The Global Fund
To Fight AIDS, Tuberculosis and Malaria

# TB AND HIV CONCEPT NOTE

## Investing for impact against tuberculosis and HIV

Countries with overlapping high burden of tuberculosis (TB) and HIV must submit a single concept note that presents each specific program in addition to any integrated and joint programming for the two diseases.

In requiring that the funding requests be presented together in a single concept note, the Global Fund aims at maximizing the impact of its investments to make an even greater contribution towards the vision of a world free of the burden of TB and HIV. Enhanced joint HIV and TB programming will allow to better target resources, to scale-up services and to increase their effectiveness and efficiency, quality and sustainability.

All concept notes should articulate an ambitious, strategically focused and technically sound investment, informed by the national health strategy and the national disease strategic plans (NSPs).

The concept note for TB and HIV is divided into the following sections:

**Section 1:** The description of the country's epidemiological and health systems context including barriers to access, the national response to date, country processes for reviewing and revising the response, and plans for further alignment of the NSPs, policies and interventions for both diseases.

**Section 2:** Information on the national funding landscape, additionality and sustainability

**Section 3:** The funding request to the Global Fund, including a programmatic gap analysis, rationale and description of the funding request, as presented in the modular template.

**Section 4:** Implementation arrangements and risk assessment.

***IMPORTANT NOTE:*** **Applicants should refer to the TB and HIV Concept Note Instructions to complete this template.**

| **Applicant Information** | | | |
|---|---|---|---|
| **Country** | **Albania** | | |
| **Funding Request Start Date** | **1 April 2016** | **End date** | **31 March 2019** |
| **Principle Recipient(s)** | **Ministry of Health** | | |

## FUNDING REQUEST SUMMARY TABLE

A funding request summary table will be automatically generated in the online grant management platform based on the information presented in the programmatic gap table and modular templates.

## SECTION 1: COUNTRY CONTEXT

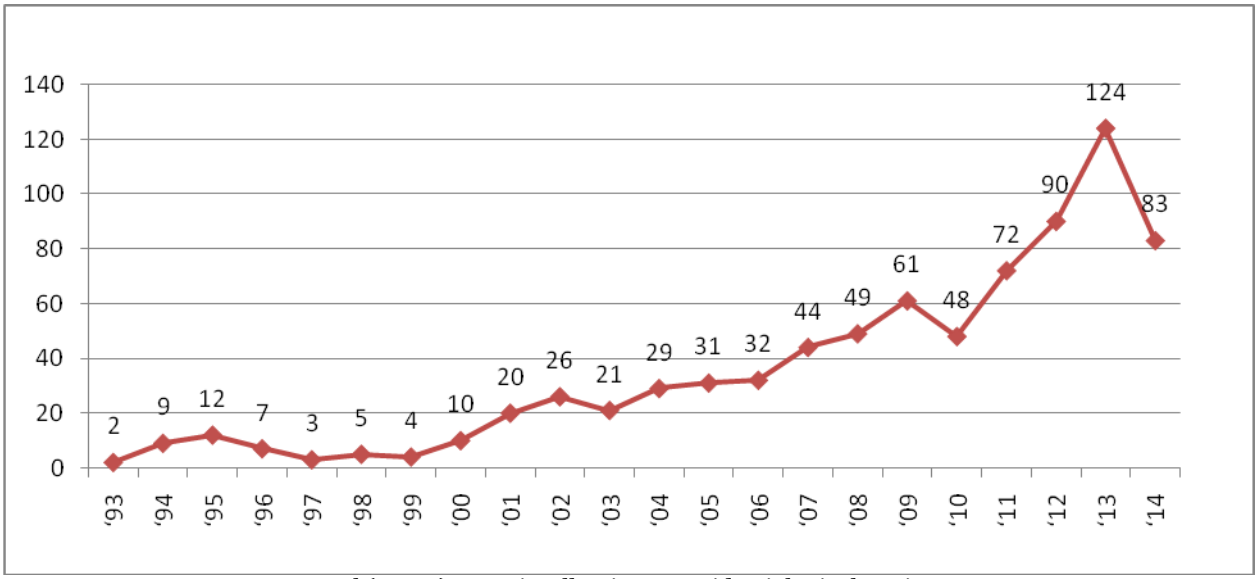
### 1.1 Country Disease, Health Systems and Community Systems Context

#### a. Epidemiological situation

Albania has relative low level HIV and TB epidemics, but there are indications that both could increase if the country's limited resources are not applied effectively to contain the epidemics.

***HIV epidemic***[1] Albania continues to have a low prevalence epidemic. Up to the end of December 2014, a total of 782 HIV cases had been reported; however, the number of new diagnoses has been increasing till 2013. Whereas the annual number of cases reported remained low until 2006 (under 40), between 2008 and 2013 the annual number of HIV diagnoses more than doubled from 49 to 124 cases. In 2014 the number of new HIV cases decreased to 83 (Figure 1).[2] The figures presented should be observed with caution. First, they are based on testing data, and as such depending on the number of HIV test conducted. In 2014 the number of HIV tests decreased to 33,419 (from 37,478 in 2013), which may explain the drop in 2014. Second, HIV testing is carried out in late stages of infection (about 60% of the new reported cases), and therefore the figures do not accurately represent the actual infection rate.

**Figure 1: Annual Number of New HIV Diagnoses: Albania, 1993-2014**




*Source:* Brown et al (2014a). *HIV in Albania: An Epidemiological Review.*

In 2014, the number of diagnoses was equivalent to 3.0 per 100,000 people (total population of Albania according to INSTAT, Census 2011). While this rate is lower compared to the 7.8 per 100,000 reported in the European region, it is more than the 2.2 per 100,000 people in the central European region.[3]

The HIV epidemic in Albania is concentrated in the capital, Tirana, in which over a quarter of the 2.9 million Albanian population lives. Overall, 50% of all HIV diagnoses were conducted in the Tirana municipality, followed by the cities of Durres and Elbasan, which are close to Tirana, and the coastal city of Vlores, in the south of Albania. However, cases have been reported in 33 of Albania's

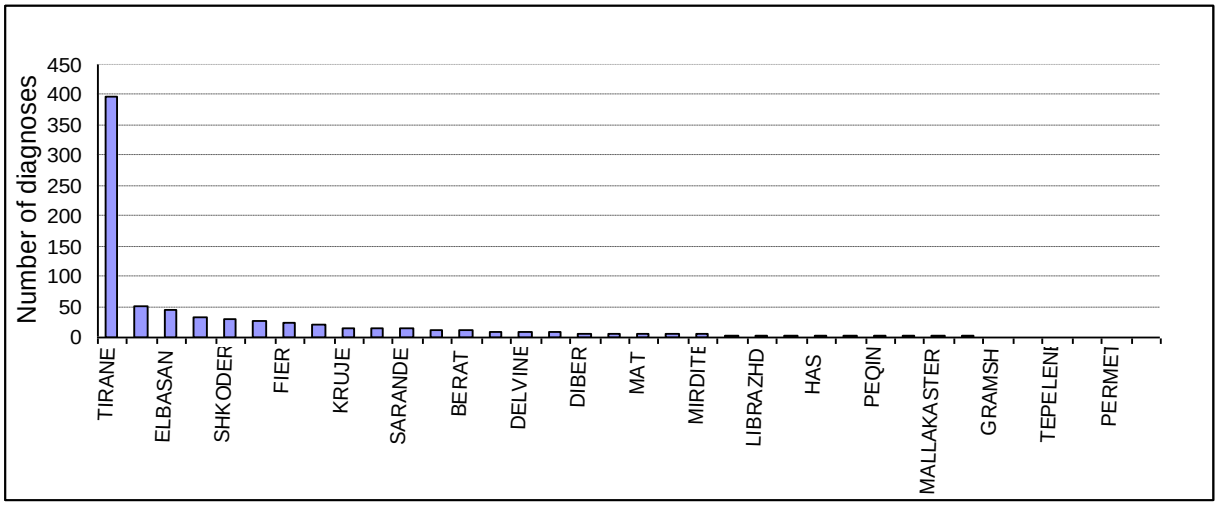
[1] Unless otherwise stated, this section is based on: A Brown, I Bozicevic, S Dvoriak and V Delpech (2014a). *HIV in Albania: An Epidemiological Review*; and A. Brown, S. Dvoriak and V. Delpech (2014b).

[2] The reason for the increased rate has not been determined with certainty but it is possible that it is due to expanded HIV testing, which has in turn led to more diagnosis.

[3] European Centre for Disease Prevention and Control and WHO Regional Office for Europe (2013). *HIV/AIDS Surveillance in Europe 2013.* Stockholm: European Centre for Disease Prevention and Control.

36 districts (Figure 2; for a map see section 3.2 Figure 6).

**Figure 2: Number of HIV Diagnoses in Albania by District 1993-2014**




*Source:. Brown et al (2014a). HIV in Albania: An Epidemiological Review.*

The UNAIDS online database 'AIDSinfo' shows a HIV prevalence among the general population in Albania of 0.0375% in 2013.[4] Formal estimates of national HIV prevalence in Albania do not exist however, and there is very limited information about the population groups within which HIV transmission is occurring.[5] This is partially because rates of HIV transmission remain low and so trends and patterns are more difficult to discern than with a more significant level of transmission. In addition, although case reporting data provides some self-reported information on routes of transmission, it does not provide information about any specific risks, particularly among persons who are considered to have acquired HIV heterosexually.

Dividing the number of HIV diagnoses in 2014 (83) by the number of HIV tests conducted (33,419)[6] provides a positivity rate of 0.24%. However, the majority of diagnoses were made at a late stage of infection, and therefore likely to be 'recommended' tests; and this implies that the rate of 0.24% is likely to underestimate actual HIV prevalence.

