.15 USD.

Thus, the total volume of procurement under both procurement mechanisms of TB drugs for DR-TB for 2 years was – 1 316 226.5354 USD (547 254.898 USD in 2022 and 768 971.6374 USD in 2023, respectively). At the same time, the budget increase totalled – 40.51%, mainly directed to procurement of drugs intended for short treatment regimens. By form of drugs, a significant share of the budget was spent on oral drugs. In the total share of expenditure, injectable forms accounted for 29% in 2022 and 18.6% in 2023. There is a downward trend in the use of injectable preparations.

Total expenditure for Bedaquiline 100 mg, reached 130 092.00 USD in 2022 and 96 114.09 USD in 2023, for the procurement of 83 096 and 52 640 tablets respectively, representing 23.8% and 12.5% respectively of the total expenditure for the reporting period. There were no purchases of Delamanida in 2022. Procurement resumed in 2023 and the total cost of Delamanid 50 mg was – 170 151.42 USD, for the purchase of 43 920 tablets, representing 22.13% of the total costs for the year. The cost of Pretomanida 200 mg, which first appeared in the procurement in 2023, ranged from 1 332 to 1 440 USD per tablet (two purchases of 30 147.52 and 27 141.49 USD), with a budgetary burden of 7.45% of the total cost for the year of 41 314 tablets. Clofazimine 100 mg; Levofloxacinum 250 mg; Linezolidum 600 mg and Moxifloxacinum 400 mg were the most purchased.

There was a significant increase in drug prices in CAPCS procurement for 2023 for all INNs.

Table 6

Volume and amount of CAPCS purchases in the Republic of Moldova in 2022–2023

Years	Subject of purchase (INN)	Object of purchase dosage	Number of tablets per purchase	Price USD per 1 tablet.	Price per 1 tablet c VAT	Amount
2022	Amikacinum	500 mg, Sol. inj. sau Pulb./sol. inj.	12 972 Fiole/ Flacoane	29,45	31,806	412 587,4
	Amoxicillinum + Acidum clavulanicum	875 mg+125 mg, Comprimate	5 472 comprimate	4,3	4,644	25 411,9
	Ethambutolum (Ethambutoli hydrochloridum)	400 mg, Comprimate	150 000 comprimate	2,521	2,7227	408 405,0
	Imipenemum + Cilastatinum	500 mg + 500 mg, Pulb./sol. perf.	14 949 flacoane	62,45	67,446	1 008 250,3
	Isoniazidum	100 mg, Comprimate	64 302 comprimate			
	Linezolidum	600 mg, Comprimate	100 000 comprimate	6,2351	6,7339	673 390,0
	Natrii paraaminosalicylas	5.52 g, Pulb./sol. oral	16 200 plicuri	30,4866	32,9255	533 393,1
	Total					**3 061 437,7**

Table 6, end

Years	Subject of purchase (INN)	Object of purchase dosage	Number of tablets per purchase	Price USD per 1 tablet.	Price per 1 tablet c VAT	Amount
2023	Amikacinum	500 mg, Sol. inj. sau Pulb./sol. inj.	11 890 fiole/flacoane	32,4	34,992	416 054,88
	Amoxicillinum + Acidum clavulanicum	875 mg+125 mg, Comprimate	15 774 comprimate	3,8504	4,1584	65 594,6016
	Cycloserinum	250 mg, Capsule	239 238 capsule	4,6536	5,0259	1 02 386,3
	Imipenemum + Cilastatinum	500 mg + 500 mg, Pulb./sol. perf.	31 151 flacoane	64,7	69,876	220,8
	Isoniazidum	100 mg, Comprimate	21 150 comprimate			
	Levofloxacinum	250 mg, Comprimate	78 500 comprimate			
	Linezolidum	600 mg, Comprimate	50 969 comprimate	8,0603	8,7051	443 690,2
	Moxifloxacinum	400 mg, Comprimate	38 633 comprimate	10,8959	11,7676	454 617,7
	Natrii paraaminosalicylas	5.52 g, Pulb./sol. oral	30 000 plicuri	32,9994	35,6394	1 069 182
	Total					**3 651 746,5**

Due to lack of proposals in 2022 for Isoniazid 100 mg and in 2023 for Isoniazid 100 mg and Levofloxacin 250 mg, they were not procured. The risks associated with low volume procurement of medicines, as well as the downward trend in TB incidence in Moldova as a whole, are inevitably reflected in the reduction in volume procurement of medicines. This risks not only affecting the prices of medicines in the long term, which will tend to increase, but also causing additional difficulties in procurement. In 2022–2023. IPUCIMP DS procured from the Global Fund:

Table 7

Volume and amount of IPUCIMP DS purchases in the Republic of Moldova in 2022-2023

Years	Subject of purchase (INN)	Object of purchase dosage	Quantity of tablets. per purchase	Price USD per 1 tab.	Amount
2022	Amoxicillin + Clavulanic acid	500 mg+125 mg	16 800	0,134	2 249,820
	Bedaquiline	100 mg	83 096	1,566	130 092 000
	Imipenem+Cilastatin	500 mg+500 mg	22 120	3,178	70 291,170
	PAS powder for oral sol	4 g	11 375	1,427	16 229,070
	Amikacin amp	500 mg/2 ml	9 300	0,853	7 928,890
	Total				**226 790,950**
2023	Pretomanide	200 mg	20 930	1,440	30 147,520
	Clofazimin	100 mg	95 300	0,549	52 308,880
	Delamanid	50 mg	16 800	2,773	46 584,924
	Moxifloxacin	400 mg	35 700	0,164	5 869,700
	Pyazinamide	400 mg	107 520	0,023	2 455,299
	Bedaquiline	100 mg	52 640	1,826	96 114,090
	Delamanid	50 mg	27 120	4,556	123 566,500
	Levofloxacin	250 mg	96 100	0,029	2 755,460
	Linezolid	600 mg	36 500	0,172	6 275,630
	Moxifloxacin	400 mg	39 400	0,151	5 966,746
	Pyrazinamide	400 mg	163 296	0,021	3 434,660
	Clofazimine	100 mg	101 900	0,505	51 439,210
	Pretomanid	200 mg	20 384	1,332	27 141,490
	Total				**454 060,109**

Lack of experience with procurement of some important DR-TB drugs through the Centralised Public Procurement Centre for Health Care (CAPCS) (i.e. Delamanid, Pretomanid) is a reason to be wary of switching to full public procurement in the medium term.

