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# Methadone Maintenance Treatment in Kosovo

## Consolidated Assessment Report

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## 1. List of Acronyms

| | |
|---|---|
| **AI** | Administrative Instruction |
| **AIDS** | Acquired Immunodeficiency Syndrome |
| **BINLEA** | Bureau of International Narcotics and Law Enforcement Affairs (see also INCB) |
| **BIO & BSS** | Behavioural and Biological Surveillance Survey |
| **CCM** | Country Coordinating Mechanism |
| **CDF** | Community Development Fund |
| **DIC** | Drop-in Centre |
| **DRD** | Drug-related Deaths |
| **EMCDDA** | European Monitoring Centre for Drugs and Drug Addiction |
| **FEFO** | First Expiry First Out |
| **FGD** | Focus Group Discussion |
| **GBV** | Gender-Based Violence |
| **GEA** | Gender Equality Act |
| **GDP** | Gross Domestic Product |
| **HCUSK** | Hospital and Clinical University Services of Kosovo |
| **HIV** | Human Immunodeficiency Virus |
| **INCB** | International Narcotics Control Board in Vienna |
| **KMA** | Kosovo Medicines Agency |
| **KPAR** | Key Populations at Risk |
| **LFA** | Local Fund Agent |
| **LMIS** | Logistics Inventory Management System |
| **MARP** | Most at Risk Populations |
| **SDG** | Sustainable Development Goals |
| **MMA** | Medicine Marketing Authorisation |
| **MMT** | Methadone Maintenance Treatment |
| **MoH** | Ministry of Health |
| **MoIA** | Ministry of Internal Affairs |
| **MoU** | Memorandum of Understanding |
| **MSM** | Men Who Have Sex With Men |
| **NGO** | Non-Governmental Organisation |
| **NSEP** | Needle and Syringe-Exchange Programs |
| **OST** | Opioid Substitution Treatment |
| **PSM** | Procurement and Supply Management |
| **PWID** | Persons who Inject Drugs |
| **PWUD** | Persons who Use Drugs |
| **SRA** | Stringent Regulatory Authority |

| | |
|---|---|
| **STG** | Standard Treatment Guideline |
| **UCCK** | University Clinical Centre of Kosovo |
| **UNFPA** | United Nations Population Fund |
| **UNICEF** | United Nations Children's Fund |
| **UNODC** | UN Office on Drugs and Crime |
| **VCT** | Voluntary Counselling and Testing |
| **WHO** | World Health Organisation |

## 2. Executive Summary

Kosovo is one of the poorest countries in Europe, with a per-capita gross domestic product of about 3,000 € and about one-third of the population living below the poverty line. Roughly one-eighth of the population live in extreme poverty. Difficult labour market conditions affect the whole population, but in particular youth and women. Unemployment rates country-wide are estimated to be 40%, bearing a high risk of undermining the country's social fabric. This situation has also held back the modernization of key sectors of Kosovo's economy.

According to the World Bank, health outcomes in Kosovo are weak, reflected - inter alia - in Kosovars' life expectancy being about 5 years lower than in the neighbouring countries and 10 years lower than in the EU. Household out-of-pocket spending on health in Kosovo is high, impoverishing and creating financial barriers to access to health services for the poor.

Kosovo is a transit country for drugs destined for Europe, but not a significant narcotics producer. Factors adversely impacting Kosovo's efforts to combat narcotics trafficking include its geographic location along traditional smuggling routes; incomplete integration of northern municipalities, especially the Mitrovica area and other Serbian enclaves along the border to Serbia; a poor economy; non-recognition of Kosovo by some states in the region, and a less than fully effective border management system.

As of yet, there is no comprehensive representative data about the actual size of the drug problem at the population level. Data collected in 2014 (in Pristina and Prizren) estimate that there are 3,946 persons who inject drugs in Pristina and 1,113 in Prizren[1]; data collected in 2016 estimate the number of PWID in all of Kosovo to be between 4,777 and 6,860[2].

Adult HIV prevalence in Kosovo remains less than 0.1% and HIV prevalence among key populations at risk is reported to be currently below 5%. Hepatitis C Virus prevalence, however, is fairly high among persons who inject drugs (27%). Due to its high rates of poverty and unemployment, increasing drug use, high mobility of Kosovars, and high-risk sexual behaviour, the country is currently regarded as vulnerable to HIV epidemic: There is a high risk of HIV reaching key populations soon and spreading rapidly due to their high stigmatization and marginalization, low access to the health system, and the lack of social support.

The Global Fund-financed Program, initiated in 2008, focuses on HIV prevention among key populations at risk and aims to scale-up the delivery of a range of comprehensive, high-quality HIV-prevention services. In this context, the program provides comprehensive services to persons who inject drugs including drop-in centres, outreach programs, needle and syringe-exchange, condoms, access to methadone maintenance treatment, as well as psychological counselling, and voluntary counselling and testing, peer education, and self-help groups.

In June 2012, the government approved the National Anti-Drug Strategy and Action Plan for 2012–2017, which emphasizes the need to mitigate the health and social consequences, arising from the misuse of drugs through a range of actions and activities – including Harm Reduction measures. However, given the multitude of issues at stake in this post conflict country, implementing comprehensive and needs-based HIV/AIDS and drug policies is not a very high priority for the government. The relevant government bodies

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[1] National Institute of Public Health of Kosovo, CDF, *HIV Integrated Behavioural and Biological Surveillance Surveys – Kosovo 2014: People who Inject Drugs in Pristina and Prizren, Men who have Sex with Men in Pristina* – funded by the Global Fund

[2] National Institute of Public Health of Kosovo, CDF, *Programmatic Mapping and Size Estimations of Key Populations in Kosovo, 2016* - funded by the Global Fund

are aware of the need for a comprehensive and sustainable implementation of services for person who use drugs, and cross-sectoral collaboration in developing a national response is in place, but ownership, commitment and capacities vary greatly between relevant ministries.

The Global Fund requested that a new assessment be done in 2016 and to recommend corrective measures to improve grant performance as well as service accessibility and quality. The assessment consisted of 2 parts – one general assessment of the MMT Program (hereafter "general MMT assessment") and one assessment focused on the methadone procurement and supply management in particular (hereafter "PSM assessment").

**The General MMT Assessment** of April 2016 revealed that there has been a considerable increase of clients since the last assessment in 2013 – especially during 2015: 193 clients received MMT in 5 sites during the period July - December 2015 as compared to 75 clients in 4 sites during the period December 2012 – May 2013. Despite this positive increase, however, the scale of the current coverage is not sufficient and the proportion of female clients in the program is still comparably low – between 1% and 3%. According to tentative data, 3% to 6% would be closer to reflecting the actual percentage of women injecting drugs in Kosovo. There is also a relatively high fluctuation of clients in the program. An important factor contributing to the delay of achieving wider coverage is the system of licensing for methadone administration: those licences are issued only to individuals – in that case to doctors, not to nurses, who, in fact are the ones most involved in the daily administration of methadone to the clients. NGOs like Labyrinth in Prizren do still not have a licence.

In order to improve the living conditions of persons who inject drugs, MMT can only be one contribution within a broader range of services. Services for this target group need to be scaled-up and diversified including a range of coordinated measures from low-threshold harm reduction services to long-term rehabilitation in support of client's stabilization, psychosocial wellbeing, and reintegration into their families and the labour market. According to the Ministry of Health, such measures are foreseen, but processes to come from strategy to action take a long time and ownership for a comprehensive, human rights and needs based drug policy is still low among some of the crucial responsible actors.

Many elements of such a comprehensive package of services are already in place in Kosovo and the MMT program has good potential to pave the way for service expansion. To what extent the responsible policy makers actually will support a comprehensive and needs-based approach sustainably, is hard to predict. As mentioned before, ownership and political will as well as capacity for programming and sustainable steering are still weak in this field.

In sum, capacity development is still needed on all levels to create better ownership, understanding, programmatic, and managerial capacities for a comprehensive response to the drug problem in the country. The Kosovar government – especially the Ministry of Health – should act very soon to sustain achievements of the MMT programme so far and accompany its extension request to the Global Fund with conrete plans and budgets for keeping up and sustaining MMT. To coordinate these measures, the ministry should install an effective drug/MMT focal point to coordinate the implementation of measures across relevant institutions. The coordinator's tasks should include monitoring and data analysis, needs assessments among different target groups, as well as the monitoring of the performance and quality of response measures. Necessary financial support to partners (including civil society) should be made through a national budget and licensing procedures should be speeded up and handled more flexibly to enable faster scaling up.

**The PSM Assessment** documented that procurement and supply management (PSM) of methadone in the context of the (developing) methadone maintenance program in Kosovo should be smooth sailing. The number of sites is limited, the sites are easily accessible in a country that is small, the product is registered on the market, and there is solid information on consumption. There is thus no systemic reason why the MOH could not take charge and ensure continuous and regular supply of methadone - provided the currently existing single procurement and supply chain is maintained (in line with the MOH assurances given).

That said, a number of strategic and tactical PSM improvements can be introduced to promote the MMT Program's future viability and expandability. Detailed specific recommendations are presented in the report per PSM phase (from selection to consumption). Amongst those, the priority PSM recommendations – i.e. with the highest potential for impact in terms of supply chain management and health impact - relate to (i) keeping the supply chain integrated, (ii) quantification and (iii) improving rational use of the methadone.

In addition to the purely technical PSM aspects, two administrative factors will be of fundamental importance to ensure effective implementation:

- It will be essential that the roles and responsibilities related to procurement and supply chain management be captured in the revised version of the Administrative Instruction, so as to minimize the risk of confusion and inaction. The stakeholders have some flexibility or leeway in deciding whether a particular task at national program level should be entrusted to the MMT focal point vs. the PSM coordinator vs. an M&E officer, provided, again, the division of labour and responsibilities is captured in unambiguous language in the revised version of the A.I or related text.
- MMT program viability and expandability will also depend on the capability, management skills, sense of ownership, and pro-active approach of the actual people in the key roles. From a PSM perspective, this applies to both the position of MMT Focal Point and the PSM Coordinator in the MOH/Pharmaceutical Services Dept.

Ultimately, and in echo of the general MMT assessment, the expandability and viability of the MMT program will depend mostly on the political will of the government/MOH to make the program effective and successful. In this context, and in the face of persisting taboos, the determined and public support of the Global Fund to the MMT program can play a determining role.

# 3. Context

## 3.1 Demographic Background

Kosovo is located in South-eastern Europe with a total area of 10,887 sq. km. The land-locked country is bordered by Albania, Macedonia, Montenegro, and Serbia. The majority of the population lives in rural towns outside of the capital city, Pristina. The Kosovo Agency for Statistics estimates that the country has 1,815,606 inhabitants. The **population** is very young: 60.2% of the inhabitants are between 15 and 24 years old. Ethnic groups are Albanian (88%), Serbs (7%), and 5% Roma, Ashkali, Egyptians, Turk, Bosniaks, and others. The ethnic Albanian and Serbian communities live largely separate, with the Serbian community mostly living in the northern Mitrovica area, which according to the NGO Labyrinth is also a hot spot for drug use.

Largely reflecting historical legacies and the still unresolved status of Kosovo, the country remains **one of the poorest countries** in Europe, with a per-capita gross domestic product (GDP) of about 3,000 €, about one-third of the population living below the poverty line, and roughly one-eighth in extreme poverty. Difficult labour market conditions affect the whole population, but in particular youth and women, with a high risk of undermining the country's social fabric. Unemployment rates country-wide are estimated to be 40%. This situation has also held back the modernization of key sectors of Kosovo's economy. Migration is a continuous issue with remittances from the diaspora largely contributing to the country's GDP. There is a widespread pessimism about the rule of law, economic prospects and political transparency among the population.

According to the World Bank, **health outcomes in Kosovo** are weak, reflected - inter alia - in Kosovars' life expectancy being about 5 years lower than in the neighbouring countries and 10 years lower than in the EU. Household out-of-pocket spending on health in Kosovo is high, impoverishing and creating financial barriers to access to health services for the poor. Due to a lack of priorities, ownership and capacity, the reform and modernization of the health sector is still in its early stages. The Health Insurance Law, passed in April 2014, provides the legal basis and framework for a mandatory health insurance scheme funded through general tax contributions and mandatory insurance premiums. Improvements in financial protection and access to quality care will, however, depend on how effectively health insurance is implemented, including the coverage of the poor.