The relatively high rates of reported transmission through sex between men and the high ratio of HIV infections occurring in men both indicate that transmission among MSM is likely to be a major risk for HIV transmission. Bio-behavioural survey data (2011)[7] show low rates of HIV infection among both MSM and PWID and no HIV infections among the Roma population sampled. The data also indicated that risk behaviours, which would be conducive to HIV transmission were present in all sub-populations studied, particularly among MSM and PWID.

*Treatment and care cascade situation analysis* The construction of the continuum of care in Albania is hampered by the absence of data collected for several key measures. Initial diagnosis is delayed until the late stages of disease due to delays in testing. More than 70 percent of newly diagnosed are symptomatic and approximately half of patients newly enrolled in ART in 2014 are very late presenters with CD4<200 cells. Following a positive HIV diagnosis, patients are referred to a psychologist and referred to the University Hospital Centre Mother Teresa (UHCMT), for HIV treatment and care. There is no active follow up of patients newly diagnosed who do not attend care – otherwise known as those who are lost to follow up. Data is missing on the percentage of those

[4] http://www.aidsinfoonline.org/devinfo/libraries/aspx/Home.aspx accessed on 24 January 2015. The database also shows HIV prevalence rates for 2011 to have been 0% among SW and 0.5% among both MSM and PWID but sources of data are not quoted.

[5] Reasonable proxies for HIV prevalence could be obtained through implementation of a national antenatal screening programme or through analysing the proportion of HIV positives found through the relative blood donation programme, but these do not exist or have not been applied.

[6] It should be noted that the majority of HIV performed tests are tests among blood donors.

[7] Integrated Bio-behavioural Survey (IBBS) Albania, 2011 (Attachment 2)

registered at the ambulatory clinic and retained in care. However, the increasing number of those starting ART during the last 5 years shows indirectly that there is a good share of those needing treatment and starting treatment (2009-34 cases; 2010-31 cases; 2011-42 cases; 2012-58 cases; 2013-70 cases). An electronic data base is not available at the ambulatory clinic to record data.

HIV treatment and care have been available since mid-2004 through the inpatient and outpatient units based at the UHCMT. The guidelines on ART are based on WHO 2004 and recommendations of 2011 and National Guidelines have not been updated since 2007. These guidelines indicate ART initiation based on CD4 counts (<350 cells/mm3) and clinical criteria.

The number of people receiving ART has increased in recent years from 161 in 2011 to 335 in 2014. The numbers initiating ART for the first time have also increased. Due to the weak procurement supply management system and bureaucracy of the process, ART stock-outs are frequent, resulting in patients not receiving any treatment or switching of drugs regimens depending on drug availability.

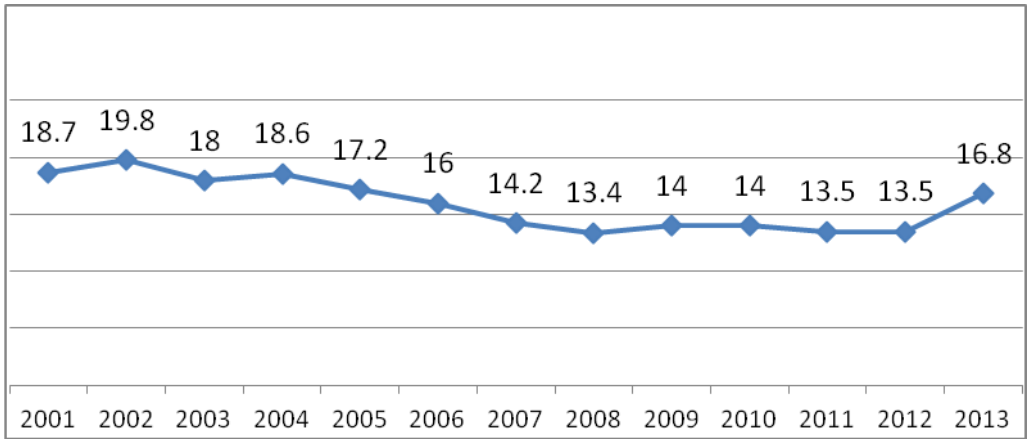
No data are available on retention on treatment after 12 months and after. However, this information is recorded in clinic notes at UHCMT. Viral load and CD4 monitoring are not performed routinely due to shortages in kits. This means the proportion of patients adherent to ART and treated successfully cannot be measured. There are no operational facilities to monitor drug resistance within Albania. Decisions to switch ART are based upon clinical indications.

Adherence is perceived to be good in two assessment performed at UHCMT. Also training of HCW on adherence and publication of guidelines and brochures are provided during the previous GF round.

***TB epidemic*** The TB epidemic in Albania, which has been stable in recent years, worsened in 2013. After ten years of a gradually decreasing incidence at an already low level (from 18.6 cases per 100,000 inhabitants in 2004 to 13.5 cases in 2012), this increased to 16.8 cases in 2013.

Following the end of the Communist era there was a significant population displacement from the north-eastern areas with high TB prevalence to the surrounding areas of Durrës and Tirana. This displacement centred especially in two areas, in Bathore in the district of Tirana and former Këneta, in the district of Durrës. As a result, there is a clear geographical distribution in TB incidence with notable differences between the various regions see Figure 4. As the red shaded areas in the map in Figure 4 show, the highest incidence in 2013 was in north-eastern districts (54/100,000) and, the lowest incidence was in the south (1.8/100,000).

**Figure 3 – TB Incidence per 100,000 People, 2001-2013**

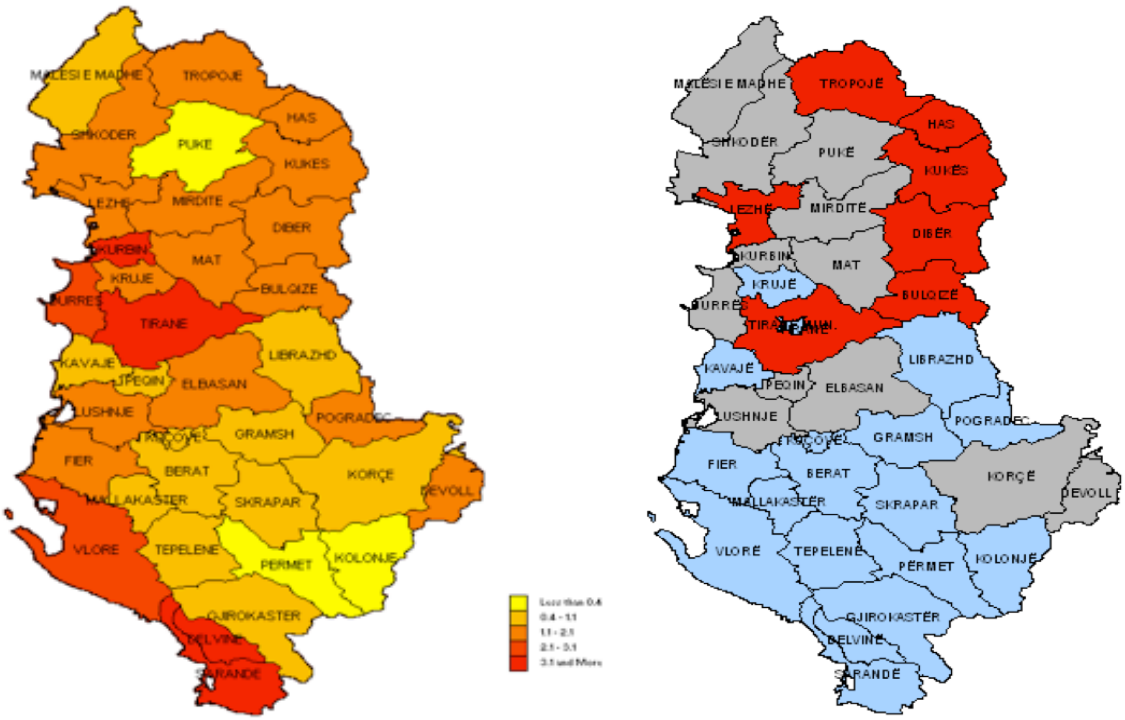



*Source: Government of Albania (2014). National TB Strategy 2015-2019*

The highest incidence is among the poorest social economic areas which are also characterised as having poor medical access. Many of those north-eastern districts border with Kosovo and there is free movement of people between Albania and Kosovo. The TB prevalence in Kosovo is three times

higher than in Albania[8] and, during summer, Albania hosts a significant influx of Kosovars. Most of these come for reasons of tourism - many also have relatives in Albania - and many are employed in the public sector in hotels and restaurants.

**Figure 4: HIV prevalence(left panel) and TB Incidence (right panel) by District, Albania**




*Source: HIV/AIDS in Albania, National Report, National AIDS Program. Institute of Public Health, December 2014; National TB Programme Annual Reports 2013 (red>20, grey>10 &<20, blue<10)*

The stable epidemiological situation of TB during the past years has resulted in TB no longer being considered to be a public health priority and, as a result, proactive and aggressive interventions against TB, and the requisite funding, have diminished. The somewhat lacklustre fight against TB in Albania has deteriorated even further due to the economic crisis[9] and accelerated health care reform in the country during the past years.

The group most affected by TB are young adults between 15 and 34 years old (38.6% of total cases) and an increasing trend in paediatric TB was observed in 2013 (see Figure 5).

The TB prevalence in children aged 0 to 14 years raised from 1.7% in 2011 and 0.7% in 2012 to 4.1% in 2013 and grew further in 2014 to 5.1% of the total TB number of cases in those years. The recent increase in child TB is considered a negative sign for the TB epidemiologic situation. Moreover, it is suspected that TB among children aged 0 to 14 years has been under-diagnosed, due to the fact that it is more difficult to diagnose TB in children and that currently diagnosis, treatment and management of TB in children are not in the direct sphere of influence of the TB control program.(see also Annex B).