Monitoring of public procurement in the Republic of Tajikistan

At the expense of the state budget, the Ministry of Health of the Republic of Tajikistan on 01.11.2022 centrally procured from a local supplier 14 000 Pretomanid 200 mg tablets for 77 courses at a price of 0.1241 USD per tablet, at a cost of 1737.4 USD, with a total final contract amount of 43 878.55 USD, against an initial tender price of 45 519.59 USD. The remaining TB drugs in 2022 were procured by UNDP from the Global Fund through the GDF for a total amount of 227 153.04 USD. In 2023, UNDP procured TB drugs for a total amount of 254 468.34 USD from the Global Fund through GDF.

Table 8

Volume and amount of procurement from the Global Fund through UNDP (GDF) in the Republic of Tajikistan in 2022–2023

Years	Object procurement object (INN)	Object of purchase dosage	Number of tablets per purchase	Price USD per 1 tablet	Amount
2022	Moxifloxacin (Moxifloxacin)	400 mg	12 600	0,15	1890
	Bedaquiline (Bedaquiline)	100 mg	50 760	1,8085	91 799,46
	Linezolid (Linezolid)	600 mg			0
	Clofazimine (Clofazimine)	100 mg			0
	Cycloserine (Cycloserine)	250 mg			0
	Delamanid	50 mg			0
	Pyrazinamide (Pyrazinamide)	400 mg	15 456	0,021	324,576
	Pretomanid	200 mg	36 400	2,00	72 800
	Imipenem/Cilastatin		7 510	2,85	21 403,5
	Amoxicillin + Clavulanic acid (Amoxicillin+Clavulanic acid)	500 mg/125 mg	4 000	0,169	678,8
	Levofloxacin (Levofloxacin)	100 mg	3 300	0,1186	391,38
	Bedaquiline (Bedaquiline)	20 mg	7 320	0,4255	3 114,66
	Linezolid (Linezolid)	150 mg	13 600	0,2727	3 708,72
	Clofazimine (Clofazimine)	50 mg	13 300	0,4040	5 373,2
	Cycloserine (Cycloserine)	125 mg	5 300	0,45	2 385
	Delamanid	25 mg	13 248	1,7710	23 462,208
	Pretomanid	200 mg	14 000	0,1241	1 737,4
	Total				**229 068,904**
2023	Levofloxacin (Levofloxacin)	250 mg	29 600	2,84	84 064
	Moxifloxacin (Moxifloxacin)	400 mg	38 900	15,00	583 500
	Bedaquiline (Bedaquiline)	100 mg	94 000	340,00	31 960 000
	Linezolid (Linezolid)	600 mg	56 900	17,03	969 007
	Pyrazinamide (Pyrazinamide)	400 mg	32 256	14,00	451 584
	Pretomanid	200 mg	26 572	34,29	911 153,88
	Imipenem/Cilastatin (Imipenem/Cilastatin)	500 mg/500 mg	3 040	28,50	86 640
	Amoxicillin + Clavulanic acid	500 mg/125 mg	1 500	16,97	25 455
	Levofloxacin (Levofloxacin)	100 mg	28 400	11,86	33 6824
	Bedaquiline (Bedaquiline)	20 mg	4 500	25,53	114 885

Table 8 end

Years	Object procurement object (INN)	Object of purchase dosage	Number of tablets per purchase	Price USD per 1 tablet	Amount
2023	Linezolid (Linezolid)	150 mg	9 100	27,27	248 157
	Clofazimine (Clofazimine)	50 mg	16 400	40,40	662 560
	Cycloserine (Cycloserine)	125 mg	8 700	45,00	391 500
	Delamanid	25 mg	11 712	85,00	995 520
	Total				**37 820 849,9**

Linezolid, Clofazemine, Cycloserine and Delamanid were not procured in 2022 due to stock availability.

Monitoring of public procurement in Ukraine

Due to the difficult financial situation caused by the full-scale war, no procurement from the state budget was conducted in Ukraine in 2022–2023. All purchases of TB drugs were made at the expense of donors: the Global Fund and USAID, without a tender through direct purchase through GDF, with the Public Health Centre of the Ministry of Health of Ukraine acting as the procuring organisation.

Table 9

Volume and amount of procurement from the Global Fund and USAID in Ukraine in 2022–2023