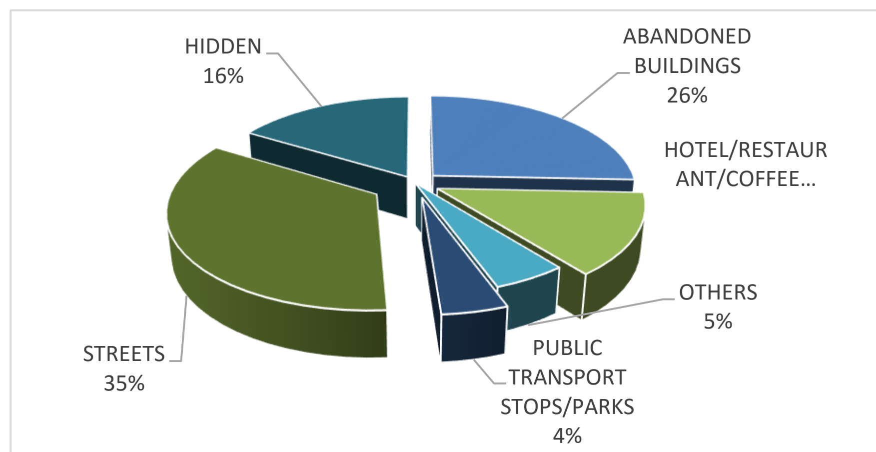
## 3.2 Drug Trafficking and Problem Drug Use

According to the 2015 Report of the Bureau of International Narcotics and Law Enforcement Affairs (BINLEA), **Kosovo is a transit country for drugs** destined for Europe, but not a significant narcotics producer. Between January and September 2014, Kosovar authorities reported seizing 672 kg of marijuana, 21 kg of cocaine, and less than two kg of heroin. These figures reflected a significant increase in seizures for marijuana and cocaine as well as a significant decrease for heroin. Factors adversely impacting Kosovo's efforts to combat narcotics trafficking include its geographic location along traditional smuggling routes; incomplete integration of northern municipalities (Mitrovica area and other Serbian enclaves along the border to Serbia); poor economy; non-recognition of Kosovo by some states in the region, and a less than fully effective border management system.

Different organisations in Kosovo collect **information on drugs and drug use**, but surveys are mostly being conducted ad hoc and on limited aspects of the issue. As yet there is no comprehensive representative data that may indicate the actual size of the drug problem at the population level. The 2014 National Report to the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) - containing data from 2012 - states that the majority of the surveyed 19 to 54 year-old persons who inject drugs (PWID) were men (88.7

%). While a large majority of PWID injected drugs at home (79.8%), a quarter of the sample injected in a shooting gallery or at another closed location where PWID gather (20.2%). The average age of respondents first injecting was 22.3 years. Heroin was the most frequently injected drug (71.1 %), and the substance was injected at least once by almost all respondents (97.3 %), followed by Methadone (28.7 %). About half of the respondents (51.8 %) had a history of drug treatment, mainly in a medical setting (72.5 %). With regard to using sterile injection equipment, 158 of 198 participants stated that they always use sterile needles and syringes (83.8%) and mentioned obtaining sterile injecting equipment at NGO premises (56.8%)[3]. The information given in the country report has been taken from the 2011 Behavioural and Biological Surveillance Study on HIV among PWID[4].

More recent data has been collected in 2014 by the "HIV Integrated Behavioural and Biological Surveillance Survey for Kosovo"[5] (Bio & BSS 2014). The survey estimated that there are 3,946 PWID in Pristina and 1,113 in Prizren. Based on these figures, it can be estimated that there are **about 30,000 persons who use drugs (PWUD) in Kosovo**. EMCDDA cites different sources and states that "*The most frequently cited estimate of the drug using population is between 10,000 – 15,000 individuals, and of these approximately 4,000 – 5,000 are thought to be heroin users."*[6]A recent mapping of PWID in Kosovo estimates that there are between 4,777 and 6,860 PWID in Kosovo[7]. The 2016 PSE mapping also provides information about the locations where PWID congregate and consume drugs:




Source: 2016 PSE Mapping, *Spots by typology where PWID congregate in Kosovo, 2016*

The Bio & BSS 2014 also looked into the **injection practices of PWID** in Pristina and Prizren: Most PWID in both cities reported injecting once a day or more and injecting on the previous day before enrolling in the survey. The majority of PWID in Pristina reported injecting at their home (73%), whereas a majority of PWID

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[3] Republic of Kosovo, Ministry of Internal Affairs, *National Report (2012 data) to the EMCDDA,* 2014

[4] Federal Ministry of Health of the Republic of Kosovo, HIV Integrated Biological and Behavioural Surveillance Survey (IBBSS) 2010

[5] National Institute of Public Health of Kosovo, CDF, *HIV Integrated Behavioural and Biological Surveillance Surveys – Kosovo 2014: People who Inject Drugs in Pristina and Prizren, Men who have Sex with Men in Pristina* – funded by the Global Fund

[6] EMCDDA country overview Kosovo, available online at http://www.emcdda.europa.eu/countries/kosovo

[7] National Institute of Public Health of Kosovo, CDF, *Programmatic Mapping and Size Estimations of Key Populations in Kosovo, 2016* - funded by the Global Fund

in Prizren reported injecting in shooting galleries (40%), followed by injecting at their home (38%). In Pristina, 6% of the PWID were women and 9% in Prizren. The survey also found that the majority of PWID in both cities reported having secondary education or more, being single, co-habituating, and employed.

In 2014, EMCDDA published a survey on **drug use and attitudes** in Kosovo that looked also into the attitudes of the general population about drugs (both legal and illegal) and persons who use drugs (PWUD). The survey concludes that although the prevalence of drug use recorded through this survey provides for a fairly low percentage of the population who admit having used (illicit) substances, the perceived availability of substances appears to be quite high. It is interesting to note that according to the survey drug addicts are more commonly perceived as patients than as criminals by the general public (35.4 % against 17.7%) while 25.7% of respondents consider drug addicts as both criminals and patients simultaneously.[8]

The 2008 Rapid Assessment and Response study published by WHO, UNICEF and UNFPA revealed the crucial and ambiguous **role of pharmacies** in this issue: the study investigated a total of 49 pharmacies from five regions throughout Kosovo (Pristina, Prizren, Peja, Mitrovica, and Gjilan) and found a number of psychoactive drugs being sold there. All of these being controlled substances and required by law on psychotropic and narcotic drugs of Kosovo to only be distributed with a medical prescription. However, the overwhelming finding from this evaluation was that pharmacies did sell psychotropic drugs without a prescription. According to the study, this was not the case for Methadone, as the two pharmacies that did have Methadone in stock would not sell it without a prescription[9]. During interviews with Methadone maintenance treatment (MMT) clients during the 2016 assessment mission however, several interview partners reported that it is not complicated to purchase Methadone at pharmacies without prescription or by "re-using" official prescriptions.

There is no reliable information on **drug-related deaths** (DRD) in Kosovo. Official information is fairly weak, - mostly due to a lack of general awareness among health professionals concerning DRD. As a result, deaths caused by drug overdoses are routinely recorded as cardiac arrest. Even though the Toxicology Laboratory of the Institute of Forensic Medicine would be capable of confirming cases of DRD, it is fairly rare for the authorities to order post-mortem toxicological analyses in cases of suspected overdose deaths because stigma still surrounds the issue of addiction and an autopsy can only be conducted if it is requested and authorised by the victim's family.

The NGO Labyrinth possesses a registry and keeps track of all cases of death among the clients it has registered. Information on eventual DCD is mostly provided by other clients and then verified by the individual's family and the police. According to information from Labyrinth, two drug users died in 2004, three in 2006, one in 2007, five in 2008 and 2009, 15 in 2010 and 17 in 2011, mainly by overdose. It is assumed that all these death cases were induced or caused by drugs[10].

During the assessment mission and discussions with staff from Labyrinth in Prizren, the NGO staff reported of a DRD which recently occurred in one of the "shooting galleries" of the city (deserted and deteriorating buildings in the city frequented by PWID to inject drugs in privacy). One of the MMT clients had an overdose and was found by neighbours who immediately informed Labyrinth staff. First aid was applied and an ambulance called immediately, but unfortunately the client passed away on the way to the hospital. During the conversation, Labyrinth staff reported that they have no other means than calling an ambulance in such incidences, because they have no breathing bags or Naloxone (an opioid antagonist and antidote) available.

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[8] Kushtrim Shaipi, Hasnije Ilazi, *National General Population Survey on drug use and attitudes in Kosovo 2014*, EMCDDA August 2014

[9] EMCDDA country overview Kosovo, available online at http://www.emcdda.europa.eu/countries/kosovo

[10] Ibid.

It was also reported that an ambulance usually only takes five to ten minutes to arrive at the site of the accident.

## 3.3 HIV/AIDS

Though **HIV prevalence** in the country is still low and has not reached large parts of the most at risk groups yet, there is a high risk of HIV reaching these target groups soon where the virus is likely to spread rapidly given the target group's high stigmatization and marginalization, their low access to the health system, and the lack of social support. While 100 HIV and AIDS cases (46 HIV, 54 AIDS and 41 AIDS-related deaths) have been officially reported in Kosovo, the country is regarded as vulnerable to the HIV epidemic due to its high rates of poverty and unemployment, increasing drug use and high-risk sexual behaviour, high mobility of Kosovars to and from countries with higher prevalence rates, a large international community, and many unaccompanied workers. Commercial sex and human trafficking represent additional epidemiologic risks, as does a population of stigmatized men who have sex with men (MSM)[11].

Data gathered until 2015 by the National Institute of Public Health indicates that **HIV is being transmitted primarily through heterosexual contact** (90%), as opposed to homosexual contact (7%), mother to child transmission (2%) and through injecting drug use (1%). Adult HIV prevalence in Kosovo however, remains less than 0.1% and HIV prevalence among key populations at risk (KPAR) is reported to be currently below 5%. According to the last biological and behavioural surveillance survey (Bio & BSS)[12] among PWID, MSM and sex workers conducted in 2014, HIV prevalence among MSM was 0.5% (five new MSM cases with HIV infection). No new HIV and AIDS cases were reported among PWID, while prevalence of Hepatitis B surface antigen for Pristina region was 5% and Hepatitis C Virus (HCV) prevalence was 27%. The Bio & BSS 2014 reveals that 89% PWID have adopted behaviours that reduce HIV (use of sterile injecting equipment the last time they injected) and 47% used a condom the last time they had sexual intercourse.

**The Global Fund-financed Program** contributes to the implementation of the National HIV/AIDS Prevention Strategy, especially covering financial gaps in prevention, care and support. It is aimed at maintaining HIV prevalence among key populations below five percent and to prevent HIV from spreading into other groups. The **MMT program in Kosovo** has been initiated in March 2012. The Global Fund principal recipient, the Community Development Fund (CDF) and the Ministry of Health (MoH) have collaborated in terms of initiation of MMT Program. The Memorandum of Understanding (MoU) between two parties has been amended with Annex 1: *"Pilot Project for administration of methadone as a substitution treatment for opioid narcotics"*. In addition, the Work Protocol for MMT in health institutions has been approved and signed by the Minister of Health on March 23rd 2012. In January 28th 2014, the MoH and CDF signed the third Annex of the MoU which redefines the roles and responsibilities of the parties in the MMT project. This Program is currently being implemented based on the "Work Protocol of Methadone Substitution Treatment in Health Institutions" approved by the MoH on 23rd March 2012 with Protocol No. 05-1609 in five institutions licensed for operation with narcotics.

The Global Fund-financed Program focuses on HIV prevention among KPAR and aims to scale-up the delivery of a range of comprehensive, high-quality HIV-prevention services that are tailored to the specific needs of KPARs. To this context, the Global Fund-financed Program provides comprehensive Harm Reduction services to PWID through multidisciplinary / drop-in centres (DIC) and outreach programs, including access to

[11] Report from the Commission to the European Parliament and the Council on Progress by Kosovo in fulfilling the requirements of the visa liberalization roadmap

[12] National Institute of Public Health of Kosovo, CDF, *HIV Integrated Behavioural and Biological Surveillance Surveys – Kosovo 2014: People who Inject Drugs in Pristina and Prizren, Men who have Sex with Men in Pristina* – funded by the Global Fund

needle and syringe-exchange programs (NSEP), condoms, access to MMT, as well as psychological counselling, voluntary counselling and testing (VCT) services, peer education and self-help groups.