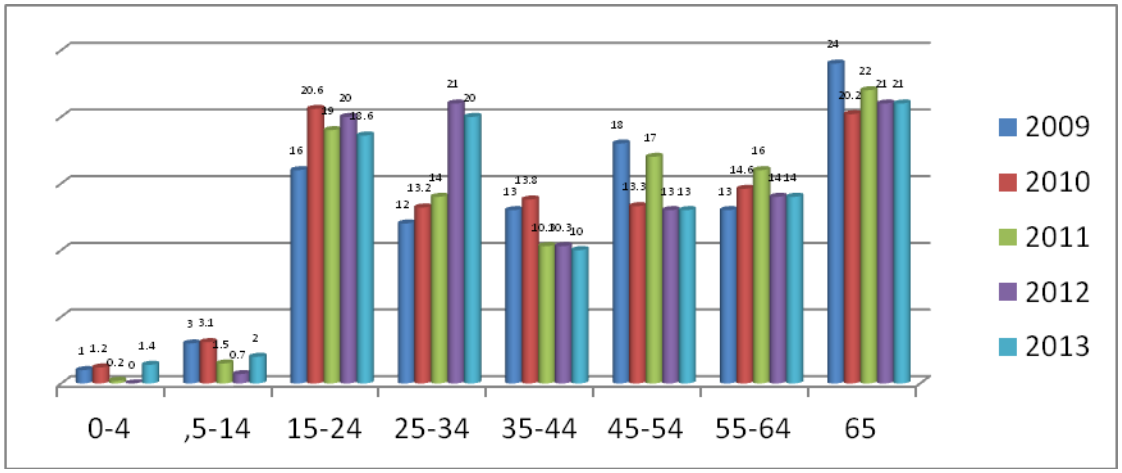
In terms of the sex differential, men continue to be twice as infected by all forms of TB compared to women. This ratio has been the same for many decades, raising suspicions of an under-diagnosis of TB among women. It is suspected that female tuberculosis patients are under-notified due to a wide range of socio-cultural factors and/or different issues related to access to health care services

[8] http://www.who.int/tb/publications/global_report/indicators_european_region.pdf

**9** The current Government took office in June 2013 and inherited an enormous internal debt which is estimated to be approximately 70% of GDP. In order to address this situation, the Government borrowed USD 300 million from the International Monetary Fund for a three-year period and another loan from the World Bank of USD 200 million. This leaves little public money for primary health care, including TB (see section 1.1 D for a more detailed explanation of health care financing). Albania's economic crisis has also been exacerbated by the economic crisis in Europe and especially in Albania's two neighbouring countries, Greece and Italy.

and health care seeking behaviour.

**Figure 5: TB Age Distribution in Albania 2009-2013**




*Source: NTP and WHO (2014), Global Report*

Annex B outlines the epidemiological situation with regard to TB in more detail.

***HIV/TB Co-infection*** The number of people with both TB and HIV is small, with two new cases in 2013[10]; however, it is a category that should not be neglected as numbers are rising, albeit slowly. Both TB and HIV services are organised vertically and there is little coordination between the two; this is discussed in more detail in subsequent sections.

According to the UNAIDS 2013 Global Report, 100% of estimated HIV positive incidence TB cases received treatment for both TB and HIV, and 55% of HIV positive TB patients were on ART, in 2012.

### b. Key affected populations

**HIV related key affected populations:**

***Men having sex with men (MSM)*** While most HIV cases are assumed to be acquired heterosexually, the 2 to 1 ratio of male to female diagnoses indicates that there may be substantial under-reporting of infections acquired through sex between men. Homosexual, bisexual and other MSM remain a hidden and stigmatised population. There are no estimates of the size of the MSM population. The latest IBBS survey (2011)[11] estimated HIV prevalence to range between 0.5 and 3.0% among MSM surveyed between 2005 and 2011. However, the IBBS sample size for each year is restricted to Tirana. This fact, combined with the unlikelihood of MSM self identifying as homo- or bisexual in a hetero-normative environment, limits the validity of this estimate.

The vulnerability and stigmatisation of this group has several associated effects. The IBBS (2011) shows that up to 75% of MSM are in sexual relationships with wives or girlfriends with many men reporting sex with other men only when abroad. Approximately one quarter to a third of sexually active MSM report having four or more male partners. Over 75% of MSM report having sex with female partners; only 14% of MSM report using condoms consistently. It is estimated that more than one-fifth of MSM inject drugs (21%), with heroin being the most frequently injected drug among MSM in Tirana.

The low rates of condom use during sex mean MSM are particularly vulnerable to HIV, while high levels of stigma cause low use of HIV testing services. Only 24% of MSM report ever having an HIV test while sexual identity is not reported with HIV testing data. This fact, combined with the 2:1 ratio of male to female diagnoses suggests that HIV prevalence among MSM is likely to be underestimated; and such men are at risk of presenting late for diagnosis.

***Transgender (TG)*** Although official size estimates of the transgender population do not exist, it

[10] WHO (2014), *Albania: Tuberculosis Profile.* http://www.who.int/tb/country/data/profiles/en/

[11] Integrated Bio-behavioural Survey (IBBS) Albania, 2011 (Attachment 2)

is generally believed that the TG community is small, around 20-25 persons located in the capital city Tirana. Initially there they could be seen in public areas like sex work hot spot, working as street sex workers. Nowadays, transgender (especially youth) are mixed with homosexuals especially at parties or other association spots.

***People who inject drugs (PWID)*** HIV prevalence among PWID appears to be low, with only 1% of diagnosis reports relating to injecting drug use[12]. Nevertheless, methadone maintenance treatment (MMT) services currently prescribe less than the recommended 60-120 mg which, combined with the reported high rates of sharing needles and syringes, suggests that there is significant potential for HIV to spread rapidly within this population.

In 2011 the Institute of Public Health (IPH), supported by UNAIDS carried out a population size estimate of the number of PWID using the multiplier and capture-recapture method.[13] It was estimated that the number of PWID ranges from 4,000 to about 6,000.[14] Among these, 32% are aged 24 years or under and the majority are unmarried (63%); and over 10% of PWID are illiterate. IBBS[15] (2011) estimates show that 0.5% of PWID are living with HIV infection. If this is applied to the mid-point of the estimated number of PWID living in Albania, this is equivalent to a HIV prevalence of 25 PWID living with HIV. The median age at first injection is 21 years, with nearly one in five first injecting at 18 years or younger. Frequent injection is common with 44% reporting multiple injections daily. The 2011 IBBS shows half of PWID clean their needles or syringes every time (21%) or almost every time (31%) with cold or hot water (57% and 7%, respectively).[16]

Most PWID are sexually active with 90% having had sex in the past 12 months, of which half have had two or more partners in this period. The median age at first sex was 16 years.

The high level of needle sharing and low condom use is of concern and could result in a major HIV outbreak if the virus took hold among this population. Despite this, only 60% of injecting drug users report ever having an HIV test. While methadone maintenance treatment (MMT) provides drug-related treatment for PWID, HIV tests are not conducted in these settings.

***Sex workers (SW)*** The Demographic and Health Survey (DHS) 2008-9 reported that 1.1% of all men reported ever having sex with SWs. Hard data on sex workers is very limited in terms of population size, their behaviour, operating methods and health status. Though many programs target trafficked or violated women, female sex workers (FSW) remain out of the loop.

Sex work is illegal in Albania and considered a criminal act[17], carrying the risk of prosecution and custodial sentences for both SWs and their clients. Two types of sex workers can be distinguished: street-based and motel/hotel/apartment-based. Street-based sex work is most visible and represents the most disadvantaged groups facing daily threats of violence, discrimination and police action, and lacking access to adequate social and health services, including HIV prevention.

The IBBS study (2011) shows that most sex workers start at a young age, with one-third around the age of 18. While most report using condoms, consistent condom use is limited, with approximately one-quarter not using condoms at last sex. Approximately a quarter of SWs use drugs, with almost 8% having injected drugs at least once in the last 12 months. More than half of these women are of Roma descent.

Previous experience and a study by UNFPA[18] identified the difficulties of working with the group. Sex workers are stigmatized and discriminated, they work through gatekeepers" (pimps, madams, taxi drivers, hotels/motels owners) and it is difficult to reach them directly. Some of them

[12] Source: HIV/AIDS in Albania, National Report, National AIDS Program. Institute of Public Health, December 2014

[13] Data on the population size estimates were obtained during a mission to Albania.

[14] European Monitoring Centre for Drugs and Drug Addiction (2013). Country Overview: Albania. Updated March 2013. Available at: http://www.emcdda.europa.eu/publications/country-overviews/at

[15] Integrated Bio-Behavioural Survey Albania, 2011 ( See Attachment 2)

[16] Data were not quoted for the percentage of persons who used sterile equipment the last time they injected.

[17] Prostitution is considered a "criminal act against morality and dignity" pursuant to section 8 of the Albanian Criminal Code *(The Penal Code* /articles 113-115 Criminal Acts against Morality and Dignity). Article 114/a foresees aggravating circumstances whereby the exploitation of prostitution is sentenced from 7 to 15 years imprisonment.

[18] National Mapping Exercise on Commercial Sex Workers in Albania; UNFPA, December 2009 (see Attachment 4)

use their mobile phones or internet to get in contact with their clients. Anecdotal information suggest that students work as sex workers during their time at university and usually stop after that. Selling sex is highly stigmatized and the group of sex workers who know and support each other is very small, at around three, which make the impact of intervention limited[19].

***PLWHA*** Almost three-quarters of HIV diagnoses are made at a late stage of HIV infection with a CD4 count of less than 350, of which almost half of them (47.1%) present with a CD4 count of less than 200. This implies that a large part of people living with HIV (PLWHA) are likely to be unaware of their HIV infection and remain undiagnosed until illness or referral brings them in for testing. Late diagnosis is likely to be associated with high rates of death, particularly within the first year of diagnosis and onward HIV transmission. A cumulative total of 122 or 17.5% of deaths have been reported among PLWHA; however, death reports are likely to be under-estimated.