Years	Procurement object (INN)	Object of purchase dosage	Number of tablets per purchase	Price USD per 1 tablet	Amount
2022	Amikacin	500 mg/2 мл	40 600	0,57	23 142
	Bedaquiline	20 mg	3 840	0,42	1 612,8
	Moxifloxacin	400 mg	418 400	0,15	62 760
	Pretomanid	200 mg	217 672	1,32	287 327,04
	Rifapentine	150 mg	1 796 952	0,25	449 238
	Rifapentine	300 mg	135 500	0,034	4 607
	Rifapentine/Izoniazid	300 mg/300 mg	32 112	0,4	12 844,8
	Pyrazinamide	150 mg	10 700	0,16	1 712
	Amoxicillin/Clavulonic acid	500 mg/125 mg	22 100	0,17	3 757
	Rifampicin/Isoniazid/Pyrazinamide	75 mg/50 mg/150 mg	29 820	0,07	2 087,4
	Rifampicin/Izoniazid	150 mg/75mg	1 538 880	0,052	80 021,76
	Rifampicin/Izoniazid	75 mg/50 mg	1 358 700	0,053	72 011,1
	Rifampicin	150 mg	270 100	0,13	35 113
	Cycloserine	250 mg	46 800	0,25	11 700
	Cycloserine	125 mg	17 400	0,45	7 830
	Delamanid	25 mg	24 336	1,77	43 074,72
	Delamanid	диспергированная форма	912	1,77	1 614,24
	Ethambutol	400 mg	647 408	0,04	25 896,32
	Ethambutol	400 mg	185 400	0,04	7 416
	Linezolid	150 mg	23 000	0,27	6 210
	Linezolid	диспергированная форма	700	0,27	189
	Clofazimine	50 mg	9 200	0,4	3 680
	Ethambutol	100 mg	67 700	0,04	2 708
	Bedaquiline	100 mg	735 268	1,81	1 330 835,08
	Pretomanid	200 mg	267 540	1,32	353 152,8
	Total				**2 830 540,06**

Table 9 end

Years	Procurement object (INN)	Object of purchase dosage	Number of tablets per purchase	Price USD per 1 tablet	Amount
2023	Bedaquiline	100 mg	1 718 320	0,65	1 116 908
	Bedaquiline	20 mg	14 940	0,43	6 424,2
	Pyrazinamide	500 mg	686 112	0,02	13 722,24
	Rifampicin/Isoniazid/Pyrazinamide	75 mg/50 mg/150 mg	61 404	0,075	4 605,3
	Rifampicin/Izoniazid/ Pyrazinamide/Etambutol	150 mg/75 mg/ 400 mg/275 mg	1 044 960	0,1	104 496
	Rifampicin	150 mg	1 382 000	0,13	179 660
	Rifampicin/Izoniazid	150 mg/75 mg	2 438 016	0,05	121 900,8
	Rifampicin/Izoniazid	75 mg/50 mg	1 367 352	0,05	68 367,6
	Ethambutol	400 mg	435 456	0,04	17 418,24
	Ethambutol	100 mg	61 300	0,2	12 260
	Moxifloxacin	400 mg	1 236 600	0,15	185 490
	Delamanid	25 mg	12 384	1,77	21 919,68
	Rifapentine/Izoniazid	300 mg/300 mg	764 460	0,3	229 338
	Cycloserine	125 mg	27 700	0,45	12 465
	Cycloserine	250 mg	1 972 200	0,25	493 050
	Clofazimine	100 mg	405 700	0,5	202 850
	Clofazimine	50 mg	17 100	0,4	6 840
	Pretomanid	200 mg	247 910	1,32	327 241,2
	Linezolid	600 mg	648 000	0,17	110 160
	Linezolid	150 mg	33 000	0,27	8 910
	Total				**3 244 026,26**

Thus, in 2022, the Global Fund purchased TB drugs worth 2 505 612.45 USD at the expense of the Global Fund.

And at the expense of USAID funds in what may indicate a lack of competition procurement from a single supplier at a fixed price.

2022, 267 540 Pretomanid 200 mg tablets were purchased for an amount of USD 352 844.1.

Also in 2023USAD funds provided 20 first- and second-line TB drugs worth USD 3 247 158.9.

General conclusions on public procurement monitoring

Monitoring of public procurement of TB drugs is important to ensure efficient use of budget funds, transparency of procurement processes and access to TB drugs. The presented country experiences show different approaches and challenges faced by countries in this area.

1. ***The Kyrgyz Republic*** *demonstrates centralised procurement of TB drugs at the state level. Various ATDs were procured in 2022 and 2023, with increased procurement in 2023. Despite a relatively transparent process, there is some reliance on local suppliers, which may limit competition and create risks for price increases.*

2. ***The Republic of Moldova*** *has a more institutionalised approach based on the national CAPCS mechanism and MTender system, which ensures a high degree of transparency. The country uses centralised tenders for procurement of ATDs and the share of injectables in the procurement structure is decreasing. Over the last two years there has been a significant increase in the budget for procurement of drugs for short treatment*

regimens. There is also a tendency to increase the share of drugs such as Bedaquiline and Delamanid, which is in line with international recommendations.

3. ***The Republic of Tajikistan** faces serious problems related to lack of public funding and limited access to quality medicines. Most ATDs are procured with funds from the Global Fund through UNDP. Public funding remains insufficient to cover needs, especially for DR-TB drugs, and significant funds are spent on tenders, supplier fees and taxes. There are delays in updating laws and regulations, limiting access to WHO-recommended prequalified drugs.*

4. ***Ukraine,** due to the full-scale war in 2022–2023, did not procure from the state budget, relying entirely on donors such as the Global Fund and USAID. Procurement was carried out through the Centre for Public Health without tenders, which limited opportunities for strategic planning and monitoring of procurement.*

When monitoring the procurement of TB drugs, we decided to pay attention to the prices of BPaL-based short regimens procured with donor funds. The table below shows comparative prices in dollars by country for 1 tablet.