Most of these services - except NSEP - are also available to drug users in two of the four **prisons in Kosovo**: the long-term male prison and the prison for women and juveniles. According to Dr. Milazim Gjocaj, director of the prison health department under the MoH, however, there are no inmates eligible for MMT in the latter facility at the moment. No MMT is available so far in the 6 detention centres in Kosovo and the prison health department would like to scale up MMT in the remaining two prisons. MMT clients may continue their treatment in police custody and remand. While waiting for their trials, they may be sent to one of the facilities where MMT is available or Methadone may be delivered to them over shorter periods of time. In prisons, multi-disciplinary teams (psychologist, psychiatrist and social worker) care for prisoners. These teams also provide information and support for up to 5 days after release from prison until clients are registered in other services (MMT sites, therapy, etc.).

In June 2013, a first assessment of the MMT Program in Kosovo was conducted in order to assess the quality of MMT services provided in the country. The assessment was conducted by Susanne Schardt and revealed that the MMT program has good potential to contribute to more social justice, equal opportunities and equal access/equity, if it is scaled up and embedded in a wider harm reduction approach (social dimension of sustainability)[13].

In February 2015, a survey on **client satisfaction in the MMT program** was conducted based on the Annex of the MoU on MMT, between the MoH and CDF (January 2014). The data was collected in all five MMT sites. Unfortunately, the coverage of clients was not very wide – especially that of female clients: From a total number of eligible 113 clients only 52 were reached, out of whom only 1 was a woman.

The client satisfaction survey found that:

- The largest proportion of responding 52 clients visit the MMT centres every day or several days per week
- The majority of them (42 or 80.8%) have not visited any other centre; while 7 clients (13.5%) declared that they visited other centres as well
- Of the responding 52 clients, 88.5% were satisfied with the services provided in the centre and only 9.6% were not satisfied at all
- Almost all of clients (92.3%) felt more or less assisted by the MMT Centres to solve their problems
- Half of interviewed clients (26 or 50%) declared that the MMT Centres staff behaved “excellent” with them; 15 clients (28.8%) stated that the MMT Centres staff behaved “good”, and 9 clients (17.3%) felt the behaviour of the MMT Centre staff was “very good”. Two clients (3.8%) weren’t satisfied at all
- Most of the respondents (34 or 65.4%) declared that they would recommend this centre to their friends, while 10 clients (19.2%) stated they would maybe recommend this centre. Only 6 of the interviewed clients (11.5%) responded negatively
- Comments and requests of interviewed clients related to a certain centre were mainly about regular methadone supply, improving the conditions (services?) of the DIC and the request for other activities in the centre[14].

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[13] Susanne Schardt, *Assessment Report Methadone Maintenance Treatment in Kosovo*, June, 2013 - – funded by the Global Fund

[14] Ministry of Health, Community Development Fund, *Client satisfaction survey among MMT Centers*, February 2015

## 3.4 Gender Aspects

Article 1.1 of the Kosovar Gender Equality Act (GEA) protects, addresses and establishes gender equality as a fundamental value for the democratic development of Kosovar society, providing equal opportunities for both men and women in Kosovo's political, economic, social and cultural life. Article 2.2 of GEA provides that equal treatment means the elimination of all forms of direct and indirect gender discrimination.

In 2014, the Embassy of Sweden in Kosovo commissioned a country gender profile for Kosovo that concluded: "*Kosovo has a fairly comprehensive legal framework and several mechanisms in place towards gender equality. Implementation remains a challenge. Many strategies exist to specify and implement institutions' legal obligations. However, action plans are rarely cross-checked with other action plans, potentially contributing to overlap. Strategies seldom receive sufficient funding for implementation. Government institutions at all levels tend not to understand how to mainstream gender within their work."* [15]

The gender profile reports about many areas in which women are being discriminated against – above all they still have very limited access to the labour market: *"No country in Europe has so few women in the formal labour market (18% of women participate, compared to 55% of men)*[16]*."* It also states that several forms of gender-based violence (GBV) exist in Kosovo, including domestic violence which appears to be the most prevalent form of GBV, particularly for women.

Unfortunately, there are no studies available on **women using drugs in Kosovo** to date and almost nothing is known about the situation that drug using women in Kosovo find themselves in. The EMCDDA survey of 2014 reports considerably lower percentages of women using both legal and illegal substances (between 3% and 6% of all PWUD) but also admits that it is very difficult to access this target group and to obtain valid data.

Discussions with the staff of Labyrinth Pristina during the assessment mission revealed a number of aspects that make it particularly difficult to access women who use drugs:

- Women drug users mostly live and consume at home where it is difficult to reach out to them
- Women who use drugs face the double stigma of drug use and gender discrimination. They do not come to services for PWUD as often as men, because they fear that stigma when seen near such a service facility
- Women drug users are more likely to exchange sex for housing, sustenance, and protection (transactional sex). Since this practice is often not perceived as sex work by the women and therefore not as risky behaviour regarding HIV, they do not use the respective services. Sex work is highly stigmatised and often linked to human trafficking, which makes it very difficult to gain access to these women
- Women are far more likely than men to be victims of domestic violence, sexual or physical abuse, forced sex work, and human trafficking. In such a context, they have very little chance to seek help in service facilities and can hardly be reached by the existing outreach activities
- Male partners – especially those who do not use drugs themselves - often discourage the woman from seeking services because they fear the stigma or because they want to keep up the woman's dependence on them

The 2008 Rapid Assessment and Response study included questions about **transactional sex**. The study found that 10% of the respondents (all men) reported having given someone money or drugs in the past 90 days to perform sex or have sex with them. An additional 8% reported having had sex with someone in

[15] Färnsveden et. al., *Country Gender Profile – an Analysis of Gender Differences at All Levels in Kosovo*, Framework for Gender Equality 2014

[16] Ibid., p.2

the past 90 days in order to get money or drugs (5% refused to respond to this question). Of those who reported "yes" to this question, all were men. The number of women who inject drugs surveyed is small and for each of these questions, 14-20% of the women refused to answer[17]. The refusal of the female interview partners in this survey indicates that sex work is obviously very highly stigmatized in the country and that women feel ashamed to answer questions about this issue.

**Women who use drugs** often experience high levels of poverty, financial dependence, violence, and abuse. This limits their ability to negotiate relationships and safer sex practices. International studies have also shown that also women who use drugs have high rates of sexually transmitted infections and are very likely to experience unwanted pregnancies. The high stigmatization along with numerous barriers in accessing health care and fear of losing custody of their children makes it risky for women to disclose their drug use when they seek services. The women interviewed at Labyrinth Pristina and Gjakova also reported that this is one factor that keeps drug using women away from the MMT program, because they are afraid to be seen entering or leaving the MMT centre.

Despite female drug users' many needs for care and support, drug services in Kosovo – like in many other countries – are mostly dominated by and oriented towards men. Women who use drugs need social and psychological support such as counselling and women-specific support groups, reproductive health services, such as contraception services beyond condom provision, and support during pregnancy. Since many drug using women in Kosovo are reluctant to seek services proactively, outreach and peer education could play an important role here. Similar to the male outreach volunteers working for Labyrinth, female outreach workers or peer educators should be involved and trained to bring information and services to women who use drugs. Support and peer education networks should be established to reduce clients' experience of isolation and stigma, offering opportunities to share their problems and strengthen their sense of community and empowerment. Services to women who use drugs could include also syringe exchange, disseminating condoms and contraception services, information about women-friendly service providers as well as providing safer use and safer sex skills.

### 3.5 National and International Response

Kosovo is working continuously to **incorporate international norms and conventions** into its laws against drugs. In 2008, the Parliament of Kosovo approved the Law on Narcotic Drugs, Psychotropic Substances and Precursors which considers the use, possession, production and trafficking of illicit drugs as violations against the Criminal Code of Kosovo. Possession of narcotic drugs, psychotropic substances or analogues are punished by a fine and by imprisonment of one to three years. However, according to Article 57 of the Criminal Code, mandatory treatment may be imposed and sentences suspended if the criminal offense was related to drug or alcohol addiction. The Law on Narcotic Drugs, Psychotropic Substances and Precursors is currently being amended. According to interview partners at the Ministry for Internal Affairs (MoIA) and the Prison Health Department however, there are only very few treatment options available in the country and these are not well known to the judges. Any person caught by the police for the possession, use, production and trafficking of drugs is considered to be a suspect or a drug-related offender. Such offenders are registered in the database of the Kosovo Police. The law specifies also the administration and management of Methadone to be used for opioid substitution treatment (OST). The administrative instructions are currently being amended by an inter-agency working group of experts.

[17] WHO, UNICEF, UNFPA (2009). Psychoactive Substance Use in Kosovo, Rapid Assessment and Response With Youth, Injecting Drug Users and Prisoners, Pristina, May 2009

In June 2012, the Government approved a **National Anti-Drug Strategy and Action Plan** for 2012–2017, which aims to build the mechanism needed to advance the fight against drugs and their negative impact through increased cooperation between responsible institutions. The strategy is based on five pillars: demand reduction and Harm Reduction; supply reduction; cooperation and coordination; support mechanisms; supervision and monitoring. General goals and specific objectives have been incorporated within these pillars. The main actors are the MoIA, the Ministry of Health (MoH), Customs, the Ministry of Education, Science and Technology (MoEST), as well as other government bodies and civil society organisations[18].

The current National Strategy emphasizes the need to mitigate the health and social consequences, arising due to the misuse of drugs through a range of actions and activities – including Harm Reduction measures[19]. But apart from Labyrinth in Pristina, Gjilan and Prizren, no other NGOs provide comprehensive Harm Reduction services. Other actions in the drug field comprise a series of measures such as prevention and education, treatment, VCT, and (both voluntary and mandatory) rehabilitation.

Due to a lack of appropriate training and understanding of state-of-the-art of drug treatment, comprehensive **services to problematic drug users are extremely limited in Kosovo** – despite future plans for the development of treatment responses and strengthening treatment capacities being outlined in the National Anti-Drug Strategy and Action Plan for 2012–17. In Pristina, the Psychiatric Clinic of the University Clinical Centre of Kosovo (UCCK) and the NGO Labyrinth, provide most of the drug treatment in the form of detoxification services, psychosocial treatment and pharmacotherapy (MMT). Labyrinth Pristina also provides other Harm Reduction services and psychosocial counselling. In 2008, UCCK created special inpatient services to treat addiction. In regional hospitals in Gjilan and Gjakova, MMT has also been installed with support from the Global Fund, but in December 2015, unfortunately the MMT site in Gjilan was closed and medical staff at the department is reluctant to resume the services. To date, treatment in public hospitals has been based solely on MMT and detoxification. Psychosocial interventions and especially social support offers are rarely used here. Labyrinth Prizren and Gjilan provide Harm Reduction services, VCT and psychosocial care, but are still not licensed to administer MMT at their premises, although capacity and necessary infrastructure are available for that since a long time at Labyrinth Prizren.

The international community has funded and commissioned several surveys and studies, capacity development measures, and other small-scale activities. To date, the Global Fund remains the biggest donor in building up a national response to prevent HIV/AIDS among KPAR and is the only international donor supporting Harm Reduction services – albeit with a very strong focus on MMT.

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[18] Government of the Republic of Kosovo, *National Strategy of Republic of Kosovo Against Narcotics and Action Plan 2012-2017*, Pristina 2012

[19] Ibid., p. 19f

# 4. Objectives and Criteria of the Assessment

The assessment sought to back-up the implementation of the R7 HIV Global Fund-financed program in Kosovo in support to the National HIV Program which includes MMT as an important element of Harm Reduction services for PWID. The aim was to assess the quality of existing measures and to recommend corrective measures to improve grant performance as well as service accessibility and quality.

**For the general MMT Assessment**, the consultant, Susanne Schardt, evaluated the implementation of current MMT programs, shortcomings of program implementation, management and coordination, assessment of drop out causes from the MMT program, client's needs, patient support programs, and most efficient ways of providing integrated care to PWID.