***Pregnant Women*** In 2013, six cases of mother-to-child transmission (MTCT) were reported. Assuming a HIV transmission rate of 25% among untreated HIV positive women[20]; this means at least 24 HIV positive women were pregnant in Albania in 2013 and 16 others in 2014. This is likely to be a conservative estimate because most people are diagnosed late and other infants who acquired their infection vertically may not yet be symptomatic and presenting for HIV testing.

Most of infants were diagnosed when they presented some clinical signs and in half of cases due to child HIV status the parents were identified and started treatment. Meanwhile only two women have received until antiretroviral treatment to prevent mother to child transmission. Albania has no antenatal screening programme.[21]

**TB and TB/HIV related key affected populations**

At risk populations for tuberculosis are **PLWHA** - for whom TB represents the first cause of mortality (see above), **prisoners**, **contacts of TB/MDR TB cases**, **TB health care workers**, and other population groups that are particularly vulnerable to TB. The latter includes **ethnic populations** (Roma, Egyptians, etc.), drug and alcohol users, poor/malnourished/homeless people, migrants (from Kosovo – incl. tourists), China, Egypt, Turkey and Arab countries; but also returning migrants), people from areas with high TB prevalence in the outskirts of the capital or northern areas (see Figure 4), patients with chronic diseases and/or institutionalised in chronic care facilities (nursing homes/ psychiatric hospitals). Epidemiologically relevant is the higher case notification among the elderly, as they can be a source of transmission in the household.

***Prison inmates***

The 5,424 prison inmates (Min. of Justice, Aug. 2015) in the 22 detention facilities in Albania are one of the highest risk groups in the country. During 2013-2014, among the total prison population (5000) there have been 13 HIV positive cases (1 female, 12 male). To date, two of them died and three have left prison. Out of the eight HIV positive prisoners seven are on ARV.

The rate of latent tuberculosis infection (LTBI) is high. A study[22] carried out among 1,684 prisoners showed a LTBI rate of 48%, while 35% of them resulted in a mantoux tuberculin skin test (TST) higher than 10 mm. Poor hygienic and sanitary conditions in prison and the release of prisoners with latent TB contribute to the risks increasing te epidemic in the general population. Chemoprophylaxis and active screening among prisoners are recognised as vital elements in containing the TB epidemic.

***Roma and Egyptian (R/E) Community*** Except for sex workers of R/E descent, HIV has not

[19] There was an attempt to provide services to sex workers through a dropping center during the implementation of the previous grant of GFATM but that was not successful. Only a limited number of sex workers visited the centers and especially the number of new comers were very small. After the GF closure the center closed.

[20] Connor EM, Sperling RS, Gelber R et al. Reuction of maternal-infant transmission of human immunodeficiency virus type 1 with zidovudine treatment. Pediatric AIDS Clinical Trials Group Protocol 076 Study Group. N Engl J Med. 1994 Nov 3;331(18):1173-80

[21] Last year, the government in collaboration with UNFPA prepared the first screening guidelines for infectious agents in pregnancy describing how testing for HIV, Hepatitis B, Syphilis and Rubella will be offered to pregnant women by using antenatal care services.

[22] Source: Report of study for active screening in the prisons in year 2009. PIU GF Round 5

been detected among the R/E population. However, there are socio-economic and cultural factors which make R/E more vulnerable with regard to their health in terms of their vulnerability to TB, their sexual wellbeing, health-seeking behavior and their vulnerability to HIV.

A recent study by UNDP and others (2015)[23] on the profiling of social exclusion of Roma and Egyptians in Albania, shows that members of the R/E community are caught in a health-based poverty trap: their poor living conditions expose them to several health risks, which - coupled with the low education level and poor access to health services, plunge them into poverty. In accessing health services, members of the R/E community face numerous barriers, such as lack of financial resources; lack of health insurance; poor health infrastructure; lack of health care providers; discriminatory practices from doctors and health professionals; limited awareness and knowledge of health services. Often, health care services are denied unless access is facilitated by community activists. Findings furthermore suggest that policy approaches to improving the health and mental health of the Roma and Egyptians should embrace an inter-sectoral approach, and recognize the psychological and behavioral consequences of intergenerational poverty and perpetual discrimination.

With a TB incidence among the R/E population of 26 per 100,000 population (2011), which is twice as much as the TB incidence in the general population[24], the vulnerability to TB of R/E communities is apparent. Features that characterize the vulnerability for HIV and STIs with reference to sexual and health-seeking behavior among the Roma have been studied by the several bio-behavioral studies that were conducted in the past (IBBS 2005, 2008 and 2011). IBBS 2011 estimates first sexual intercourse at 24% between 10-14 years and 84% reporting first sex before the age of 18. Early sexual initiation and ergo higher risk for HIV and STIs is associated with not going to school and thus not being exposed to the school prevention programs. Females are more likely to have sex at younger ages and one in five Roma women (21,3%) are forced by their partners to have unwanted sex.[25]. Half of the respondents (52%) did not use a condom in the last 12 months. Despite the fact that the majority of respondents (84.8%) know where to obtain condoms, only 1.7 % uses them with regular partner, as compared to almost 43 % use condoms with non-regular partners. The main reason given for not using condoms was that the respondents "did not like them". The IBBS 2011 showed low levels of reported alcohol consumption, drug-injecting behavior, or engagement in commercial sex or non-regular partners in the last 12 months.

### c. Key human rights barriers and gender inequalities that may impede access to health services

Prevailing gender differentials, stigma and discrimination, and poverty impede access to appropriate services. Albania is a traditional and patriarchal society in which stigma and discrimination play a significant role in preventing members of key affected populations accessing HIV testing for earlier diagnosis, TB testing and treatment of HIV and TB infection. The reality is that those not covered by health insurance lack the very basic human right of access to health care. The country has no policy to ensure that key vulnerable groups are targeted with appropriate health services. Both HIV and TB patients facing socio-economic problems do not receive financial support, and very often these patients become marginalised.

It is suspected that female HIV and TB patients are under-notified due to a wide range of socio-cultural characteristics and/or different factors related to access to health care services or health care seeking behaviour. The key factors are known to be domestic violence and gender inequality.

***Domestic violence*** Women's vulnerability to violence and risky sexual behaviour impacts on

[23] In the framework UN Support to Social Inclusion Initiative funded by the Government of Switzerland, UNDP has conducted the study "The Social Exclusion profile of Roma and Egyptians in Albania", launched October 2015. Social exclusion is examined in relation to the following services: employment and vocational training, education, health, social housing, justice, and social protection.

[24] NTP (2008). *Identification of Infectious TB Cases within Prisons and Among the Roma Population.* (Attachment 3)

[25] see also Government of Albania (2015). *National Strategy for the Prevention and Control of HIV/AIDS in Albania 2015-2019.* (Attachment 6)

the transmission of STI and HIV; and the incidence of domestic violence has become worse. Domestic violence remains largely hidden, supported by the traditional and patriarchal attitudes of some minority groups; and this is further exacerbated by the failure of law enforcement agencies to address domestic abuse. Data from the United Nations Development Programme (UNDP)[26] indicate that in 2013 59.4 percent of women aged 18 and above had experienced some form of physical, sexual or psychological violence. Alcoholism, unemployment and poverty are cited as the main reasons. The higher economic dependence of women contributes to violence.

***Gender inequality*** In terms of gender inequality, 51% of university graduates are women but their potential is not fully realised in the economy. They represent 41.6% of the formal workforce, they own 27 percent of businesses, and they earn 82 percent of a man's income. Traditional gender roles and stereotyping hamper women from using their competencies and becoming economically independent. For example: (a) 60.3 percent of working women work part-time; (b) women spend 306 minutes a day on household work compared to men who spend 47 minutes; and (c) only 8 percent of properties are owned by women. [27]

Prevention and treatment of violence is part of the primary healthcare service package in the form of telephone counselling help lines, social support services and health care provision.[28] It has been noted earlier that prevalence rates for women with regard to TB and HIV are much less than for men and that one of the reasons for this might be women's reluctance to seek appropriate health care services due to their less dominant role in the household.

***Stigma and discrimination*** While there is a strong legal protection for those living with HIV, the society for PLWHA reports high levels of HIV stigma with anecdotal evidence of challenges, and discrimination in terms of education and employment.

While Albania has anti-discrimination laws that relate to lesbian gay, bisexual and transgender (LGBT) persons, the country remains a hetero-normative society and homosexual, bisexual and other MSM remain a hidden and stigmatised population in Albania. LGBT persons are not visible in the media, and LGBT NGOs report high levels of stigma including verbal and physical abuse. It is likely that the high proportion of MSM who also report being in sexual relationships with women, and the few reports of same sex contact at HIV diagnosis, is in part due to actual and/or perceived homophobia in society.[29]

**c. Context of health systems and community systems**

***Health System Context***[30] Albania's public health system, which is overseen by the MoH, has changed little since Communist times. It is rigidly structured and centralised, and is experiencing difficulty in meeting the medical needs of the population. Doctors and nurses are often cut off from new techniques and developments in medicine and, consequently, the system is finding it hard to cope with modern day health issues such as drug use, TB, HIV/AIDS and STIs.

Since 1990 Albania's health system has been going through a series of reforms and processes to better address the needs of the population and comply with quality standard service delivery. One of the major reforms took place in 1995, when the Council of Ministers decided to establish the health insurance system. This began as a scheme covering reimbursement of drugs and family physicians salaries, based on a per capita coverage. In 2009 it was expanded to include hospitals and then all levels of health care. As a result, primary health care centres have become more independent in terms of self-management and expenditures. The structure of the state system and the implications of health sector reform on HIV and TB service provision are described in Annex C.