Table 10

Comparison of procurement prices of BPaL regimen drugs by country in 2022-2023

	Kyrgyzstan		Molodova		Tajikistan		Ukraine	
	2022	2023	2022	2023	2022	2023	2022	2023
	Global Fund		Global Fund		Global Fund		Global Fund	USAID
Bedaquiline	1,447	0,94	1,566	1,826	1,8085	1,8085/ 2,1277	1,81	0,65
Pretomanid	2	1,319		1,44–1,332	2	2/0,1241	1,32	1,32
Linezolid	0,273	0,2727	6,7339** (0,355USD)	0,172/ 8,7051** (0,459US)	0,36	0,2727	0,17	0,17
Moxifloxacin	0,16	0,16/0,24*		0,164– 0,151/ 11,7676** (0,621USD)		0,15	0,15	0,15

* – purchases from the state budget
** – prices in Moldovan lei (exchange rate to $ - 0.056

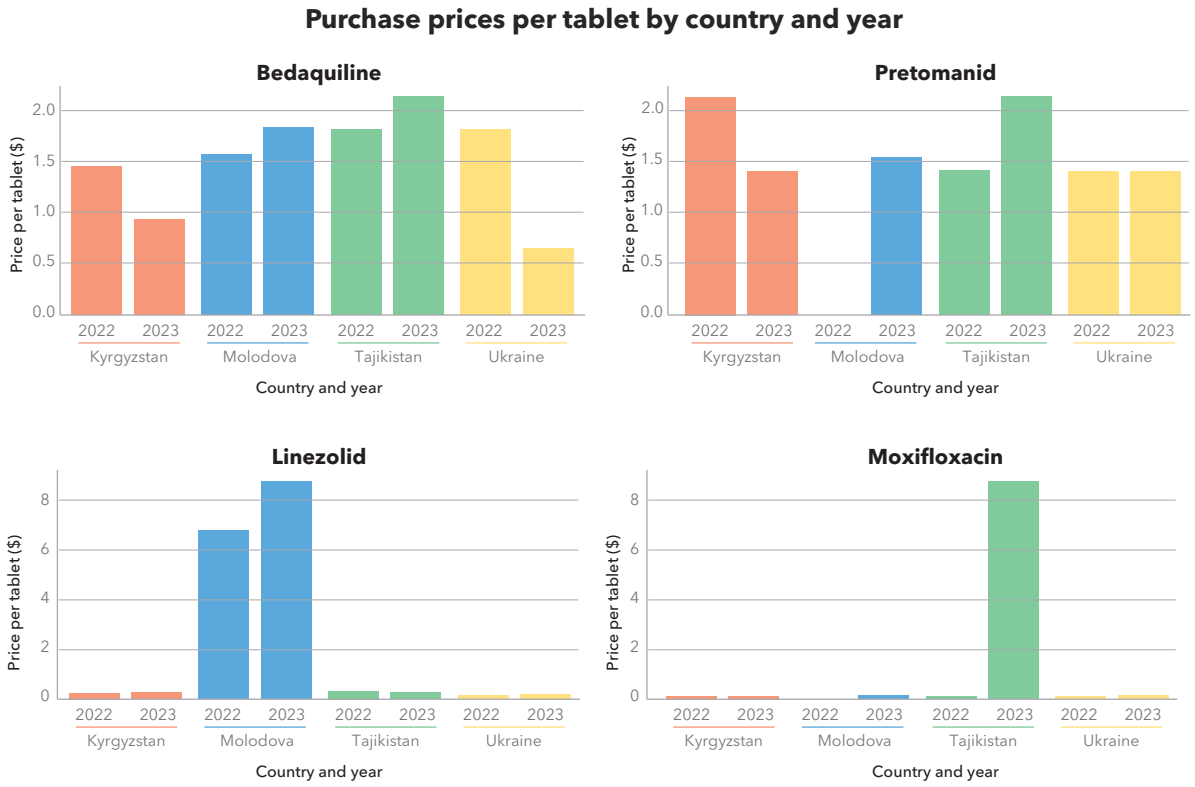

Figure 8. **Procurement prices by country in 2022–2023**

Analysis of purchase prices by country and year in dollars

1. Bedaquiline:

Kyrgyzstan: The price decreases from 1.447 in 2022 to 0.94 in 2023, indicating that the drug will become cheaper in 2023 when procured through GDF – Global Fund.

Moldova: The price increased from 1.566 in 2022 to 1.826 in 2023, which may indicate the impact of price fluctuations or supply conditions.

Tajikistan: Purchases in 2022 at 1.8085 and in 2023 at 2.1277 indicate a small price increase.

Ukraine: USAID-funded procurement in 2023 at a price of 0.65, which is significantly lower than other countries' prices in these years. This is due to general price reductions and favourable conditions under USAID subsidies.

2. Pretomanid:

Kyrgyzstan: Price decreased from 2 in 2022 to 1,319 in 2023, indicating improved supply conditions, procurement volume and overall price reduction.

Moldova: The price in 2023 was 1.44 – comparable to prices in Kyrgyzstan.

Tajikistan: It was possible to procure from the state budget, the price decreased in 2022 from 2 to 0.1241, indicating procurement from the state budget.

Ukraine: : In 2023, the price is 1.32 – stable and below the price of previous years.

3. Linezolid:

Kyrgyzstan: The price remained almost the same: 0.273 in 2022 and 0.2727 in 2023.

Moldova: Price decreased from 6.7339 in 2022 to 0.172 in 2023, procured from the state budget.

Tajikistan: The price decreases from 0.36 in 2021-2022 to 0.2727 in 2022–2023, which is a significant decrease in value.

Ukraine: In 2023-2024, the price is 0.17, which is in line with prices for this drug in other countries.

4. Moxifloxacin:

Kyrgyzstan: The price is stable at 0.16 in 2022 and 0.24 in 2023.

Moldova: Price decreased from 11.7676 to 0.164 (purchases from the state budget).

Ukraine: In 2023-2024, the price is 0.15, which is similar and lower than prices in other countries.