According to the terms of reference of the assignment, the **main objectives** were to

- identify quality factors which need to be enhanced/strengthened in order to enhance the effectiveness of the Global Fund-supported MMT program in Kosovo;
- look at quality factors affecting coverage, obstacles to enrolment, and drop-out;
- provide a status update/progress on recommendations derived from the 2013 MMT assessment in the three categories of the 2013 assessment: MMT, PWID services and policy level;
- propose solutions/way forward within a specified timeline in order to improve the overall quality of the MMT program in Kosovo

Other aspects of the assessment included a capacity needs assessment among relevant institutions and recommendations for concrete actions during the extension period of Global Fund-financed Round 7 that Kosovo plans to apply for by mid-2016. The mission was conducted in parallel with the Local Fund Agent (LFA) assessment mission on procurement and supply management (PSM) of Methadone within the Global Fund-financed programme (consultant: PSM specialist Ms Veerle Coignez). Therefore, this assessment did not look into PSM issues. Also, time for meetings, interviews and focus group discussions (FDGs) was limited and individual client interviews had to be reduced in favour of conducting more FGDs. The mission in Kosovo took place between April 11$^{th}$ and 15$^{th}$, 2016 and first findings and recommendations were shared and discussed with CDF, the Ministry of Health, and Labyrinth Pristina in the form of a Debriefing at the end of the mission.

**For the PSM Assessment**, the consultant Veerle Coignez was tasked to re-assess the strengths and weaknesses of the current methadone PSM system with a view towards general improvement of service quality and future expandability of the MMT program. In this context, the PSM expert reviewed the situation in the MOH and the NGO sector respectively, as well as the possible scenario of the MOH taking on an increasingly pro-active role. The technical findings were used to feed into the responses to the following general macro-level questions:

- What are the PSM-related strengths and weaknesses in the current MMT context?
- What effects are to be anticipated if the MOH takes over procurement and supply of methadone?
- What needs to be considered or set up in PSM terms in order to ensure MMT viability and expandability?
- What are the customer issues to be taken into account alongside the PSM technical issues?

## 5. Methodology

As stated in the Inception Report, the assessment focused not only on relevant documents and meetings with the project partners, policy makers (ministries) and intermediaries (service providers). The consultants also visited several sites, as well as the warehouse where methadone is stored in Pristina, the site in Prizren. Interviews were also conducted with the target group itself (PWID) to gather first-hand information on clients' living conditions, their satisfaction with the services provided (and the service providers' staff), needs, and recommendations for service improvement.

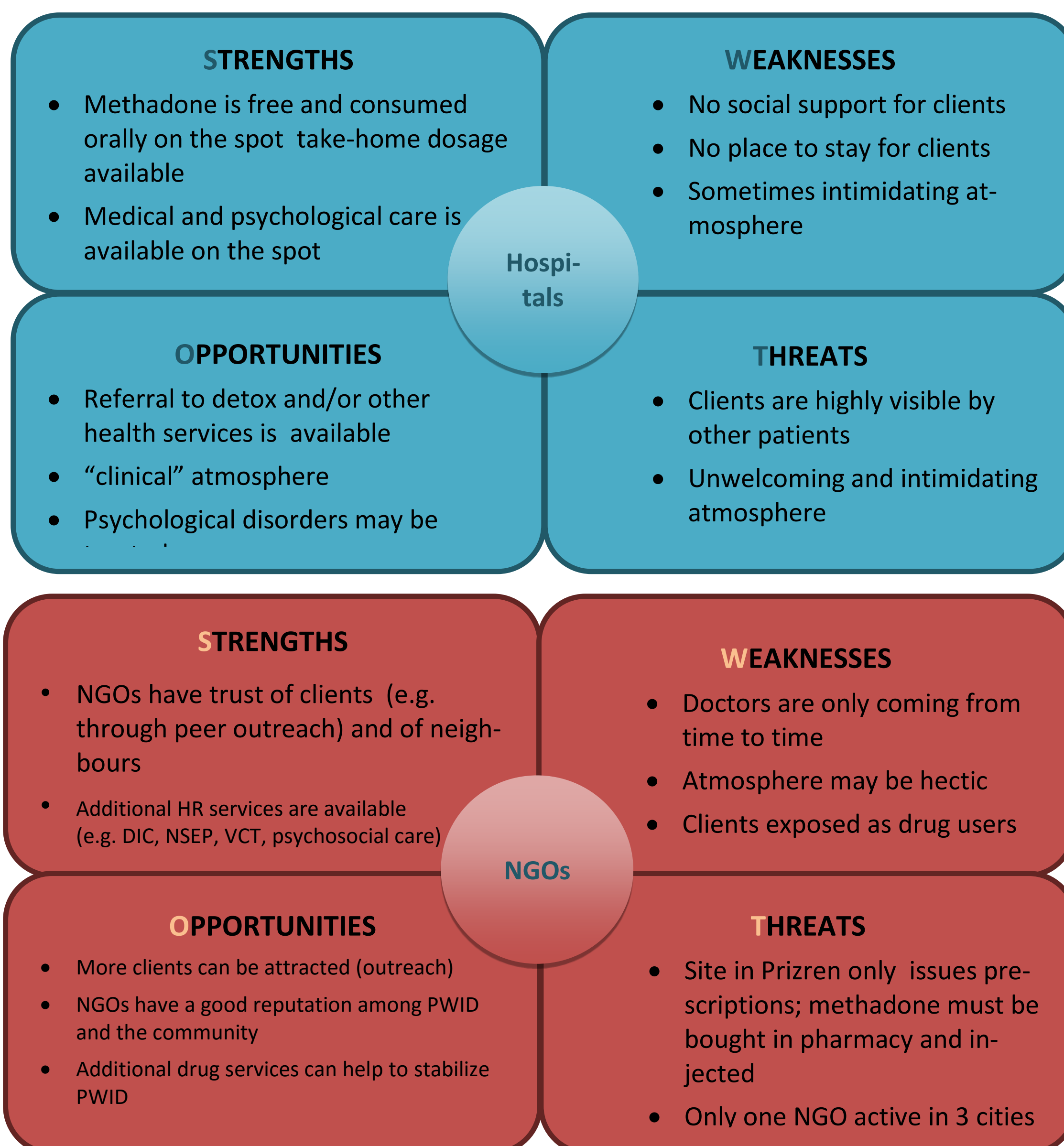
The following methods were used during the assessment:

- **Desk review** of relevant documents
- **Individual semi-structured interviews**:
  - 1 client at Labyrinth in Pristina (female)
  - 1 client at Gjakova regional hospital (male)
- **Focus group discussions and visits**:
  - CDF: **Dr. Edona Deva**, HIV Program Manager
  - MoH: **Dr. Imet Rrahmani**, Minister of Health; **Dr. Izet Sadiku**, Deputy Minister of Health
  - **Dr. Gani Shabani,** Permanent Secretary; **Dr. Pashk Buzhala**, acting director of Dept. for Health Services; **Dr. Laura Shehu**, HIV/AIDS focal point / national ADS coordinator; **Mr. Bekim Fusha**, Director of Dept. for Pharmaceuticals
  - **Dr. Milazim H. Gjocaj,** Director of Prison Health Dept.
  - MoIA: **Mr. Nehat Mustafa**, Deputy Minister and Coordinator of National Anti-Drug Council
  - Kosovo Police: **Mr. Bajram Nuhiu**, Chief of Prevention and Cooperation Sector / Anti-Drug Trafficking Dept.
  - Labyrinth staff in Prizren and Pristina: **Erroll Shporta** director of Labyrinth Prizren and **Safet Blakaj** director of Labyrinth in Pristina (and nurses, peer outreach workers, psychologists and other staff of the NGOs in both cities)
  - Gjilan regional hospital: **Dr. Besim Guda**, director; **Jeton Shkodra**, head nurse at MMT center; pharmacist of the hospital's central pharmacy
  - UCCK Psychiatric Clinic Pristina: head nurse at Clinic and MMT center and pharmacist at hospital's centrall pharmacy
  - Gjakova regional hospital: **Dr. Ilir Grezda,** doctor for MMT admin at regional hospital, **Mr. Besnik Stuja,** Coordinator of mental health dept.; **Dr. Zef Komani,** national representative of mental health sector to MoH; pharmacist at hospital's central pharmacy
  - 3 MMT clients at Labyrinth DIC, Pristina (all male)
  - 3 MMT clients at the Gjakova Regional Hospital (2 male / 1 female)
  - MOH Warehouse where methadone is stored
  - Meeting with **Dr. Zabergja** representative of the Kosovo Medical Agency.

# 6. General MMT Assessment

## 6.1. Main Results of Assessment

### 6.1.1 SWOT Analysis of MMT services at hospitals and NGO sites




For most of the MMT Centers **stigma remains the main reason why PWID hesitate to join the MMT Program**. NGO sites are usually located in the inner cities where there is a relatively high risk of being observed while entering or leaving the site. During interviews, some clients said they preferred the hospital sites because there they were seen as “normal patients”, not as drug users. Since the MMT centres are located in the mental health departments, this may lead to different sorts of stigma, however. The fear of being

identified as a drug user is a major obstacle to accessing the MMT program – especially for women – and although most PWID know about the MMT Program and drug services, many still prefer to buy methadone at pharmacies and consume it in a private place.

Though **hospital sites** may also offer detox, treatment of psychological disorders and other health services easily, the "clinical" atmosphere intimidates some clients. The biggest shortcoming – according to interviews with clients – is the fact that the medical staff is not trained to respond adequately to the special needs of IDUs. They often are unwelcoming, if not threatening, and clients often feel stigmatised by them also. Labyrinth has conducted several information meetings with doctors to enhance their understanding of the special needs and challenges in working with PWID, but it could be interesting to find out whether clients only go to MMT centres at hospitals because there is no other option or whether they really feel satisfied with the service there. In 2013, the problem of intimidating doctors was mentioned frequently during interviews with clients. This time, that problem was not mentioned – clients rather referred to nurses being rather supportive. As was the case during the last assessment, clients interviewed at hospital sites missed psychosocial support and other low-threshold services in the MMT centres at hospitals. It was, however, interesting to hear that some of the MMT clients at hospitals reported they preferred the clinical setting to the sometimes hectic setting at Labyrinth where they also felt more exposed "as drug users".

While it is an advantage that MMT clients have a choice between settings, when looking at the data in the table below, the numbers are quite clear: the MMT site operated by Labyrinth has been most successful at building and maintaining its client base. When given a choice, potential clients, as those in Pristina, appear to strongly prefer a NGO setting.

| Number of Patients 2014-2016 | October 2014 (from WHO Assessment) | December 2015 | March 2016 |
|---|---|---|---|
| MOH Hospital Pristina | 16 | 22 | 15 |
| MOH Hospital Gjakova | 10 | 18 | 21 |
| MOH Hospital Giljan | 24 | Closed | Closed |
| Labyrinth MTT Site | 47 | 84 | 90 |
| Prison | 1 | 5 | 4 |

**NGOs** have a better reputation of being client-friendly, understanding, and supportive. The additional offers provided there are also valuable to the clients, but NGOs could provide more low-threshold services for the immediate needs of drug users in general. Since the only NGO working in this field is Labyrinth (as it was in 2013), there is a high risk that staff becomes overburdened by the task to meet the needs of all clients asking for support at their facilities. What makes their situation even more complicated is the fact that they often are ex-users themselves and thus also bear the burden of social stigma. Despite having received capacity building on project management and OST with the support of international donor organisations in the past, they receive little to no support from the Kosovar government and often have to rely on a "trial and error" method to conduct their tasks. Professional networking with Harm Reduction service providers in the region (e.g. with HOPS in Macedonia) has improved and there is some mutual support now, but Labyrinth staff still acts very much on its own.