All Albanians are legally entitled by law to equal access to healthcare. Healthcare is funded by the

[26] UNDP (2013). *Factsheets on Domestic Violence, Gender Inequality and Women in Politics*. Tirana. http://www.al.undp.org/content/albania/en/home/library/poverty/domestic-violence-albania-and-eu-countries/

[27] *Ibid.*

[28] Government of Albania (2015), *op. cit.*

[29] Brown et al (2014b), *op. cit.*

[30] Information on the health system, unless otherwise stated, is based on http://www.europecities.com/en/633/albania/health/, downloaded in November 2014.

Government and private practice is limited to a small niche sector. In theory, access to health care is free through the health insurance scheme. Those unable to work, children, pregnant women and all TB and HIV-registered patients receive free health care. Those eligible to work but who are unemployed receive health care which is dependent on registration of intention to find paid employment. While contact with health services is free, patients are asked to pay a contribution (usually less than USD 40) for interventions and prescriptions. The exception is HIV, where first and second line ART is paid for by the Government. The Global Fund has only supported 50 patients on second line till March 2015, and the stock is available till Q3/Q4 2015.

While the state system is supposed to be financed through insurance contributions from those employed and their employers, unemployment and poverty in Albania is rife and few can afford to pay the contribution for medicines. As a result, many people fail to obtain much needed medicine and medical care, while the failure to collect a substantial amount of contributions means that the healthcare system is strongly reliant on charitable aid for medical supplies and drugs.

The majority of the population live in the countryside, which places an increased burden on the health system because there are not enough health facilities to deal with the rural population. Hence healthcare provision is better in urban areas and rural inhabitants' needs are not equally met.

Measures are being taken on identified access barriers as indicated in the following table:

| Barrier | Measures |
|---|---|
| Limited access to health services if un-insured. | Abolition of the health insurance and switch to the health financing through the general taxation in 2017. |
| Co-payment of medicines other than ARV, in the outpatient care, that are partially reimbursed by Health Insurance Fund | Expansion of the list of medicines that are fully reimbursed.<br>Decrease of the price of medicines using international price referral models and revision of the margins of profit. |
| Limited access to the medication of opportunistic infections given that the patients should have the prescription filled by a GP in order to benefit from Health Insurance. This referral path from the Infectious Diseases Specialist to the GP is compromised by the breach of confidentiality and anonimity (as referred by HIV patients) | Revision of the regulation of the referral of the diagnosed patients back to the GP. Infectious Diseases Specialists will be given the competence to fill the prescription on the reimbursed medicines. |
| Limited capacities and poor performance of microbiology labs at hospitals. | Public Private Partnership Solution to boost the performance of hospital labs. |
| Limited access to voluntary testing. | Revision of the Package of Services at PHC Centers, allowing for testing capabilities. |

***Health Financing*** Total Government expenditure on health in 2014 was US$ 400,003,010 and US$ 345,167,630 in 2013. While the Albanian economy has been growing steadily in spite of the global economic recession, and gross national income per capita has doubled over the past decade, the public share of the country's gross national product (GNP) remains low at only 2.8%. About US$ 580 per capita is spent on health, the lowest figure compared to neighbouring middle-income countries. As a result of low public spending on health, the remaining 60% of health expenditure must come from direct out-of-pocket payments from the general population.[31] Table 1 sets out how the health sector expenditure is financed, while Table 2 shows the proportion of the Government budget that goes towards health in addition to funds from health insurance.

***Community Systems*** Overall, civil society in Albania is still relatively young: fifty years of communist rule have left little room for an organised, mature civil society. As a result, civil society organisations (CSO) have only begun to emerge relatively recently. They face significant challenges with regard to organisational and institutional capacity to deliver high-quality, sustained services

[31] These estimates are based on household survey data and were provided by the Deputy Minister of Health in a personal communication on 8 December 2014.

covering large geographic areas. Most CSOs have relatively small numbers of staff, often dominated by a strong director, and rely heavily on external funding, which usually only covers a short timeframe. This leaves CSOs particularly vulnerable to the effects of unpredictable funding and donor-driven projects. Very few CSOs have been able to create longer-term stability with guaranteed funding to sustain programmes with a clear long-term organisational vision.

**Table 1: Total Health Financial Expenditure/Resources 2013**

| Funding Source | 2012 | | 2013 | |
|---|---|---|---|---|
| | US$ 000s | Percent | US$ 000s | Percent |
| Government budget | 49,466,910 | 16.0 | 49,982,980 | 14.3 |
| Health insurance fund | 245,955,220 | 79.5 | 295,184,650 | 84.4 |
| Global Fund | 230,974 | 0.1 | 180,595 | 0.1 |
| Other donors | 11,318,700 | 3.7 | 292,189 | 0.1 |
| Other sources[32] | 2,261,926 | 0.7 | 4,192,003 | 1.2 |
| Total | 309,246,286 | 100 | 349,836,822 | 100 |

*Source: Ministry of Health, 28 January 2015*

**Table 2: Proportion of Government Budget Expended on Health, Including Health Insurance Funds 2013**

| Component | Percentage |
|---|---|
| Health insurance contributions | 23.8 |
| State budget transfer for primary healthcare services | 30.6 |
| State budget transfer for hospital services | 45.2 |
| Other revenues | 0.4 |
| TOTAL | 100.0 |

*Source: Deputy Minister of Health (2014), op. cit.*

Continuity and comprehensiveness of services require affective partnerships and referral networks. CSOs often see other CSOs as competitors in a small market rather than as potential partners; and this hampers effective networking. These competitive attitudes often play an even more important role between CSOs and government organisations – with mutual distrust.

'Community systems' primarily refers to NGO service providers who mostly provide services to relatives of key populations and otherwise play a relatively passive role. HIV-related stigma and discrimination and the marginalised position of MSM, PWID and SWs, result in a very low level of organisation among these groups themselves. This leaves them dependent on services that are often donor-driven and/or supply-driven by NGO service providers, and which fail to meet their real needs. While a PLWHA Association has been established, a similar level of community organisation among key populations has been absent to date.

The weaknesses and gaps described above result in services that: a) lack a clear client perspective; b) fail to provide continuity and high quality comprehensive services; and c) fail to achieve clear results. Despite these shortcomings, there is a positive development towards stronger and more stable CSOs, which can do more and better fulfil a role that complements the programmes and services offered by Government agencies. However, sustained investments are needed in the civil society sector to further sustain this positive trend.

In the case of TB, CSOs and NGOs must be brought into partnership with national health and social welfare systems to ensure that their work for health is better understood; for example, such as the 'Respiratory Health and TB Centre' NGO that was active during the implementation of the GF Rnd. 5 grant. Former TB patients are becoming increasingly involved in the planning and

[32] Ministry of Justice and Ministry of South Welfare and Youth

implementation of interventions, as was seen during the development of the new National TB Strategy (NTS). However, TB patients do not perform in an organised manner, forming a network or community organisation or NGO.

The Community Systems Strengthening (CSS) Framework is one of Government's priorities and, together with the UN Programme of Cooperation through the Health and Social Inclusion Programme, the country has initiated the establishment of an NGO forum and local level networks. This is a major step toward enhancing community engagement and effectiveness in improving health outcomes and increasing their collaboration with, and influence on, the public and private sectors.

HIV service provision has benefited from various services organised by CSOs, mainly in the areas of capacity building and awareness-raising. However, specific services such as MMT and harm reduction have been available on a small scale and largely delivered in city centres, especially Tirana. A need is recognised to strengthen community-based initiatives in the regions through CSOs and also ad hoc community based actions.

Civil society has not yet learned how to fully mobilise itself to address the gaps in TB and HIV testing and treatment adherence, i.e. where medical intervention require a parallel activity in the non-medical sphere.

## 1.2 National Disease Strategic Plans

### Separate National TB and HIV programs

Both programs have been in operation distinctly and systems to manage TB and HIV are currently administratively separate. However, overall coordination mechanisms, e.g. through the MoH and the CCM, are present. Furthermore, the Government has an increased focus on collaborative activities between HIV and TB. In line with EU regulations and directives the Ministry is working on a new national law on infectious diseases and it is considered that this will address HIV-TB collaborative activities.

### National HIV program

Albania's national response to HIV has been guided by the National Strategy of Prevention and Control of HIV/AIDS in Albania (NSPCHA)2009-2014[33]; a summary of recent developments is contained in Annex C.

***Goal and strategy*** The overall goal of the NSPCHA was to ensure that Albania remains a low HIV prevalence country. It had three strategic priorities: (i) prevention of new HIV/STI infection in key groups and the general population; (ii) improved treatment, care and support to PLWHA; and (iii) improve system infrastructure and enhance health provider capacity to ensure the delivery of a high quality and timely service to all people affected by HIV/AIDS and STIs.

A new strategy was developed in December 2014 and approved in January 2015.[34] It incorporates a number of new and reinforces previous strategies:

- Emphasising the need for timely and accurate epidemiological data through case reporting and regular IBBS;
- Prioritising the prevention of mother to child transmission of HIV (PMTCT).
- Re-emphasising the importance of and strengthening targeted prevention interventions among key populations, in particular MSM and PWID;
- Improving the provision of treatment and care for PLWHA, including revising the CD4 threshold for ART for initiation of treatment in line with WHO guidelines[35] and introducing

[33] Government of Albania (2009), *National Strategy for the Prevention and Control of HIV/AIDS in Albania 2009-2014.* (See Attachment 5)

[34] Government of Albania (2015), *National Strategy for the Prevention and Control of HIV/AIDS in Albania 2015-2019.* (See Attachment 6, 7 and 8.)

newer antiretroviral drugs (ARVs).

- Early diagnosis of HIV, improving the laboratory monitoring of PLWHA, and diagnosis and treatment of opportunistic and co-infections.
- Promoting provider-initiated HIV testing and counselling (PITC) in routine health settings including STI and TB clinics and, in particular, antenatal settings.
- Improving the practical delivery of HIV services by strengthening procurement and supply management (PSM), M&E and programme management.