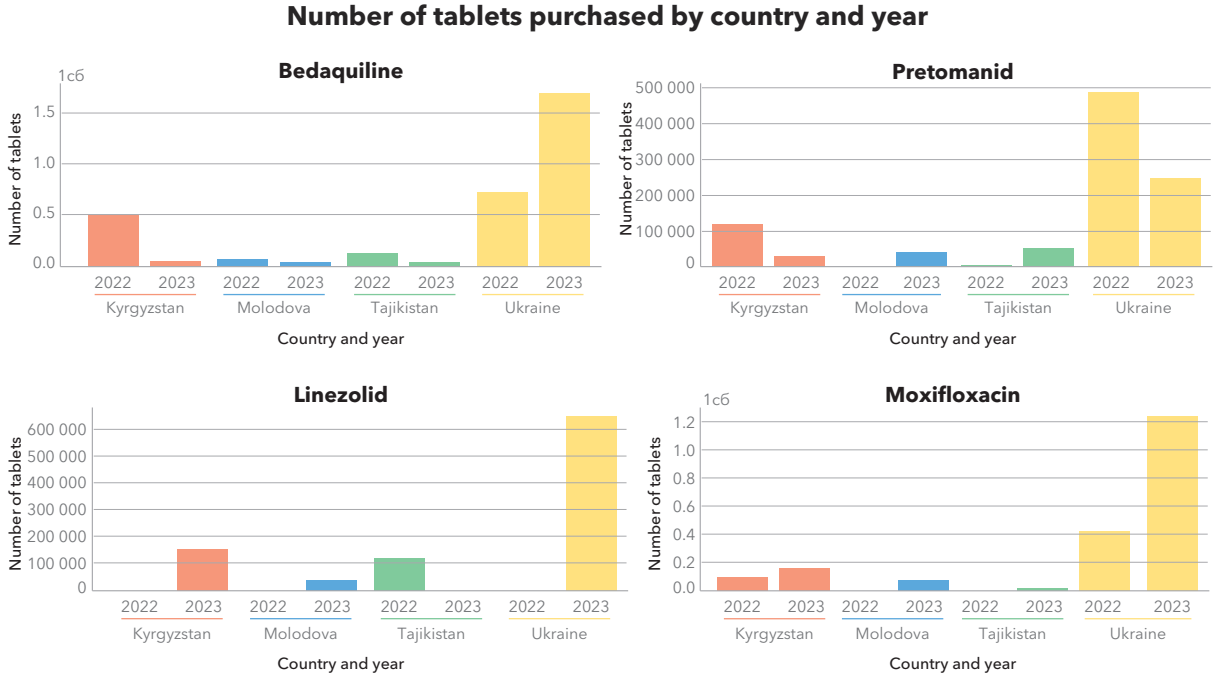

Figure 9. **Procurement volume by country 2022–2023.**

Price reductions have been observed in many countries, especially in the case of publicly funded purchases. This indicates successful attempts by governments to reduce the cost of medicines through public funding.

The price of Bedaquiline in Ukraine in 2023–2024 (0.65) is the lowest among all countries, which can be attributed to global price reductions, amid advocacy by the Stop TB Partnership, the TB Europe Coalition and many other partners, when manufacturers reduced prices not only for Bedaquiline and other TB drugs, but also for a number of diagnostic tests.

Pretomanid and Linezolid also showed significant cost reductions in some countries at the expense of the state budget, as in Tajikistan and Moldova.

Table 11

Number of drugs procured for BPaL regimen by country in 2022–2023

Number of tablets procured								
	Kyrgyzstan		Molodova		Tajikistan		Ukraine	
Years	2022	2023	2022	2023	2022	2023	2022	2023
Donor	Global Fund	Global Fund	Global Fund	Global Fund	Global Fund	Global Fund	Global Fund	USAID
Bedaquiline	515 120	61 100	83 096	52 640	127 088	50 760	735 268	1 718 320
Pretomanid	119 028	29 822		41 314	7 644	50 400	485 212	247 910
Linezolid	0	153 800		36 500	118 600	0	0	648 000
Moxifloxacin	89 100	150 000		75 100	0	12 600	418 400	1 236 600

Bedaquilin: Ukraine shows the largest procurement volumes in 2022 with additional growth in 2023, thanks to USAID funding. In Kyrgyzstan and Tajikistan, procurement was also substantial, but markedly lower.

Pretomanid: Ukraine is also leading in terms of purchases in 2022 and 2023. In Kyrgyzstan, the number of purchases of Pretomanid in 2023 has significantly decreased compared to 2022.

Linezolid: Linezolid procurement was highest in Ukraine in 2023–2024, while Kyrgyzstan only saw procurement in 2023 and Tajikistan only procured it in 2022.

Moxifloxacin: Ukraine is also a leader in Moxifloxacin procurement, especially in 2023–2024. Kyrgyzstan shows an increase in procurement from 2022 to 2023.

SHARING LESSONS LEARNT AND PRACTICES

Sharing lessons learned and practices plays an important role in improving the effectiveness of tuberculosis control programmes internationally. In each country, adopting modern approaches to procurement, record keeping and distribution of TB drugs helps to maintain the quality and accessibility of treatment for people with TB.

Sharing Lessons Learned, Kyrgyz Republic

The National Centre for Phthisiology under the Ministry of Health of the Kyrgyz Republic conducts regular monitoring of consumption and accounting of TB drugs balances. Responsible drug management specialists in each oblast use the Quant TB programme to conduct regular analysis of consumption and accounting of TB drug residues, paying attention to expiry dates and storage of TB drugs in the regions. These data are sent quarterly to the specialist responsible for drug management at the National Centre for Phthisiology, who also uses the Quant TB programme to analyse consumption and stock levels and, based on the consolidated data for the country, makes the next order of TB drugs. Drugs are purchased centrally from the state budget once a year. Second-line drugs can be procured twice a year through the Global Fund, if necessary. Thanks to this practice, all drugs are utilised in a timely manner in the country without situations when drugs expire.

> Centralised procurement allows the programme to systematise procurement, ensure uniform oversight, record keeping and quality of medicines, reduce supplier prices, and prevent inappropriate and unjustified purchases of TB medicines.

The National Centre for Phthisiology procures TB drugs with a buffer of at least half a year's supply to avoid shortages.