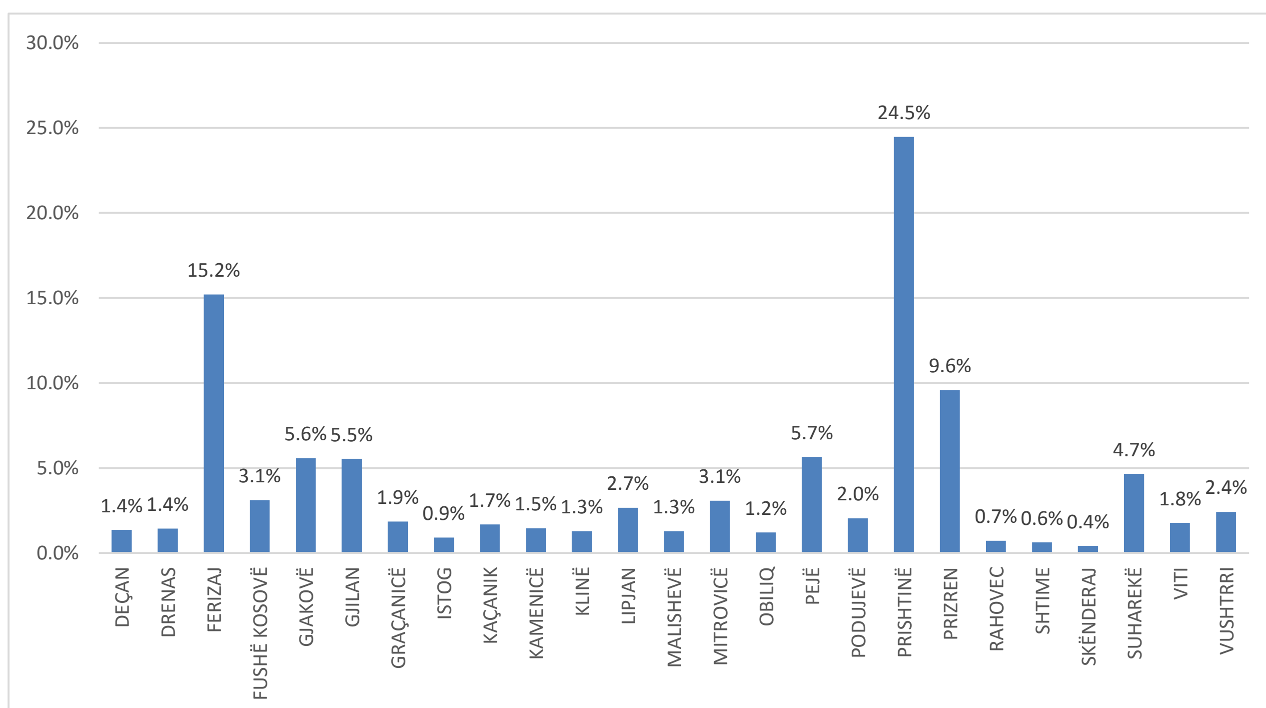
Encouraging more NGOs to become active in this field would take some burden off the Labyrinth staff and help to increase diversification of service offers, different approaches and services as well as transparency. **Creating a network of professionals working in this field across institutions** may help to enhance knowledge and skills and to coordinate services better. In addition, PWUD would have more choice in finding services that truly suit them.

There are several ways in which drug services in other countries have tried to solve the issue of PWID being discriminated and exposed when seen visiting a service facility: some NGOs "keep a low profile" by opening

facilities in remote areas that are not frequented so much by other citizens – sometimes even with entrances through the backyard. Other service providers rely on public advocacy for drug users' rights and needs and information among the neighbourhood. With regard to following a human-rights approach, the latter solution is certainly better to reduce stigma and discrimination against PWID in general and to come to terms with the community in which the site is located. Providing a larger variety of services to PWUD in more locations would make these facilities more attractive to clients and help to reduce the stigma and discrimination of clients.

**Closer cooperation with the local communities** (community centres, services, stakeholders, police etc.) could be very fruitful to create a more enabling environment for clients. Local approaches are "closer" to the actual problem and responses can be tailor-made and flexible. Consequently, local, community based responses are widely recognised as a very effective way of turning strategies into reality. Hence, there should be more MMT centres in more communities – and local authorities should be involved in the development of the program and additional services from the beginning. Regions or cities within the country where high drug use was mentioned in the interviews and group discussions were Ferizaj, Mitrovica, and Peja. But before expanding MMT to other municipalities or regions, data should be evaluated. The recent mapping of PWID in Kosovo provides a good basis for choosing additional municipalities:

*Proportional distribution of PWID by Municipalities in Kosovo, 2016*[20]




[20] National Institute of Public Health of Kosovo, CDF, *Programmatic Mapping and Size Estimations of Key Populations in Kosovo, 2016* - funded by the Global Fund

### 6.1.2 Analysis according to OECD-DAC criteria

#### *6.1.2.1 Relevance: Are we doing the right thing?*

The MMT program is certainly relevant since it **contributes to solving crucial development issues** in Kosovo such as poverty by responding to an increase in injecting drug use. Kosovo faces significant socio-economic and political challenges that may foster a rapid spread of the HIV epidemic if they are not addressed properly.

National laws, strategies and action plans in this sector all **reflect international standards** and Kosovo co-operates and exchanges information with neighbours through informal bilateral and multilateral meetings. Guidelines for the implementation of national laws and Strategies are being developed across sectors and with high-ranking expert input – including civil society organisations. Scientific research is mentioned as an integral part of the Drug Strategy and Action Plan but valid and comprehensive data is still lacking or poorly used at ministry levels, although the number of surveys and studies conducted on the issue has increased over the past years. Hence, it is unclear whether and to what extent a contribution can be made to the achievement of the health sector-policies and strategies and whether drug problems in the country are being addresses adequately.

Given the multitude of issues at stake in this post conflict country, the priority for implementing comprehensive and needs-based HIV/AIDS and drug policies among the government is not very high. The cross-sectoral collaboration in drafting the national response (natl. Anti-drugs committee / working groups) and revision of administrative instructions are highly relevant and the government is aware of the need for a comprehensive and sustainable implementation of drug services, but **ownership, commitment and capacities vary greatly between relevant ministries**. The MoIA along with the National Anti-Drug trafficking Department of the Kosovo Police strongly support a comprehensive approach including prevention, Harm Reduction, treatment and rehabilitation as well as law enforcement, whereas the MoH showed somewhat less commitment for implementation and still seems mostly concerned with drafting and amending relevant national documents.

#### *6.1.2.2. Effectiveness: Are we reaching the objectives?*

The Global Fund grant agreement states the following **4 objectives** with a view to achieving the goal *to maintain HIV prevalence among key populations at the currently low level (below 5%) and prevent HIV from spreading into other groups*:

1. To reduce HIV vulnerability among key populations at higher risk (KPAR) with a special focus on PWID (including in prisons), female sex workers, MSM, and young people
2. To improve the quality of life of PLHIV in Kosovo by promoting a supportive environment
3. To create a supportive environment for a sustainable national response to HIV and AIDS in Kosovo
4. To strengthen the evidence base for a targeted and effective national response to HIV and AIDS

In March 2016, the overall rating of the program by the Global Fund was B2 *"Inadequate but potential demonstrated"*[21].

The 2016 assessment revealed that there has been a **considerable increase of clients** since the last assessment in 2013 – and especially during 2015: Data provided by CDF shows that 193 clients received OST in the period July - December 2015. From the 193 clients that were enrolled in the MMT Program during this period, 123 were ongoing clients (from 123 clients, 5 dropped-out, 15 were lost to follow up, 3 died and 10

[21] http://www.theglobalfund.org/en/portfolio/country/grant/?grant=KOS-711-G04-H

clients were on and off the treatment); 46 were new clients (out of these 46 clients, 4 dropped out, 12 were lost to follow up, and 2 clients were on and off treatment); 24 were repeated clients (1 dropped out, 6 were lost to follow up, 3 clients were on and off the treatment)[22]. In the period December 2012 – May 2013 there were only 75 OST clients in 4 sites. MMT in prison started in September 2013 and currently has 37 clients.

Despite this positive increase, however, the scale of the current **MMT coverage is not sufficient** and there is still a **considerable fluctuation of clients**. There are waiting lists of clients who seek MMT at Labyrinth Pristina and many clients are forced to travel between cities to receive Methadone there. This is especially so for the former clients of the Gjilan MMT site which was closed in December 2015. The proportion of female clients in the MMT program also increased since 2013, but is still comparably low – between 1% and 3%. According to tentative data, 3% to 6% would be closer to reflecting the actual percentage of women injecting drugs in Kosovo. Measures need to be taken to keep clients on the program and to enrol more women. The survey on client satisfaction of 2015 is a good basis for new measures. Such surveys should be conducted regularly and additional services should be offered along with MMT to attract more clients and to keep them in the service system.

An important factor contributing to a delay of achieving the objectives is certainly the **system of licencing for MMT administration**: those licences are issued only to individuals – in that case to doctors, not to nurses, who, in fact are involved daily in the administration of Methadone to the clients. NGOs like Labyrinth in Prizren do still not have a licence, although they have been waiting for it for more than three years. The example of MMT in prison shows that when a license is given to an institution (or hospital department), this makes procedures much easier: the central prison hospital has the licence and can coordinate necessary activities flexibly.

All MMT clients reported that first **access to the program** had been relatively easy and they had been well informed about available MMT services. Most clients learned about the program through friends. Since all experts reported about increasing poly-drug use, MMT should not – and cannot – be the only response to this development. **A broader range of Harm Reduction services**, such as increased outreach, drop-in facilities with opportunities to wash and change clothes, social support, specialised support to women who use drugs, and a case management of clients within a referral mutually coordinated system should be established where drug use is high. **Outreach and support to female drug users** definitely needs to be increased and services for female clients should be established.

**Drop-out rates at MMT sites** seem to have declined since 2013, but according to data provided by CDF and interviews with the professionals they are still relatively high. Some reasons for this (from client interviews) were that clients are imprisoned or moved to other countries (in the region) where they expect better treatment. Both at clinics and NGO sites, the clients complained about a lack of possibilities to see a doctor regularly to discuss dosage issues with them. Since most clients receive take-home dosages, the stabilizing effect that a regular MMT administration and regular consultations with the doctor can have is not as strong as it could be. The rather poor adherence rates are certainly also related to the fact that clients are forced to travel to the MMT centres and that it is often cheaper and less cumbersome to buy Methadone at pharmacies – especially when clients have jobs and no time to travel.

#### *6.1.2.3 Efficiency: Are we cost and time efficient?*

The **division of tasks and responsibilities between cooperating partners** (Global Fund, CDF, MoH, clinics, and Labyrinth) is determined by the grant documents and efforts have been undertaken in the past to further harmonize activities to achieve maximum efficiency. Since the Global Fund demands increasing

[22] information collected by CDF from the different MMT centres

government contribution to health and disease programs, the MoH plays a crucial role in making the MMT program achievements sustainable. The assessment revealed a **lack of leadership at the MoH**, however, where the focus lies still largely on setting standards and guidelines rather than coordinating and steering their implementation. There is an obvious **need for more programmatic capacity**, including adequate data and information collection and using this information for concrete programmatic action. Regarding time efficiency, it must be said that these weaknesses at the central policy making level cause unnecessary delays in qualitative and coordinated service provision for PWID.

Access to the MMT programme is relatively easy and **supply shortages** that were an issue in 2013 have been solved; numbers of clients have increased especially during the last year. Regarding **modes of delivery**, the way in which Methadone is administered is far from efficient (see section 6.1). In addition, closing the MMT site in Gjilan Regional Hospital has caused unnecessary problems and risks for its 13 MMT clients who now either have to travel to Pristina or to Prizren.

With a view to **cost-efficiency**, the MMT Program may have improved on the supply side (procurement) since the last assessment in 2013, but currently there are considerable quantities of Methadone in stock which are about to expire by mid-2016, and it is yet unclear whether sufficient supply will be available in time when the expiry date is reached. PSM issues are discussed in further detail in chapter 7 of this report.

Since the administration of MMT forces many clients to travel between cities to obtain their dosage or to pay for prescriptions and Methadone, **the benefactors of the program bare a huge burden regarding cost and time**. According to clients interviewed during the assessment mission, this fact also bears high risks of clients dropping out of the MMT programme and returning to risky consumption patterns. In any case, the important effect of stabilising PWID through MMT is endangered by this situation (see also section 6.3).

##### *6.1.2.4 Impact: Do we contribute to higher benefits?*

The program does make some **contribution to the health sector** in the country, but in order to contribute to achieving the Sustainable Development Goals, a lot more action needs to be taken. There is good potential to make positive contributions to cross-cutting issues and overarching policies, such as human rights, rule of law, and different dimensions of poverty alleviation – including improving the living conditions of the target groups - but these issues should be tackled within the overall health reform in the country.