***Implementation to date*** In September 2014 an independent evaluation identified the strengths and weaknesses of the national HIV response (see Annex D). Strengths included:

- The availability of 'free' health care which includes access to HIV testing and treatment, beneficial both for PLWHA and also in reducing barriers to testing for those populations most at risk. The number of people receiving ART has increased with support from both domestic resources and Global Fund finances. HIV testing is being provided through a network of HIV voluntary counselling and testing (VCT) centres;
- A central public health laboratory with public health infrastructure, a dedicated HIV/AIDS coordinator and well-established HIV prevention services;
- Some targeted services for key populations are being provided, e.g. the provision of MMT for PWID through support from both domestic resources and Global Fund financing, although harm reduction activities are minimal;
- Highly skilled HIV clinicians and a dedicated HIV clinic with free and accessible ARVs. The IPH has passionate and committed epidemiological expertise with established HIV surveillance systems for monitoring testing and epidemiological trends;
- Committed and active NGOs that provide a critical role in the delivery of prevention activities, including services; and
- A strong legal framework that protects PLWHA (2008) and other key groups such as lesbian, gay, bisexual and transgender (LGBT) against discrimination (2010).

Data from the 2011 IBBS[36] provides evidence that this additional support was beginning to have success. For example:

- Levels of knowledge about HIV prevention measures and STI symptoms were higher among MSM in 2011 than in previous survey rounds.
- More PWID (36.7%) identified needle exchange programmes (NEPs) as a source of sterile needles and syringes compared to 27.7% in 2008 and only 11% in 2005. Almost half of all PWID (47%) reported obtaining syringes from outreach workers in 2011 compared to only 10% in 2008. Almost two-thirds of PWID reported that they had received needles and syringes from NEPs in the last 12 months.
- Access to drug treatment for PWID, particularly with methadone, improved from 2008 to 2011. In 2011, only just over one-third (35.4%) reported never having received any treatment for their drug use compared to almost two-thirds (64%) in 2008. In 2011, more than one-quarter of those interviewed (28.4%) were currently on treatment compared to only 10.8% in 2008.

***Limitation and lessons learned*** Limitations to the implementation of the HIV Strategy largely reflect the limited financial resources for health and HIV and competing priorities within the health sector. These problems have been particularly severe since the end of the Global Fund's Round 5 grant. They include inadequate HIV surveillance and lack of routine monitoring, the need to strengthen Government financial and political support to HIV, inadequate levels of HIV testing sub-optimal ART provision, and the need for a stronger network of NGOs (see also Annex E). Lessons learned are:

[35] WHO (2013), *Consolidated Guidelines on the Use of ARVs for Treating and Preventing HIV Infection; Recommendations for a Public Health Approach*. June 2013. Geneva. http://apps.who.int/iris/bitsream/10665/85321/1/9789241505727_eng.pdf?ua=1

[36] Government of Albania (2011). *Albania Biological Behavioural Surveillance Study – Final Report.* (see Attachment 2)

- Targeted services need to be specific to particular key populations;
- HIV services should be integrated into general health service provision;
- Medium- to long-term funding is an essential foundation for initiatives which seek to build NGO organisational capacity and effectiveness;
- Effective management and treatment of PLWHA requires prompt diagnosis, effective monitoring and diagnosis and treatment of other infections, particularly TB , in addition to the provision of ART;
- A firm commitment to co-finance services is needed from Government;
- Capacity needs strengthening in several areas including monitoring and procurement and supply management.

**National TB program**

As a result of the measures taken to control TB during the past few years, Albania has managed to implement the DOTS strategy throughout the country but the DOT component (one of the five constituents of DOTS) is not applied in all districts in Albania. The new National TB Strategy 2015-2020 (NTS)[37] was designed to build on the successes of the past few years while tackling the factors that constrain improvements in TB control.

***Goal and strategy***

The overarching goal of the NTS is to consolidate the achievements made to date in the fight against TB and reduce TB by the end of 2019. The strategy has four objectives:

1. Ensure quality health care service for all TB patients.
2. Reduce human suffering and the socioeconomic burden of TB.
3. Protect groups that are vulnerable to TB, TB/HIV and MDR.
4. Protect and promote human rights in TB prevention, treatment and control.

***Implementation to date*** Achievements in TB control in Albania are in large part due to the previous TB programme, the NTS 2009-2014, and donor investment.[38] The implementation of the Global Fund Round 5 grant played an important role in revitalising and facilitating the country's fight against TB; it supported the establishment of the necessary physical infrastructure for TB diagnostics and treatment, and strengthened the health system's capacity to address TB. In addition, economic growth has had a positive impact on achievements in TB, with the middle class and the employed having better access to services due to their ability to pay for direct and indirect costs; increasing urbanisation has certainly brought a much larger segment of the population closer to care. Finally, educational improvement has played a role in improving health-seeking behaviours.

The NTS objectives were ambitious but with the exception of a decrease in TB incidence, three out of five targets were achieved, i.e. (i) reaching and maintaining a high percentage of treatment success for positive sputum TB cases (more than 90%); (ii) reducing and maintaining the mortality rate at less than five cases per 100,000 inhabitants; and (iii) more than 75% detection of new cases with smear-positive pulmonary TB. Two targets were not achieved i.e. (i) maintain TB incidence at less than 15 new cases per 100,000 population per year for the next five years by lowering the TB incidence rate to 14 new cases per 100,000 population per year by 2019; (ii) maintain MDR prevalence at less than 2%.

With Global Fund support, some population groups received active screening for the first time. For example, TB screening was conducted in all Albanian prisons resulting in the testing of 1,684 prison inmates of whom 48% had latent TB infection. The screening of 1,000 Roma people, mainly in Tirana, found that 8% (82) of them had TB.

The implementation of these activities was facilitated by collaboration between the HIV and TB Programmes. TB/HIV 'round tables' were started with representatives from the Department of Infectious Diseases, the Pulmonology Department and Public Health Department and the

[37] See Attachment 9
[38] See also Attachment 10

University Hospital Center Mother Teresa (UHCMT), and covered the area of coordination of TB and PLWHA treatment, purified protein derivative (PPD) testing and Isoniazid prophylaxis.

***Limitation and lessons learned*** Lessons learned from implementing the national TB strategy and key limitations of the TB response, concerning the general response and the Round 5 Global Fund grant in particular, are presented here (see Annex G for all lessons learned and Annex F for clinical limitations):

- Ensuring DOT for all TB patients for the whole duration of the treatment is of critical importance. For this to happen, there is need for political will and adequate financial support; in particular, budget allocations are needed: (a) to provide the necessary staff and logistical support for performing basic activities such as supervision and monitoring; and (b) for TB drugs so as to avoid stock-outs.
- There is a need to strengthen integration and coordinated planning so that: (a) TB control is integrated into primary health care; (b) dedicated TB wards are provided in hospitals to minimise cross-infections and avoid overcrowding of facilities for TB patients; (c) more pulmonologists are recruited; (d) private clinics with appropriate facilities are integrated into the TB control programme; and (e) paediatricians, family doctors and nurses are adequately trained in and supervised on TB diagnostic and treatment services for children.
- Pay greater attention to the needs of vulnerable and poor people, and deal with TB-HIV by: (a) screening high risk groups for the development of TB in addition to detecting TB infection among close contacts of TB patients; (b) ensuring a strong supportive legal framework.
- Measures for TB infection control must be further strengthened to ensure access to proper MDR-TB case management and correct airborne infection control measures.
- There is a need to address requirements for MDR-TB.
- Family physicians required training on TB.
- The establishment of the referral system has hampered TB patients' immediate access to services through lack of health insurance
- There is an absence of civil society involvement in TB identification and treatment.
- The National TB Manual required updating to include regulation for the provision of services for key vulnerable groups.

**Joint TB-HIV Activities within the National HIV and TB Programs**

Joint TB/HIV activities were organised for the first time during Global Fund Round 5 implementation. Interventions included the establishment of a joint coordination committee, screening of TB patients for HIV infection and screening of HIV patients for latent TB infection, and information exchange. Unfortunately, however, following the end of the Global Fund programme, these activities were discontinued due to lack of funds.

The new NTS outlines the ambition of seeking to offer HIV testing to all people with TB. Nonetheless, it also recognises challenges in this area including the need to refer patients for HIV testing and limited capacity outside Tirana. The Strategy also recognises a number of groups that are particularly vulnerable to TB including PWID; however, the number of PWID diagnosed with TB remains low although it is recognised that this could be because of under-reporting of injecting drug use in TB treatment settings. The Strategy also recognises the importance of cooperation between TB, HIV programmes and NGOs and that this was strengthened during the period of Global Fund financing under Round 5. However, it is also acknowledged that those gains were not sustained.

The stated NTS policy with regard to HIV/TB is to provide national programmes and their related stakeholders with direction for the implementation of joint TB/HIV activities through a National Coordination Programme for Joint TB/HIV Activities. It is intended that both the HIV and TB programmes, including their partners, should collaborate to ensure access to integrated services for TB/HIV prevention, diagnosis, treatment and care. It is also recommended that all household contacts of an index case infected with HIV are advised of and tested for HIV.

***Lesson learned***

- Need to develop and formally adopt a joint TB/HIV strategy to ensure the effective and ongoing implementation of joint activities.
- The National Coordination Programme for Joint TB/HIV Activities must have clear and agreed terms of reference.
- TB patients should be screened for HIV infection upon commencing treatment with anti-TB drugs.
- Provision should made to provide HIV tests for TB patients hospitalised at UHCMT; and HIV testing should be introduced at regional hospitals that treat TB patients.
- HIV patients should be screened for TB and latent TB on an annual basis, with a proportion undergoing screening for TB infection through IGRA testing.
- Visits to a primary patient's house, by the contact's investigators, are an important aspect of TB control.
- PPD and IGRA should be made available at public health care facilities.
- PLWHA living in the same house or in close contact with TB patients must be treated with chemoprophylaxis to prevent active TB infection.
- PLWHA who have a negative skin test for TB, as well as non-reactive control skin tests, should be considered to be immune- unresponsive.