Exchange of lessons learnt, Republic of Moldova

National directives and policies aimed at reducing the burden of DR-TB and access to the benefits of innovation are among the priority commitments of the MoH and are governed by the provisions of the NTPP and relevant treatment guidelines (adult TB and paediatric TB), which are updated according to the latest WHO recommendations.

Centralised planning and procurement of medicines allows rational planning, budgeting and management of medicines (for both national and donor resources).

In 2023, coverage of modified short-treatment oral regimens for DR-TB is 30.16%, with an increase of 21.54% from 2022. In the first six months of 2024 BPaL/M coverage under programme implementation is more than 85%.

There are two procurement mechanisms in Moldova to ensure access to quality TB drugs, including for the introduction of short-course regimens for resistant TB: (1) the Centre for

Centralised Public Procurement in Health Care (CAPCS) for domestic resources, a subordinate institution of the MoH, and (2) the Global Drug Facility (GDF) international procurement mechanism, through the Global Fund's Principal Recipient Contracting Authority and the government recipient, UCIMP.

Both at national level and on the international procurement platform, government regulatory quality standards are respected: purchasing products that have been requalified by WHO or meet European or regional standards.

At the time of opening of the public tender, both registered and non-registered medicines are accepted for participation, provided there are certificates certifying the quality of the product for non-registered medicines.

TB drugs purchased and imported into Moldova under technical assistance programmes are exempt from VAT, customs tax and tax for customs procedures. A value added tax of 8% is applied to all medicines in the Republic of Moldova.

The total procurement volume under both procurement mechanisms for DR-TB drugs for 2 years totalled 1 316 226,5354 USD (547 254,898 USD in 2022 and 768 971,6374 USD in 2023, respectively). At the same time, the budget increase amounted to 40.51%, mainly aimed at procurement of drugs for short-term treatment regimens.

In terms of formulations, a significant share of the budget was spent on oral preparations. In the total share of expenditure, injectable forms accounted for 29% in 2022 and 18.6% in 2023. There is a decreasing trend in the use of injectable preparations.

> Based on the lessons learnt in the Republic of Moldova and good practices from other countries, it is recommended to: Continue to improve and optimise procurement procedures, maintain the quality of medicines and create a competitive environment to reduce the cost of medicines and ensure efficient use of allocated funds, with timely provision of the most modern, effective and safe treatment regimens and medicines to people with TB.

Involve TB representatives from affected communities and nongovernmental organisations in the medicines management group of the NPPT at all stages of work. Develop alternative/procurement mechanisms that promote competition in the pharmaceutical sector, with the introduction of public procurement through international agencies. Include Pretomanid in the list of essential medicines. Conduct a comparative cost analysis of TB treatment regimens.

Explore the possibilities:

- ***granting legislative and procedural privileges for the purchase of TB and other drugs purchased under national programmes for the treatment of socially significant diseases.***
- ***alternatives for implementing procurement for several years, given the declining trends in TB incidence.***
- ***establishment of a state pharmaceutical warehouse at the Institute of Phthisiopulmonology "Cyril Draganiuk".***

Sharing Lessons Learned, Republic of Tajikistan

The Ministry of Health and the TB Service of the Republic of Tajikistan, based on the experience gained, plans to develop a short-term plan:

- Ensure guaranteed quality of TB drugs for procurement with state budget funds (WHO prequalification, approval by the GF Expert Commission and/or registration in countries with SROs) by reviewing the regulatory framework for procurement of medical products and fulfilling the requirements to allow only registered drugs to participate in public tenders. In the absence of TB drugs registered in the country, consider the possibility of procurement through organisations established by the UN and other international platforms, where a good example is the experience of procurement of Pretomanid 200mg through GDF in 2022.
- Ensure procurement of TB drugs of guaranteed quality by increasing government funding to allow procurement of drugs for treatment of DR-TB and preventive treatment (100%), taking into account the buffer stock, as well as drugs for DR-TB (2024 – 15%, 2025 – 20%, 2026 – 25%).
- Develop an Instruction for calculating the drug needs of TB drugs, including the basic methodology for forecasting and formulating drug needs.
- Develop a national plan for introduction/expansion of new treatment regimens for DS-TB, DR-TB and TPT recommended by WHO and monitor its implementation to reduce the risk of ATDs shortages and expiry.
- Improve the prescribing and use of TB drugs under the new short DR-TB regimens through capacity building of health care providers and regular supervision and on-the-job training.
- Exempt drugs and pharmaceutical products purchased with state budget funds for the National TB Programme from taxes and fees.
- Amend the regulation on registration or prepare a separate regulation to provide for simplified registration of WHO prequalified and SRO-registered medicines.
- Incentivising registration of quality-assured medicines (reduced registration fees, simplified procedures, etc.).
- The country's entry into the WHO Collaborative Registration Procedure.
- Amendments to the law on procurement or development of a separate law on procurement of medicines to guarantee the procurement of quality medicines (quality as one of the selection criteria, possibility of procurement through platforms – flexibility in procurement, budget cycles for priority health programmes).
- Development and issuance of a Government Resolution regulating direct procurement of drugs for critical diseases and diagnostics from international platforms.

Sharing Lessons Learnt, Ukraine

Full-scale war caused a 7.3% increase in TB incidence in 2023 compared to 2022, with a 44% increase in incidence among children.

Due to active implementation of short MDR-TB treatment regimens included in the national Standard of TB Care, 26% more short regimens were prescribed in 2023 than 2022. This was reflected in a 15% decrease in the prescription of individual treatment regimens. There was a 17% decrease in the number of people with TB on palliative regimens.

> Despite the emergency situation, Ukraine is fully stocked with all necessary drugs to treat all forms of TB, including paediatric doses. The Global Fund, as well as USAID, has secured funding for the supply of ATDs to Ukraine starting in 2022. As requested by donors, all ATDs procured are WHO prequalified.