Necessary **budget allocations** for a more comprehensive drug service enhancement need to be made if a true impact is to be made for the benefit of PWUD in Kosovo. It should be borne in mind that in order to improve the living conditions of PWID, MMT can only be one contribution and that a broader range of services to PWUD should be developed (or scaled-up) around it. This includes a range of coordinated services from low-threshold Harm Reduction services to long-term rehabilitation to support client's stabilization, psychosocial wellbeing, livelihoods, and reintegration into their families.

The MMT program has good potential to meet **local and national dynamics**, but more communities should be included in a **scaling up and decentralization** of the program. There is potential to contribute to more social justice, equal opportunities and equal access/equity, if MMT is embedded in a wider Harm Reduction approach (social dimension of sustainability) and in needs-based integrated local approaches. The benefits of this approach for communities could be advocated prominently on the local level and among local stakeholders.

According to the MoH, measures to scale up and diversify services to PWUD are foreseen, but processes to come from strategy to action take a long time and ownership for a comprehensive, human rights and needs based drug policy is still low among some of the crucial stakeholders. What seems to be lacking also, is a **wider coordinated concept combined with the necessary programming activities** that comprises a variety of services across the country and strategies for a comprehensive and coordinated response across all relevant actors in this field.

##### *6.1.2.5 Sustainability: Will the changes last?*

Methadone maintenance treatment is not only an internationally accepted instrument to stabilize PWID, enable their contact with further medical and social care, and to prevent blood-borne diseases, such as HIV. It is also an important measure to reach out to and support the increasing number of socially deprived heroin users in Kosovo. To what extent the responsible policy makers actually will support the approach sustainably, is hard to predict. As mentioned before, ownership and political will as well as capacity for **programming and sustainable steering are still weak in this field**.

Many elements of a **comprehensive package of services for PWID** are already in place in Kosovo and the MMT program has good potential to not only stem HIV and HCV among PWID, but also to contribute to more social justice, equal opportunities and equal access/equity, if it is developed further, scaled up, decentralized, and embedded in a wider national approach (social dimension of sustainability).

## 6.2 Capacity Needs Assessment

As stated in the Inception Report, a capacity needs assessment was conducted during the assessment mission in April, albeit only indirectly, because of the limited time allocated for the meetings. However, some recommendations are given in this report.

During the interviews and FGD, it was interesting to note that a **lack of in-depth knowledge as well as misconceptions** about the needs and rights of PWUD and the benefits and limits of different approaches prevail on all levels. Though reference to international guidelines and standards was often made in conversations, these are often not fully understood or misinterpreted. It has become obvious that more capacity and knowledge – especially about **how such guidelines have been put into good practice** in other countries - is needed here.

**Capacity needs at NGO level:**

- State of the art Harm Reduction service provision (including international quality standards and good quality examples from other countries)
- Quality standards and good practice examples in social work for PWUD and their families
- Developing services for women who use drugs (including outreach)
- Advocacy and lobbying for human rights of PWUD
- Cooperation and referral between medical and psychosocial services for PWUD

**Capacity needs at medical level:**

- Communicating with PWID (human rights based approach)
- Creating an enabling and user-friendly atmosphere
- International quality standards in MMT and other medical services for PWID (incl. dosage, take-home and control issues)
- Cooperation and referral between medical and psycho-social services for PWUD
- Knowledge about different state-of-the-art responses to drug related problems (Harm Reduction, long-term therapy, 12 step approach, detox, etc.)

**Capacity needs at MoH:**

- Programming, steering and coordinating policies across different actors ("putting policy in practice and managing cooperation")
- Data collection and processing, data evaluation and translating data into policies (incl. cost-effectiveness of different approaches/services, needs assessments, and feasibility studies)

- Monitoring quality of services for PWUD (incl. OST) based on international standards
- Knowledge about different state-of-the-art responses to drug related problems (Harm Reduction, long-term therapy, 12 step approach, detox, etc.)
- Involving civil society in responses to drug related problems and services for PWUD
- State of the art primary prevention methods (for different age groups)

**Capacity needs of the police (high-ranking and street level):**

- Community policing (cooperation with services for PWUD, local authorities, neighbourhoods, etc.)
- Human rights of PWUD and implications for police behaviour towards PWUD
- The role of the police in a Harm Reduction approach (discretion, support of services, etc.)
- State of the art primary prevention methods (for different age groups)

## 6.3 Conclusions and Recommendations

### 6.3.1 Conclusions

***"The MMT Dilemma"*: Bring MMT to the clients – stop forcing clients to go to the MMT**

The **benefits of MMT** are that clients reduce the consumption of impure street drugs and injecting (which reduces not only the risk of an HIV and/or HCV infection, but also of abscesses and other health risks). Drug consumption in unsafe places is reduced. This also reduces the risk of DRD and other severe health risks.

And, clients should receive Methadone for free and on a regular maintenance dosage that allows them to **stabilise gradually**. All OST guidelines recommend that stabilisation (and little to no by-consumption) of clients should be achieved before take-home is given. This is not the case in Kosovo, where take-home is given frequently even to new clients and over period of up to one week and urine controls are the exception. Since de facto only 4 MMT sites exist in the country so far (2 in Pristina, 1 in Gjakova, 1 in prison), MMT clients are forced to travel a lot and spend a considerably amount of money to obtain their dosage: some clients estimated about 30,- € per month; other interview partners estimate even costs up to 50,- €/month. In Prizren, clients have to pay for the prescription as well as for the Methadone which they have to buy in pharmacies (about 7,- € per 10ml). Though all MMT clients receive an official "certificate" for their take-home Methadone, they are still at high risk of stigma, harassment and theft. As a matter of fact, the officially free MMT is not cost-free at all and the way it is administered makes it almost impossible for new MMT clients to stabilize or to work on a regular basis. It is obvious that **this dilemma also has a strong influence on the MMT adherence rates**.

**Take-home doses are a pragmatic compromise** while MMT is not scaled up and decentralised, and sites are not open all year round. But according to all sources, many clients find it hard to ration the take-home Methadone over the period it is provided for and often use up and/or inject large quantities of the take-home doses – which induces a high risk of overdose. If take-home doses are not sufficient, clients will buy methadone in pharmacies illegally to "substitute legal methadone with illegal methadone". In any case, **risky consumption patterns prevail that may defeat the purpose of OST as a stabilising and risk-reducing measure.**

All clients and NGO staff interviewed during this mission reported that this procedure is not at all effective and needs to be changed urgently. Doctors at the MMT site in Gjakova regional hospital strongly opted for **dispensing Methadone every day all year round** and give **take-home only to stabilized clients** after consultation with their doctor - which is in accordance with international standard and practice in most countries today. All interview partners agreed that more MMT sites need to be established across Kosovo, especially in places where many PWID live (see also section 6.1).

Both in the public hospitals and at MoH, the **security issue around MMT** was mentioned frequently. Doctors and nurses have experienced problems with clients and at the MoH these fears lead to an obvious reluctance to invest more in MMT and other services for PWUD. In order to overcome the latent fear of security issues attached to MMT and to improve the control of by-consumption and documentation, the MeDoSys® dispensing and documentation system was briefly discussed with the Health Minister. This method works with dispensing machines which allow for Methadone to be administered safely, accurately, and fully documented through an automatic IT-based system for dosing, dispensing, monitoring, and documenting. The system also requires less medical staff. Apart from Germany and other EU countries, the system has been introduced in Bosnia and in countries outside Europe – e.g. in Nepal, India, Malaysia, and Tajikistan.

PWUD – especially women using drugs - still face high **stigma and discrimination among the population**. Media reports about drug-related issues are mostly negative and only recently one TV station openly attempted to discredit the MMT program. To date there are no advocacy measures taken – either by the government or by civil society organisations to **reduce the prevailing negative attitude towards PWUD**. Poor ownership among the responsible government bodies for the country's approach to drugs certainly plays a role here. In the future, there should be a **clear commitment among all relevant stakeholders** for a comprehensive health-oriented and human-rights-based approach towards PWUD that is pro-actively communicated to the public and media.

**Status update on the recommendations derived from the 2013 MMT assessment:**

| **Recommendation 2013** | **Status update 2016** |
| --- | --- |
| **1. Research and data collection:**<br><br>epidemiological research related to drugs in the general population and its specific groups;<br><br>the development of an information system on drugs and all drug-related data, from the continued research of respective institutions/agencies/actors;<br><br>the evaluation of the effectiveness of preventive and treatment programs and measures at the national level,<br><br>the distribution of research results and information concerning drugs. | The Bio & BSS 2014 and the Mapping PSE 2016 provide valuable data to work with; The Police collects data on a more regular basis and MMT sites report regularly.<br><br>The ownership of the MoH to work with the provide data is still not high and research data does not seem to be translated into programmatic action. |
| **2. Methadone Maintenance Treatment:**<br><br>Regional scale-up: more communities – based on assessment of IDU (heroin) prevalence<br><br>Enhance outreach and services to address the needs of female IDUs<br><br>Install firm regulations for cooperation between medical and social services<br><br>Allow for more NGOs to supply methadone directly in the facility (esp. Prizren)<br><br>Conduct regular assessments of client satisfaction to enhance adherence to MMT | No scale-up so far in communities. MMT is available in prisons now, but Gjilan MMT was closed in December 2015, leaving only 4 community sites instead of 5 as before. Labyrinth Prizren is still not allowed to administer MMT at the facility.<br><br>Although obviously some more women have joined the MMT program, they are still underrepresented and there is still no specialised outreach for women who use drugs<br><br>A client satisfaction survey has been conducted in February 2015. |

| **3. IDU services:**<br>Encourage the forming of more NGOs providing IDU services<br>Scale-up (broaden) harm reduction services (DIC, outreach, NSEP, food, shower, social support) through NGOs.<br>Install a referral system from outreach up to long-term abstinence therapy involving all relevant stakeholders<br>Scale-up sensitisation of (community) police on HR and IDU<br>Install standards for staff behaviour towards clients (rights based, welcoming, trustworthy and supportive) | To date there is still only one NGO providing services to PWID. Their scale of services is still limited due to budget and space constraints.<br>A referral system – or rather a system of cooperation and information exchange – exists between Labyrinth and hospitals as well as with the police.<br>Police at national level seem to be supportive of the harm reduction approach and there is anecdotal information that the cooperation with local police officers is good – at least in Prizren. Labyrinth conducts sensitization sessions with police.<br>There is no systematized reporting of rights violations against PWID. The client satisfaction survey of 2015 revealed high levels of contentment with the services provided.<br>The attitude of medical staff towards clients seems to have improved, but it is very hard to judge how this translates into client-friendly behaviour. |
|---|---|
| **4. Policy level:**<br>Apply a rights-based approach towards drug users<br>Base policy decisions on facts (data) and needs<br>Support a more professional surveillance of the drug problem (data collection and processing, translating data into policies)<br>Diversify forms of services (approaches and methods = *„comprehensive services"*) for IDUs (from low-threshold to abstinence and reintegration) to achieve better access, coverage and adherence of clients<br>Support the diversification of service providers (different NGOs and public services, different professions)<br>Install regular and institutionalised multi-disciplinary and multi-stakeholder coordination to achieve an integrated and diversified response to the drug issue (e.g. *four-pillar policy*) | The rights-based approach is officially followed, but not advocated pro-actively (see also section 6.3)<br>Data collection improves, but not sufficiently translated into action and insufficiently used to coordinate the implementation of an adequate response across relevant institutions.<br>No diversification of services and service providers so far.<br>Several multi-disciplinary teams are working on the issue, but there is not much commitment to their recommendations from the MoH. To date, still very few stakeholders are involved in tackling the issue. |

### 6.3.2 Recommendations

The Kosovar government – especially the MoH – should **act now to sustain achievements of the MMT program** so far. The Global Fund-financed extension request should be accompanied by concrete plans

and budgets for keeping up and sustaining MMT. Government-lead measures should be coordinated, financed, monitoried and steered in a cross-sectoral approach that includes civil society organisations as active and eaqual partners in the approach. The Global Fund-funded program should **invest in capacity development measures on all levels** to ensure sustainability of the MMT program within a wider rights and needs based national reponse to drug problems that meets state-of-the-art quality standards.

**Female outreach workers and peer educators** should be involved and trained to bring information and services to women who use drugs. **Support networks** should be established and services should be brought to women who use drugs and are reluctant to seek services (see also section 3.4).