**Linkage of the programs with the national health strategy**

Albania has two other strategies relevant to HIV and TB that relate to health more broadly: the National Health System Strategy 2007-2013; and the Public Health and Health Promotion Strategy entitled 'Towards a Healthy Country and Healthy People.'

***National Health System Strategy 2007-2013*** The NHSS[39] aimed to improve the health of the population by providing responsive services and financial protection against the catastrophic costs of disease. Its four priorities are: (i) to increase the capacity and efficiency of current health services; (ii) increase access to health services; (iii) improve health system financing; and (iv) improve health system governance. Within (i), there are four goals: (1) reduce financial, geographic, cultural and professional barriers; (2) articulate a network of services able to ensure continuity of care; (3) provide widespread free essential public health services; and (4) provide solid pharmaceutical coverage. The HIV programme is one of five vertical public health programmes which seek to ensure access for the whole population within the third of these goals. Other programmes are mental health, public dental health, immunisation and health promotion.

The NTS is part of the National Health System Strategy and as such is an integral part of the goals noted above. The NTS strategic objectives are in line with the health reforms.

***Public Health and Health Promotion Strategy*** In addition, Albania has a Public Health and Health Promotion Strategy entitled 'Towards a Healthy Country and Healthy People'[40] which identifies the key public health issues as: cardiovascular disease/cancer; accidents; respiratory diseases; mental health; diarrhoeal diseases, and sexual and reproductive health (SRH) which includes cervical cancer and HIV. The strategy contains general targets and actions for the HIV response. These are broadly consistent with the HIV strategy although the public health strategy prioritises HIV prevention among school youth rather than among any other group.

**Country process for development of National Disease Strategic Plans**

There was a debate as to whether or not Albania should submit a combined HIV/TB application to the Global Fund or separate disease-specific requests. Initially the CCM decided on the latter because of the country's vertical disease management structure, the different degrees of

[39] http://www.sdcheath.ch/en/Home/Intervention/Bilateral_Development_Cooperation/Western_Balkan#AlbaniaHealth systems strategy

[40] Government of Albania (2007). *Towards a Healthy Country with Healthy People: Public Health and Health Promotion Strategy 2007-2013*. http://www.shendetesia.gov.al/files/userfiles/Baza_Ligjore/Dokumenta_strategjike/6.pdf

preparedness of those systems and the different areas of focus of the proposed programmes. However, later in 2014 on the advice of the Global Fund, it was decided to submit a joint proposal that would build on the recognition of the importance of greater HIV/TB collaboration and then put this collaboration into operation. Both diseases' national strategies were developed in 2014 but in a somewhat vertical manner, although the TB strategy is more explicit concerning HIV/TB collaboration.

***HIV*** Following a Ministerial Order in March 2014, a working group was established comprising eight persons from the MoH, the IPH, the Department of Infectious Diseases at UHCMT, the HIF and a PLWHA representative. The group held eight or more meetings including round tables in June and July 2014 on issues relating to MSM, PLWHA, PWID, treatment and care, the Roma community and PMTCT. In addition to members of the working group, the round tables were attended by other stakeholders including government officials, NGO staff, representatives of key populations and affected communities and representatives of international agencies, including UNAIDS, the United nations Population Fund (UNFPA) and the United Nations Children's Fund (UNICEF).

Following those consultations, members of the working group drafted relevant sections of the strategy. Technical support was provided through WHO, financed by the Global Fund. Specific areas of technical support included an epidemiological analysis conducted in August 2014, and costing of the strategy and the analysis of approaches to surveillance, treatment and care, which were conducted in November 2014.

The draft strategy document was finalised in mid-December 2014 and its action plan and budget were formally approved by the Government of Albania in January 2015.

***Tuberculosis*** Following a Ministerial Order in March 2014, a new TB strategy was developed with a draft circulated in July 2014 and a working group established, comprising ten members from the MoH, IPH, Paediatric Department at UHCMT and the Pulmonary Clinic at the University Hospital 'Shefqet Ndroqi' (UHSN). The working group has held ten meetings and four consultative meetings/round tables with stakeholders[41], including Government officials, NGO staff and key population representatives. The strategy was finalised in July 2014, and its action plan and budget were formally approved by the Government in January 2015.

## 1.3 Joint planning and alignment of TB and HIV Strategies, Policies and Interventions

### a. Plans for further alignment HIV and TB

Cooperation between TB and HIV programmes was strengthened during the time that both programmes were being supported by the Global Fund under Round 5. However, these gains were not sustained once Global Fund financing ended.

The NTS 2015-2019 highlights the need for improving coordination among HIV prevention and care services and, separately, for TB in order to offer HIV testing to all people with TB. But it also recognises challenges in this area, including the need to refer patients for HIV testing and limited capacity outside Tirana. The Strategy also recognises: (a) groups that are particularly vulnerable to TB, including PWID. However, the number of PWID diagnosed with TB remains low although it is acknowledged that this could be because of underreporting of injecting drug use in TB treatment settings; and (b) the importance of cooperation between TB and HIV programmes and NGOs, which was strengthened during the period of Global Fund financing but not sustained.

Systems to manage TB and HIV are currently administratively separate in Albania although there are some overall coordination mechanisms, e.g. through the MoH and CCM. Nevertheless,

[41] TB governance bodies include: Common Country Mechanism for HIV and TB (CCM); National Public Health Council (DCM no.339, date 4.05.2011, pursuant to article 11 of the Law no. 10138, date 11.05.2009 "On Public Health"); National Coordinating Committee on Immunization (Order of Minister of Health no.158, date 18.03.2010, pursuant to article 31 of the Law no. 10138, date 11.05.2009 "On Public Health"); National Committee on Hospital acquired infections (Order of Minister of Health no.102, date 19.02.2009.

there are a number of areas in which TB/HIV collaboration needs to improve including:

- Establishing a regular consultative forum for TB and HIV responses;
- Ensuring PITC for people diagnosed with TB;
- Ensuring appropriate TB screening for PLWHA;
- Ensuring provision of TB preventative treatment for PLWHA; and
- Ensuring appropriate measures to prevent TB transmission in health facilities treating people with HIV.

Although the country originally decided to submit two separate disease proposals, the importance of greater HIV/TB collaboration is recognised and the eventual decision to submit a joint disease Concept Note reflects the country's intention to strengthen this collaboration. This has resulted in five cross cutting strategies in the current HIV and TB programmes outlined below in Table 3.

**Table 3: Plans for Future Alignment of HIV and TB Cross-cutting Strategies and Interventions**

| Area for Joint Cross-cutting Collaboration | Proposed Interventions (from the Operational Plan) | Expected Outcome |
|---|---|---|
| Consultative forum for national TB and HIV programme responses | • Selection of members of the TB and HIV Technical Experts Group (TEG).<br>• Definition of the TEG's terms of reference (TOR).<br>• Drafting the TEG's operational plan and agenda for key meetings during the period 2016-2018.<br>• Establishing a mechanisms for the cross-cutting coordination of international technical assistance from WHO and UNAIDS.<br>• Agreeing the budget for the TEG and technical assistance.<br>• Developing strategies to involve HIV and TB CSOs and coordinate their activities. | a) The development of New HIV/TB Guidelines to clearly address what should be done, by whom, when and how; and<br>b) a human resources plan for the training, supervision and assessment of the New HIV/TB Guidelines' implementation. |
| Provision of PITC for people diagnosed with TB | • Identification of districts and municipalities with higher incidence of population at risk for HIV and/or TB to develop pilot and demonstration districts and municipalities to achieve the expected outcomes.<br>• Assign specific responsibilities for pilot's implementation to district epidemiologist supported by TB and HIV specialists from the regional level. | a) 100 % of TB and HIV suspects at IPH tested for HIV and TB infection;<br>b) Registration, counselling and implementation of preventive and curative measures as per the New HIV/TB Guidelines (for example, Isoniazid chemoprophylaxis for TB-infected patients and PLWHA);<br>c) Linking TB and HIV infection registries at the district, regional and central levels; and<br>d) Supervision and evaluation of preventive and curative activities undertaken. |
| Provision of appropriate TB screening for PLWHA | • Provide guidelines to all districts and municipalities.<br>• Estimate costs, supplies, training needs and ensure sufficient budget and supplies.<br>• Assign responsibilities to staff to implement and monitor. | a) The HIV Programme will ensure that TB screening is carried out systematically in IPH to the HIV vulnerable risk group as Identified in the HIV Epidemiology Report 2014.<br>b) All HIV-TB infected persons will be registered and appropriate prevention and care measures |

| | | |
|---|---|---|
| | | administered at the PHI level. |
| Provision of TB preventative treatment for PLWHA | • Start in pilot districts with the groups most vulnerable to HIV.<br>• Develop an HR training plan and administer training step-by-step to district staff to implement the New HIV/TB Guidelines<br>• Assign responsibilities to implement and monitor outcomes. | 100% of PLWHA will be registered at the IPH and provided with appropriate prevention and/or care according to the New HIV/TB Guidelines. |
| Put in place appropriate measures to prevent TB transmission in health facilities treating people with HIV | • Identify districts and municipalities with HIV treatment centres and train their staff to implement the New HIV/TB Guidelines.<br>• TB patients who are HIV positive should be hospitalised until the TB smear test is negative. | 100% of PLWHA attending prevention and treatment centres should have a clear chest X Ray and those TB X Ray suspects should be separated and tested urgently with TB bacteriological examination. |

**b. Key barriers to TB and HIV alignment**

Potential obstacles for alignment of HIV and TB include:

- legislative and policy framework development necessary to the effective functioning of the NTP may take more time than expected;
- Attitudinal change is hard to achieve. It may take longer than expected to change the mentality of decision-makers and TB service providers from that of vertical disease health service delivery to a broader-based more holistic public health way of thinking;
- In terms of addressing the needs of key populations: while prison inmates are a 'captive audience', so to speak, existing as they do within the rigid framework of the penal system, it will require a concerted effort to reach the highly mobile R/E population, track them down and maintain contact, and overcome their suspicions of authority to convince them to access services and treatment; and
- More advocacy may be needed to ensure that the Government continue to support the TB programme.