The procurement of ATDs is based on the principle of taking into account stock balances, expected supplies, number of people on treatment and number of new cases.

It should be noted that not all TB drugs are registered in the country. Such drugs include the paediatric form of Clofazimine (50), the paediatric form of Linezolid (150 mg), the paediatric form of Delamanid (25 mg), Rifabutin, Rifapentin (150 mg and 300 mg), and the combination drug Rifapentin/Izoniazid (300 mg/300 mg).

Despite stable donor funding and rare delays in the supply of TB drugs, there are instances of short-term shortages in the supply of medicines to people with TB. At the time of analysis, there are shortages of: Pyrazinamide, Rifampicin, Rifampentine and Ethambutol. It is recommended to have a 6-month buffer stock of ATDs to minimise drug stock-outs.

As of September 2024, Ukraine is stocked with drugs to treat drug-resistant TB, but there are not enough drugs to treat susceptible TB.

The national TB programme needs to:

- *Analyse why the number of people with TB with bacterial excretion.*
- *Analyse the decline in the number of people with TB on palliative care.*
- *Establish a 6-month buffer stock of ATDs.*
- *Strengthen monitoring of drug expenditure.*
- *Review ATDs needs further expand the use of new MDR-TB treatment regimens.*
- *When introducing new TB treatment regimens, provide for a transition period to utilise stockpiles of TB drugs and build up demand according to the implemented regimens.*

General conclusions on sharing lessons learnt and practices

Studies of experience and good practices in other countries have shown that centralised management and record keeping of ATDs procurement significantly improves the efficiency of TB programmes. Measures such as buffer stocks, international procurement through UN platforms, etc., introduction of new treatment regimens, and improving the quality of medicines increase the effectiveness of TB interventions. Continued experience sharing and improvement of existing drug management mechanisms will enable countries to respond more quickly to challenges and improve treatment outcomes for people with TB.

DATA ON NUMBER OF PEOPLE IN NEED OF SHORT-TERM TREATMENT REGIMENS

Data on the implementation of short-term drug-resistant TB regimens in countries such as the Kyrgyz Republic, Republic of Moldova, Republic of Tajikistan and Ukraine show significant progress in 2023. These regimens, particularly BPaL-based regimens, have become a key tool in DR-TB control, providing effective treatment and shortening the duration of therapy. International organisations play an important role in supporting these initiatives, which contributes to their successful implementation.

Number of people in need of short-term MDR-TB treatment regimens in the Kyrgyz Republic

In the Kyrgyz Republic in 2022, a total of 127 people with pre-XDR-TB and intolerant to other MDR-TB drugs were planned to be recruited for treatment with BPaL-based regimens. At the end of 2022, 71 people were recruited to BPaL-based regimens under programme use, and this figure increased to 74 in 2023. The standard and modified DR-TB treatment regimens had 72 and 30 enrolments in 2022 and 47 and 97 in 2023, respectively. Meanwhile, 677 people in 2022 and 541 people in 2023 were recruited to the individualised treatment regimen. According to the programme's preliminary data, more intensive recruitment to BPaL-based regimes is underway in 2024. The programme is on track to increase enrolment in short courses of treatment from 45% in 2024 to 60% in 2027. The programme has included relevant indicators in the Global Fund proposal. A total of 218 people (46% of patients out of the potentially eligible 470 patients) were recruited for short course DR-TB treatment in 2023, meaning that 252 people (54%) could start treatment with short course DR-TB regimens. Overall, the country exceeds the expected target of 45% for 2024. This implies that the country has made significant progress in this area. However, despite the significant progress and exceeding the expected indicator in 2023, given the experience of countries that have successfully introduced short-term DR-TB treatment regimens, where up to 80% of people with DR-TB start treatment with short-term regimens, it is recommended to increase the percentage of enrolment in short-term DR-TB treatment courses and increase this figure 60% in 2024 and 80% by 2026.

Number of people in need of short-term MDR-TB treatment regimens in the Republic of Moldova

In the Republic of Moldova, thanks to systematic work and good programme preparation, in the first 6 months of 2024, almost all people with drug-resistant TB (more than 80% of all people diagnosed with drug-resistant TB) are being recruited on short-term treatment regimens. BPaL-based regimens, according to WHO recommendations, are the regimens of first choice for people identified with drug-resistant TB. Thus, out of 231 people with MDR-TB and pre-XDR-TB, 154 people were recruited on BPaL-based regimens and 11 people on the 9-month modified regimen recommended by WHO in operational

research. Whereas 66 people were referred to individualised treatment regimes. In earlier timeframes in the Republic of Moldova, BPaL-based regimens were available exclusively in a research setting for a limited number of people with DR-TB (10 people in 2022) and were not recruited in programme settings. However, the 9-month modified regimen recommended by WHO recruited 116 out of 490 people with MDR-TB and pre-XDR-TB in 2022 and 178 out of 520 detected in 2023, respectively.

Number of people in need of short-term MDR-TB treatment regimens in the Republic of Tajikistan

In 2022, patient recruitment for short regimens for drug-resistant TB was conducted as part of operational research supported by international partners (GF/UNDP, USAID/ETICA, MSF). As a result, 141 people were enrolled on treatment. The number of patients on short regimens increased to 152 in 2023. Due to the completion of studies and delayed initiation of programme use of BPaL-based short regimens for DR-TB treatment, there have been challenges related to delayed revision and approval of TB treatment guidelines, which may affect patient enrolment in 2024.

In 2022, 141 patients were taken on short-term regimens for DR-TB, of which 32 patients (29%) were treated with BPaL. In 2023, the number of patients increased to 154, of whom 51 (33%) were treated with BPaL. Meanwhile, about 224 patients (59%) could be included in short-term treatment regimes.