Based on the status update in section 6.3, **several issues from the MMT assessment conducted in 2013 are still pending**. A number of recommendations have already been included in the previous sections and explained in more detail. Further capacity building could be achieved through study visits, specialised trainings, advocacy and sensitization, and professional networking.

During a discussion with Dr Edona Deva following the debriefing session, it was decided to split the following recommendations as bullet points for the Global Fund-funded program and the Kosovar government. The recommendations to the government are discussed in more detail in section 6.3.3:

| Global Fund-financed program | Government |
|---|---|
| Support trainings for medical staff (doctors and nurses) on state-of-the-art OST administration | Install a drug/MMT focal point at MoH (with the necessary mandate and budget to coordinate the implementation of measures across relevant institutions, monitor and analyse data, assess needs of PWUD and other target groups, monitor performance and quality of response measures, allocate necessary financial support to implementation partners) |
| Conduct a rapid needs assessment and feasibility study for the expansion of services for PWID (incl. MMT) | Change licensing procedures from individual licenses for doctors to institutional departments, organisations, for more doctors and nurses / allow for more MMT sites at NGO facilities |
| Support advocacy/sensitisation of the public and media – about human rights aspects around drug use & national approach to drug policy (testimonials, success stories, etc.) | Amend national strategy including concrete action plan for implementation and definition of roles and responsibilities among relevant actors to prepare for transition and sustainability - until mid-2016 (before/with extension request to the Global Fund ) |
| Support trainings on state-of-the-art drug abuse prevention activities – adapt to current standards | Scale-up and decentralise MMT sites in more communities – based on assessment and feasibility study |
| Conduct regular and assessments of MMT client satisfaction to enhance adherence to MMT | Install closer cooperation between medical and social services to stabilize clients |
| Support trainings about standards for behaviour towards PWUD (rights based, welcoming, trustworthy and supportive) – for NGOs, medical staff, police, judiciary system, etc. | Scale-up harm reduction services (DIC, outreach, NSEP, food, shower, social support) through NGOs and Diversify therapeutic offers for PWUD (MMT, Harm Reduction, long-term, rehabilitation etc.) |
| Support study tours to good practice examples in OST and services for PWUD | Scale up MMT and social support for IDUs in penitentiary system (before, during, after) |

### 6.3.3 Recommended Priorities for the Kosovar government

- Amend the national strategy including a concrete action plan, budgeting, and time-line for implementation and definition of roles and responsibilities among relevant actors to prepare for transition and sustainability - until mid-2016 (before/with extension request to the Global Fund)
- Revise and amend comprehensive national administrative instructions and treatment protocols based on international quality standards and practices – until mid-2016 (before/with extension request to the Global Fund); conduct regular monitoring activities to ensure that these guidelines and protocols are actually implemented in the MMT centres
- Issue licences for MMT to institutions (hospitals, NGOs) instead of individuals within 2016 – as basis for scaling up and decentralisation of MMT
- Install a capable national drug policy/MMT coordinator - with the necessary mandate and budget to coordinate the implementation of measures across relevant institutions, monitor and analyse data, assess needs of PWUD, monitor performance and quality of response measures, allocate necessary financial support to implementation partners incl. civil society organisations
- Diversify and scale up MMT sites (NGO sites, public hospitals, penitentiary system) based on a needs assessment and feasibility study and link MMT to broader social support of clients
- Clearly define cooperation, coordination, roles, responsibilities, and referral across professions, line ministries, NGOs, private institutions, and other relevant actors *(who, what, how, when)*
- Integrate NGOs and private organisations as integral partners in implementing the national strategy and action plan *(sustainable funding of defined services)*

Without a harmonised, coordinated and diversified response, there is a high risk that PWUD will be left out of the system, developing even harsher health and social problems than they already have. However, since a comprehensive national response it still in its early stages of development and implementation, there is still a “window of opportunity” to come up with a truly comprehensive approach that stems the risk of HIV reaching key populations and meets the needs of PWUD and the wider society respectively. But this window is closing, if policy does not reflect reality and if the government continues to treat this issue as a low priority.

# 7. Methadone Procurement and Supply Management (PSM) Assessment

This section focuses specifically on the procurement and supply management (PSM) of methadone in the context of the (developing) MMT Program. The PSM assessment of April 2016 leads to the conclusion that maintaining an uninterrupted supply of methadone for the MMT program in Kosovo should be smooth sailing. The number of sites is limited, the sites are easily accessible in a country that is small, a methadone product is registered on the market, and there is solid information on consumption. If problems have arisen in the past with Global Fund-funded procurement, it is mainly due, it seems, to lack of ownership and/or coordination, inexperience dealing with the International Narcotics Control Board (INCB) in Vienna, and failure to use available information for procurement and management decisions.

Looking towards the future, it should be possible to ensure a continuous and regular supply - especially if the current procurement and supply chain remains an integrated one as it is currently (see discussion under section 7.5 – Procurement). Specific steps at the different stages of the PSM cycle can further facilitate a continuous targeted supply of methadone in this context.

## 7.1 Regulatory Framework

As has been mentioned, the regulatory constellation and the respective or prospective roles of MMT stake-holders in Kosovo are currently in flux. This also affects some of the legal and regulatory texts that focus specifically on methadone itself, as a medicine:

1. The 2007 Law on Psychotropic Substances 02/L-128: Methadone is one of the substances covered under this law. The law is currently under revision, but according to a representative of the Kosovo Medical Agency (KMA), the changes are mostly focused on adding new products under the purview of this law. It will not affect the MMT program.
2. Methadone is listed in the Essential Medicines List. A search of the MOH website did not yield results, but the information was provided by the KMA representative and should be accurate.
3. There may or may not be the equivalent of a Standard Treatment Guideline (STG) on methadone. The responses varied depending on the interlocutor: the KMA representative and Labyrinth director were quite sure there was a STG; the Gjakova MMT doctor stated there was no STG. Interlocutors may have confused the concept of STG with the abovementioned Protocol No. 05-1609.
4. Administrative Instruction 1/2015: As per the account of the KMA representative, this text establishes that any narcotic, including methadone, can only be imported in Kosovo if (1) it is covered by a valid KMA marketing authorization and (2) it is imported by an economic operator specifically licensed by KMA to import, store, and distribute narcotics. This A.I. has a profound impact on product selection for the MMT program going forward. This is addressed more in detail further in the report.

## 7.2 Selection

Since the introduction of A.I. 1/2015, an economic operator licensed to handle narcotics can only bring in methadone that is registered on the market in Kosovo. There are currently 2 products registered: one in syrup form and one in tablet form. The syrup form is commonly preferred by MMT program implementers - and drug addicts. The syrup product registered on the Kosovo market is manufactured by the company Alkaloid, in Skopje, Macedonia.

The only viable alternative to bring in methadone is as a donation to the MOH, but it can then only be processed by a licensed economic operator contracted by the MOH (i.e. not by the PR). It is in the interest of the MOH to encourage other manufacturers to register their methadone product in the market, in order to promote competition and cost-effectiveness. Given that several bids have been received from EU-based manufacturers in past tenders, there appears to be interest, especially if the registration process is made easy for products that are already covered by internationally recognized stringent regulatory authorities (SRAs).

***Recommendation:***
The MOH should encourage manufacturers to register their product in Kosovo, either through direct contact with them or through Kosovar suppliers in the market.

## 7.3 Quantification

Unfounded quantification at the moment of procurement has been a contributing factor to the loss to expiry that occurred in 2014 and that is bound to occur again in June 2016 (preparations are ongoing to send excess supply to Albania where stock-out looms). While there is an argument to be made for target-based quantification at the moment of budget planning, it is essential, at the moment of actual procurement, to correct the target-based quantification against actual and realistically projected patient numbers, average dosing per patient, as well as what is in stock. This is especially important when target-based quantification during budget planning uses ambitious targets and dosage per patient, significantly beyond actual consumption. Note: It goes without saying that good quality data should be available, for best results. (See also section 7.4 – LMIS).

Looking towards the future, and assuming the MOH takes over procurement for the MMT Program, it would be logical that the final responsibility for accurate quantification lay with the MOH Pharmaceutical Services Dept. and the PSM Coordinator in particular.

***Recommendations:***
1. It is recommended that the revised version of A.I. 10/2010 clearly define which entity has the final responsibility for quantification. The PSM coordinator in the MOH Pharmaceutical Dept. would be a logical choice assuming continuation of a single procurement process for all sites.
2. At the moment of procurement, target-based quantification should be corrected against actual (and realistically projected) patient numbers and average dosage per patient, as well as available stock and remaining shelf life.

## 7.4 LMIS

To date, the MMT Program has a basic LMIS system in place, based on paper and computer-based records[23]. Each MMT site maintains a file for each registered patient. Further, consumption is captured by the dispensing nurse/doctor, at the moment of dispensing, in a simple, logical form (document). Based on the site visits undertaken, responsible staff diligently records the instances of dispensing and the dosages dispensed per patient. All these data combined, reported monthly, produce a reliable set of data on actual consumption in the MMT program in its entirety – covering the hospital sites, as well as the Labyrinth and prison sites. The monthly reports also include data on the patient/client base of each site (e.g. who is a regular client vs. new client vs. returnee; the designations are based on the consumption pattern). In addition to the monthly reports, the MMT sites also produce a summary report on stock movement on a quarterly basis.

While consumption is diligently recorded and reporting, record keeping and reporting of remaining stock appears to be less diligent at some sites, and could therefore be a potential source of error. Based on the site visits and responses received, it cannot be comfortably concluded that staff systematically undertakes physical stock verification - at the central pharmacy and at the dispensing site - before sending off the monthly or quarterly reports. It is not excluded that staff at times simply deducts "consumption" mathematically from the previously reported (non-verified) end balance, to yield a new available stock number. The risk of significant discrepancies developing is however minor, given the limited stock quantities involved at MMT sites. Regular visits by the M&E officer, reported by all sites and the MOH warehouse staff, is also an effective means of preventing build-up of discrepancies between the mathematically calculated end balances and actual remaining stock[24].

Looking toward the future, the current integrated LMIS system can be considered functional; it provides all the necessary information for procurement and supply chain management decisions. The MMT program could switch to a "live" reporting and database system at some point in time, but there is no urgency: given the limited scope, it is not difficult to keep track using the current document and computer-based system.

What will be important is that the stakeholders determine and consolidate, in the revised version of the A.I. , the measures required, if any, to maintain the current integrated LMIS system, after the MOH takes over PSM responsibility.

***Recommendations:***

1. It is recommended to continue the current system of recording consumption and stock at the MMT dispensing sites. The reliability of the LMIS data could be further strengthened by reminding or in-

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[23] Due to time constraints and the way the visit was conceived, it was not possible to do the usual in-depth analysis and verification/validation of the LMIS system. The findings below are based on sample verification exercises.

[24] Note: No M&E visits have been done since the M&E officer went on maternity leave at the beginning of the year. Another MOH M&E officer collects and consolidates the data for the MOH but does not undertake any visits.

structing relevant staff members to complement the mathematical exercise (prior end balance – recorded consumption = new end balance) with an actual physical stock verification before sending the report, at the end of every month.

2. The database, which currently integrates data from the hospital, NGO, and prison sites, should continue to be maintained as an integrated system. The stakeholders should identify and determine (i) who has the ultimate responsibility for continuing to gather, consolidate, and validate the data in the database (e.g., M&E officer and/or the MMT focal point) as well as (ii) any supporting measures as needed.
3. The data should actually be used for procurement and management decisions, and for feedback to the sites (e.g., MMT focal point and PSM coordinator).

## 7.5 Procurement

To date, CDF has been responsible for procurement for the MMT program. The 2014 procurement of methadone suffered from complications, partly related to the fact that the methadone was imported from abroad which required interaction with INCB. MMT sites visited consistently reported that they experienced low stock or stock-out for a few months in the summer of 2014, while there was also loss to expiry at the same time. Loss to expiry looms again by the end of June 2016. As per the March 2016 stock-out/oversupply risk analysis (SORA), approximately 1,000 bottles of methadone will likely remain unused by the Kosovo MMT Program. Efforts are underway to move the excess supply to Albania, which is coping with stock-out risk.

At the time of the PSM visit, a new Global Fund-funded procurement was underway. The bid opening took place on April 15, 2016. The tender instructions had been somewhat contradictory and, likely as a result, the tender yielded 2 different/opposite bids: One bid corresponded to the stipulations in line with the A.I. 1/2015, but not to the tender stipulation that the product be SRA approved. The second bid yielded an SRA approved product but one that is not registered in Kosovo. The Global Fund only imposes specific quality assurance requirements for a select number of key products. For all other products, including methadone, the Global Fund position is that procurement should follow national requirements. By selecting the first bid the PR will be in compliance with national stipulations.

1. It is anticipated that if the PR procures in line with A.I 1//2015, the lead time for getting methadone into the supply chain will be minimized, given that it will not require extraordinary interactions with KMA, ICB, and custom clearance. By procuring in accordance to the law, it can be reasonably expected that fresh supplies will be in the supply chain by the time the current supply runs out.
2. Looking towards the future, and assuming the MOH takes over procurement for all MMT sites, the responsibility for preparing the required quantities and technical specifications would fall to the MOH/Pharmaceutical Dept. This information would then be passed on to the MOH/ Procurement Dept. for the organization of the actual tender. The MOH/Procurement Dept. advertises all its procurements on the MOH website – in Albanian, Serbian, and English - exclusively. Any party can apply and will be considered eligible if meeting the requirements. The MOH can be expected to only procure locally registered products.

   Note: It would be remiss not to signal that there is a (small) chance of complication after Global Fund funding ends, as a result of the fact that the MOH is no longer fully responsible for the management of

the secondary and tertiary health care facilities (where most MMT sites are located). The prison system too has its own procurement and supply system, whereby the MOH/Procurement Dept. is used as the procurement *agent* only. What should best remain as one single procurement and supply chain could thus possibly be splintered into three parts. If the supply chain were to splinter, it would make the coordination role and monitoring responsibility of the MMT focal point more demanding and even more important, and it would also likely complicate the quantification and supply management coordination role of the PSM coordinator.

At this point in time, we consider the chance of this complication occurring limited. The MOH/Pharmaceutical Dept. stated explicitly in response to a written question on April 19, 2016 that the plan is to maintain one single supply chain, whereby the MOH will do the procurement for <u>all</u> sites. (A precedent exists in the procurement of ARVs and vaccines). The same message was given to the Global Fund during the Country Team visit in the week after the PSM visit. While it remains to be monitored that this is indeed formally agreed upon by all parties and consolidated in the revised Administrative Instruction, the working assumption for now is therefore that the procurement and supply chain will not splinter. In our opinion, this would be the most straightforward and preferable scenario.

***Recommendations:***

1. As was already verbally communicated to the PR during the visit, it is strongly recommended that the PR contract in line with national regulations and according to A.I 1/2015 and arrange for delivery with the selected supplier in 2 tranches at appropriate intervals, whereby the product carries at least 18 months of remaining shelf life *upon the moment of delivery.* Some methadone products have a shelf life of close to 3 years, in that case a minimum of 2 -2.5 years remaining shelf life upon delivery can be required.
2. The first delivery should take place by mid-June ideally, by end June 2016 at the latest (current stock will last until end July 2016).
3. Regarding future procurements, the MOH should, at the time of each new procurement, review the target-based quantification and adjust final procurement quantities in function of up-to-date program information regarding consumption, patient load, and available stock. This analysis will also enable the MOH to time the different tranches in the delivery schedule. It is further recommended to explore procurement of methadone in bigger size bottles (e.g. 0.5 or 1 liter bottles) for cost-effectiveness considerations and procurement of simple alternatives for making dispensing more efficient (e.g. containers with a pump system).

## 7.6. Storage

Methadone should not be easily accessible to drug addicts or other interested parties, for obvious reasons, including security of the staff. While safes were found in every site, they were not always used as intended.

<u>MOH Warehouse</u>

The security situation was worst in the MOH warehouse, were the safes were again found standing empty, original wrapping still around the handles, while the available stock is kept in the original boxes (stored on pallets). The glass door to the room where the methadone is stored was found unlocked. The safes are

likely not large enough to hold the whole stock when a fresh delivery arrives, but this should not prevent storing however many bottles can be stored in the safes. And as long as not all methadone fits in the safes, the door should be locked at all time at a minimum.

A new management company has been hired to manage the warehouse for the MOH (since the beginning of the year). It could not produce any delivery documents from prior to their arrival; it did not know what happened with the expired methadone (no longer in the storage room); and it had not updated the methadone stock cards yet. On the positive side, the available stock was organized in function of available shelf life: products with June 2016 expiry were clearly separated from products with Oct. 2016 expiry. Based on the visit to the MOH and other sites, it was possible to conclude definitively that the current issues with loss to expiry were not the result of, or exacerbated by, lack of adherence to the FEFO principle.

Situation in Other MMT Sites Visited

| | | |
|---|---|---|
| Pristina UCCK Pharmacy | There is a safe is in the dispensing area but not in the central pharmacy (methadone is however behind 3 locked doors there; only pharmacist has key). | Excellent stock card keeping in central pharmacy; stock card and actual stock were aligned. |
| Gjakova MMT site | Both safes were placed in the central pharmacy, one of which was unused (problems with lock?). There was no safe in the dispensing area, where methadone was kept in a cupboard behind locked door. | Good stock card keeping in central pharmacy; stock card and actual stock were aligned. The cupboard in the dispensing area included one bottle of expired methadone (forgotten) and one bottle of locally available methadone, which had been confiscated from a client. The nurse was keeping all empty (used) bottles, unsure whether she was allowed to discard them or not. |
| Labyrinth Pristina MMT site | There was a safe in the dispensing area (different from the safes in the other MMT sites; possibly easier to break open). | The stock card was not logically organized |

In conclusion, there is room for improvement in the use of the available safes in the different sites.

***Recommendations:***

1. The safes in the MOH warehouse should be used as intended, to the extent possible. Under no circumstances should methadone be kept in an unlocked room, unless all methadone is safely stored in the safe.
2. In MMT sites, all methadone should ideally be locked in a proper safe at both the dispensing point and in central pharmacy.

3. It is recommended to use M&E visits to gather any questions MMT staff may have (e.g. regarding what to do with confiscated or forgotten expired products or empty bottles) and provide feedback and information as needed.

## 7.7 Distribution

The distribution of methadone is not problematic currently, and it is also not expected to become so in the future. Distribution is organized as a pull system, whereby sites send in a request for replenishment to the MOH, when stock is low. Sites tend to work on a 3-monthly cycle, but will order earlier if needed. Staff in all sites reported they make sure to order well in advance to avoid risk of stock-out. None had encountered instances of unexplained or excessive delay in delivery. No stock-out was encountered in any of the sites since summer 2014.

Actual delivery is done by a “distribution committee”, currently consisting of 4 members, of CDF and the MOH respectively. All four assigned people need to be present for distribution to take place. Sometimes, delay of a few days can occur if one of the members cannot join. There is currently no provision for alternate members, which would ease the constraints or burden of distribution.

***Recommendation:***
It is recommended that the MOH appoint, in addition to the official members of the distribution committee, an equal number of alternate members, in order to ease constraints that may exist for the organization of distribution rounds.

## 7.8 Rational Use of Methadone

It could not be established conclusively if an actual standard treatment guideline (STG) exists beyond the limited guidance given in the Protocol No. 05-1609. Responses varied depending on the interlocutors.

Regardless, a clear pattern could be identified in the actual practice of methadone maintenance in Kosovo: all interlocutors in the different sites – doctors as well as dispensing nurses as well as Labyrinth staff – repeated that the starting dose for any client is no more than 40 to 60mg for the first 2-3 days[25], which then needs to be adjusted upwards according to individual need. Everybody also quoted 120 mg as the maximum dose. Further, based on sample review of patient dispensing records, dosing over the months tended to be stable, e.g. at 60, 80, and 120 mg. There was no sign of using the MMT program as a detox program, as is the case in some other Eastern European/Central Asian countries. Most of this is in line with international best practices, as propagated among others by the UN Office on Drugs and Crime (UNODC).

[25] Note: This is higher than recommended in the 2012 UNODC MMT toolkit, which recommends no higher than 15-30mg the first days. The tool kit was focused on South Asian countries, where methadone may not be so freely available and tolerance may thus be lower.

It is recommended that the best practices be comprehensively codified as such in an official standard treatment guideline.

On the other hand, and as described in Chapter 6, there is a widespread practice of allowing patients to take home not only week-end doses but also doses for a whole week (or two). This was explained as a necessary evil, given the limited number of sites (now 4) and the time and expenses required to travel to the sites. Nobody seems to harbour any illusions that many of the intravenous drug users may not have the self-discipline not to abuse their take-home doses. Stories abounded in all sites of clients injecting their week-end dose and then going to the pharmacy, sometimes just outside the hospital premises, for supplementation.

Further, there was widespread reporting of doctors easily being “persuaded” to write a prescription for methadone (every doctor can; no special license required), and the product has also been shown to be easily obtainable in pharmacies, even without prescription. In principle, the MOH/Health inspectorate is responsible for monitoring doctor prescribing and dispensing practices. It does not seem to be done often or rigorously.

From a PSM perspective, the easy access to methadone outside the MMT program makes it an uphill battle for MMT sites to stabilize their clients and keep them stabilized, given that the existing environment makes it so easy to relapse. It also makes the MOH more vulnerable to accusations of creating or contributing to a problem of methadone addition in the country, as was attempted in the week of the PSM visit. The most broad-based and effective means to improve rational use of methadone have already been discussed in Chapter 6 – i.e. increasing number of MMT sites and reducing the need for take home doses. In addition, two PSM-specific measures that focus on prescription and dispensing practices can further increase impact:

***PSM-specific recommendations in addition to the general rational use related recommendations in Chapter 6:***

1. A standard treatment guideline or treatment protocol with comprehensive and detailed guidance on dosage and dispensing rates should be developed, in line with international best practices.
2. Improve rational use of methadone by reining in easy access to methadone from pharmacies, without or with prescription also easily obtained

## 7.9 Final Considerations

Based on the visits and meetings, it can be concluded that there is no systemic reason why PSM should be or become (more) problematic for the MMT Program after the MOH “take-over” - *provided* the currently existing single procurement and supply chain is maintained, in line with the MOH assurances given.

The key elements are in place: MMT sites are easily accessible in a country that is small, there is a registered product in the market and more can be added, and there is solid information on consumption. Further, the main PSM change that could be envisaged after a halt is called to Global Fund funding of methadone procurement - namely a guaranteed switch to procurement of locally registered product only - is already coming to pass under the current procurement.

That said, a number of strategic and tactical PSM improvements can be introduced to promote the MMT Program’s future viability and expandability. Among all the recommended steps that can be undertaken, the key PSM-specific recommendations with highest potential impact relate to keeping the supply chain

integrated, using LMIS information to improve quantification and procurement, and improving rational use of the methadone through improving compliance with prescription and dispensing regulations:

1. Keep procurement and supply chain management integrated as it is now.
2. Actually use the available LMIS information for effective procurement and supply management decisions. In particular, at the moment of procurement, correct target-based quantification against actual (and realistically projected) patient numbers and average dosage per patient, as well as available stock and remaining shelf life. The information can also be used to time the different tranches of the delivery schedule, whereby products should carry a minimum shelf life of 18 months at the time of delivery.
3. Improve rational use of methadone through improving compliance with prescription and dispensing regulations – i.e. by reining in easy access to methadone from pharmacies, without or with prescription also easily obtained.

Moving away from the purely technical PSM aspects, the following will be equally important to ensure effective implementation:

- It will be essential that the roles and responsibilities related to procurement and supply chain management be captured in the revised version of the A.I., so as to minimize the risk of confusion and inaction. The stakeholders have some flexibility or leeway in deciding whether a particular task should be entrusted to the MMT focal point vs. the PSM coordinator vs. an M&E officer, provided, again, it is captured in unambiguous language in the revised version of the A.I or related text.
- As is the case anywhere, MMT program viability and expandability will depend on the capability, management skills, sense of ownership, and pro-active approach of the actual people in the key roles. From a PSM perspective, this applies to both the position of MMT Focal Point and the PSM Coordinator in the MOH/Pharmaceutical Services Dept.

Finally, the expandability and viability of the MMT program will ultimately depend mostly on the political will of the government/MOH to make the program effective and successful. In the face of persisting taboos, the determined and public support of the Global Fund to the MMT approach can play a role of capital importance.

## Map of Kosovo

Source: https://en.wikivoyage.org/wiki/Kosovo