The programme plans to recruit 220 people for short-term DR-TB treatment, of whom 170 will be treated with BPaL (42% of the total number of patients). The WHO projection is to recruit 462 patients (70% of the total). The Global Fund grant for 2024 assumes enrolment of 520 patients (78%).

Table 12

Forecast of the number of people with DR-TB in the Republic of Tajikistan in 2024-2025 (TWG Protocol of 06.02.2024)

Treatment regimes	LU-TB registration, 2022	LU-TB registration, 2023	WHO mission forecast for 2024	Plan, GF Grant 2024	NTP forecast for 2024	NTP forecast for 2025
mSTR	109	103	50	165	50	50
BPaLM/C	4	6	332	250	120	260
BPaL	28	45	80	105	50	80
Long treatment regimes	345	318	198	120	200	160
TOTAL by LU-TB regimes	**486**	**472**	**660**	**670**	**530**	**670**

The figures in the Global Fund grant are closest to 80%, reflecting best practice in countries that have successfully implemented short-term regimes. If the DR-TB guidelines are approved in a timely manner and consiliums work effectively, 520 people will be accepted for treatment in 2024, out of an estimated 538 potential applicants. Thus, about 18 people may not be able to get on short-term treatment courses.

In 2023, of the 472 patients identified, 154 were recruited for short courses of treatment. Based on best practice, a further 224 people could have started treatment if the guidelines for programme use were adopted in 2023.

Number of people in need of short-term MDR-TB treatment regimens in Ukraine

The National TB Programme does not currently separate the BPaL, BPaLM, short 9-month regimen separately. The statistics generally track short 6–9 month regimens. The study, conducted from July 2022 to January 2023, included 358 people, of whom 318 successfully completed treatment and recovered (89.9%).

In 2022, of the identified 4 889 people with DR-TB (MDR-TB – 3 909 and pre-XDR-TB – 980) treated with short-term DR-TB regimens, 1 650 received treatment.

In 2023, of the identified 4 889 people with DR-TB (MDR-TB – 3 924 and pre-XDR-TB – 965), 2 233 people were recruited to short-term regimens.

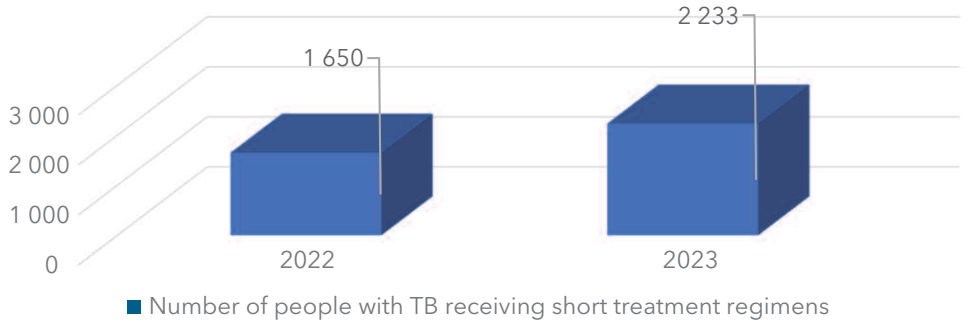

Figure 10. **Number of people receiving short DR-TB treatment regimens in Ukraine in 2022–2023.**

Given that WHO recommendations for programme implementation of 6-month BPaL-based treatment regimens were announced in 2022, the enrolment of 33% – 1 650 people with DR-TB out of a potential 4 889 candidates for treatment indicates significant progress in this direction. Whereas, in 2023, already 46% (2 233 people) with DR-TB have been recruited to short-term DR-TB treatment regimens. That is, in 2023, an additional 1 678 people (34%) could potentially be recruited to short-term DR-TB treatment regimens.

Overall conclusion on the number of people in need of short-term treatment regimens

The introduction of short-course regimens for DR-TB treatment in the Kyrgyz Republic, Republic of Moldova, Republic of Tajikistan and Ukraine show positive results reflected in improved DR-TB treatment efficacy, reduced deaths and loss to follow-up. The countries showed a significant increase in the number of patients treated with short regimens in 2022–2023.

For example, the Kyrgyz Republic, having had a good start with approved DR-TB guidelines, has already recruited 46% of potential candidates for short-term DR-TB treatment regimens in 2023, but further increases are planned in small steps: 55% in 2025 and 60% 2026.

In the Republic of Moldova, adaptation and management approval with extensive preparations for programme introduction of BPaL-based regimens took slightly longer and recruitment did not start until 2024. However, despite the late start the recruitment of 80% of people from the pool of potential candidates for short-term treatment regimens in 2024 is admirable.

The Republic of Tajikistan had a good enrolment rate for short-term DR-TB treatment regimens in operational trials in 2022–2023. However, due to the delayed approval of the national DR-TB management guidelines, programme enrolment of patients on short-term DR-TB treatment regimens is expected to be seriously delayed in 2024.

Ukraine, despite the difficult situation of organising TB care in the context of a full-scale war, was able to reach 33% of potential candidates for short-term DR-TB treatment regimens as early as 2022. In early 2023, having approved the updated medical standard "Tuberculosis", it has already covered 46% of potential candidates for short-term DR-TB treatment.

CONCLUSION: Countries have shown good progress with the initiation of short-term DR-TB treatment regimens. However, in order to improve treatment adherence among people with TB, achieve treatment efficacy targets, and rationally utilise funding, there is a need to:

- *Finalise and update the registration of all TB drugs, and approve updated DR-TB treatment standards.*
- *Initiate and expand the procurement of BPaL-based short-term treatment regimens from the budget.*
- *Increase the proportion of patients treated with short-term regimens.*
- *Continue monitoring by third-party communities to ensure the objectivity of the assessment.*
- *Introduce an indicator in the global TB report on the number of people on short-term treatment in countries to reflect the overall situation.*

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