## SECTION 2: FUNDING LANDSCAPE, ADDITIONALITY AND SUSTAINABILITY

### 2.1 Overall Funding Landscape for Upcoming Implementation Period

**a. Availability and Source of Funds**

***HIV*** With the exception of funding from the Global Fund and some small activities in terms of awareness raising and capacity building, all financing for the national response to HIV comes from domestic sources, including the Health Insurance Fund (HIF) and the central Government budget. There is some other financial support for the health system from international sources, e.g. the Swiss Government and the World Bank, but this has no specific focus on HIV. In addition, some international agencies provide limited amounts of technical assistance to the national HIV response. Since the end of the GF Round 5 grant in 2012, the Global Fund has been providing limited support through Continuation of Services funding for OST and second-line ART.

Table 4 presents an overview of the availability of funds for the components of the current HIV strategy (NSPCHA 2015-2019). In none of these areas are funding levels adequate. However, there are some sub-areas that are better funded than others, e.g. the provision of first and second-line ART, and these areas have been excluded from this proposal.

The previous Global Fund grant did encourage the Government to increase its investment in some areas of the HIV response, including the provision of ART, testing and counselling services and some elements of methadone provision. However, this has not yet occurred to the extent that

might have been hoped for. It is expected that the 'willingness to pay' provisions under the New Funding Model will increase the Government's attention to and focus on these matters.

Currently, there are two main strategies for trying to address HIV-related funding gaps. The first relates to the commitment of the Government to expand its areas of financial provision, e.g. to include all second-line ART. Starting from January 2014 the Government will cover all first and second line therapy and will apply for salvage therapy (a new generation of HIV drugs) for patients who develop resistance; The second involves ensuring that the HIF covers the appropriate costs of HIV treatment and care.

**Table 4: Availability of Funding for National HIV Strategy Components**

| Strategic Component | Availability of Funds | Comment |
|---|---|---|
| I. Prevention of new HIV infections among groups at risk | Very low | The only funding available is for methadone services from the Government and the Global Fund. Services have been severely scaled back since the end of the Round 5 Global Fund grant. |
| II. Increased coverage and frequency of HIV testing through existing VCT and health services | Low | Some testing is provided through VCT centres but at low levels. Little if any PITC is available in routine health services, including antenatal services. |
| III. Prevention of vertical HIV transmission from mother to child | Moderate | The Government pays for treatment for female PLWHA and new-born babies. Rapid tests are provided free at the Department of Health and, from 2015 onwards, within antenatal clinics. UNAIDS is also working on awareness raising and capacity building in three cities; Elbasan and Shkodra in 2014, and Vlora in 2015. |
| IV. Prevention of new HIV infections and STIs among the general population | Low | The Government currently supports the provision of rapid tests at the Department of Health and, from 2015, within primary health care. |
| V. HIV/AIDS prevention, care and treatment support systems | Moderate (but not adequate) | Some systems exist, including VCT and blood safety. However, systems are inadequate to ensure that prevention, care and treatment are provided effectively. |
| VI. Improve treatment, care and support for PLWHA | Moderate (but not adequate) | Government is providing first and second line ART. However, there are significant funding gaps related to laboratory monitoring, treatment of opportunistic infections and adequacy of treatment guidelines. PMTCT measures are inadequate. |
| VII. Social care and support | Low | Some mechanisms exist under social support systems paid for with public funds) but these are limited. An Order of the Minister on the support of children under 18 years of age and their families (agreed by the MoH and the Ministry of Social Welfare and Youth) is still pending at the Ministry of Finance. |
| VIII. Monitoring, impact assessment and research | Low | Minimal monitoring is conducted, e.g. case reporting, and no surveillance studies since the end of Global Fund Round 5 grant. |

***Tuberculosis*** The previous Global Fund grant did have the effect of encouraging the Government to increase TB funding during the project's implementation period: all dispensaries were reconstructed; the bacteriological diagnosis network became functional at the district level; the DOTS strategy was initiated and expanded; a large number of publications, protocols and guidelines on TB control were published; and there was a significant capacity building programme for specialists, doctors and nurses in ambulatory care.

However, after a promising start there has not been an expansion of Government-funded

activities to the extent that might have been hoped for. It is expected that the 'willingness to pay' provisions under the New Funding Model will increase the Government's attention to and focus on these matters. The current availability of funding for the National TB Strategy components are shown in Table 5.

**Table 5: Availability of Funding for National TB Strategy Components**

| Strategic Component | Availability of Funds | Comment |
|---|---|---|
| I. Ensure quality health care service for all TB patients | Moderate | First line drugs are provided by the Government, as are some DOT activities provided by dispensary staff including pulmonologists and nurses. Their salaries are paid by the Government and their responsibilities include contact tracing, referral of problematic patients/contacts and Izoniazid chemoprophylaxis. |
| II. Reduce human suffering and social-economic burden of TB | Low | This component is broad and includes timely diagnosis to reduce the viral load of TB in community and thus reduce the chances of infectivity, ensure prompt treatment, reduce the chances of severe TB disease and lead to better treatment outcomes, thus further reducing human suffering.<br>TB patients receive free treatment and laboratory tests but only after they have been diagnosed with TB. Prior to the positive diagnosis, any tests needed have to be paid for by the patient unless they have health insurance.<br>Social assistance for TB patients is provided by public social services institutions following completion of treatment. Sometimes treatment lasts for six to eight months, during which time the patient has no financial and/or social aid. |
| III. Protect groups that are vulnerable to TB, TB/HIV and MDR. | None | There is no budget for this component, which includes the control of TB patients' close contacts and key populations; controlling MDR; preventing TB infection and other airborne infections; increasing cooperation between TB and HIV programmes and the implementation of joint TB-HIV activities<br>There is no legislation to address infection control among vulnerable groups, although this in the pipeline. The policy gap, and the need for legislation in this area, has become more obvious in recent years and relates mainly to the on going health reform and the establishment of a reference system that does not allow uninsured people access to health care services. Once the appropriate legislation is in place, guidelines will be drafted to cover the screening and treatment of these groups.<br>There is a plan to support the establishment of community services. Steps are also being taken to address the lack of treatment for MDR patients, which will be supported by MoH funds ; currently MDR patients have to travel to neighbouring countries such as Kosovo for their treatment. |
| IV. Protect and promote human rights in TB prevention, treatment and control. | None | This component is also unfunded. It covers: (a) health education for TB patients and the general population, the establishment of collaboration and links with key partners (MoH, WHO, USAID), Government departments; and regional and district level health facilities; and (b) the development of print, video, radio and television information education communication (IEC) publicity materials and events. |

### b. Leveraged other donor resources by the proposed Global Fund investment

No funds have been leveraged from other donors for either programme. However, WHO has continuously supported the NTS and provided a significant amount of technical assistance.

### c. Planned actions to address significant funding gaps

As part of the national strategies on HIV/AIDS and TB the government finances the improvement of HIV and TB treatment and prevention services, showing increased responsibility in

those areas. PMTCT and screening for infectious agents in pregnancy are now in the primary health care packages. In addition, guidelines and plans are funded, including those on PMTCT, syphilis control, screening every pregnancy for infectious agents, and screening laboratory guidelines .

Meanwhile, the VCT centers are now part of the public health directories with the staff paid 100% by the state budget. Also kits and reagents as well as activities and maintenance have been fully funded for the first time by the state budget, though the allocations are not fully sufficient to cover all voluntary testing activities.

The modalities of funding for other prevention activities in different vulnerable groups such as PWID, Roma, MSM, FSW have been discussed and some of the activities are planned to be integrated with other public initiatives to preserve their sustainability. Some integrated activities have been started with funding from government public health structures and also in collaboration with social and education services. Most of HIV testing for key at risk population has been provided by the government in government structures like VCT centers or the Institute of Public Health or public health laboratories. Testing at the place of service will be taken over by the state when GF will finish and procurement problems related to such services will be resolved.

The government has committed itself for many years to provide 100% first line ARV treatment and later partial 2nd line HIV treatment. Starting from March 2015 the Government covers all patients on first and second line ART.

***Tuberculosis*** Of the several gaps identified in the TB response under Section 1, the following mitigating actions will be taken:

- The weak political and financial commitment of the Government has changed since the new Government came into power in 2013. This is evident through the involvement of the Deputy Minister for Health in the elaboration of the new NTS and this Concept Note, and the willingness of the Government to increase counterpart funding for TB.
- The insufficient management and supervision capacities at NTP level, its placement in the Pulmonary Department and lack of clinical management to support the epidemiological findings will be addressed by the appointment of a NTP Programme Coordinator at the Institute of Public Health. Staff assigned to the NTP will work full-time on TB and NTP will be provided with the supervisory and management capacities necessary to run an effective programme.
- The Government is working on the establishment of a sustainable system for the procurement, purchase and management of drugs which will improve the PSM for medicines, laboratory test kits, and other medical supplies. The design of a new procurement supply management system (PSM) for TB will address the current lack of a reliable system for the supply and distribution of TB drugs.
- Improvements to the policy framework to support the prevention and treatment of TB cases: all TB and suspected TB cases will receive free testing and services, and close contact investigation will be enforced and supported.
- Insufficient and unevenly distributed human resources will be addressed once the NTP becomes a programme in its own right with a programme director and dedicated premises.
- Inadequate access to health care services will be tackled through the training of dispensary health care workers (HCWs) and other staff under the new programme, who will then work with community groups to discuss and implement ways to access harder to reach populations, such as the Roma.
- Addressing the Roma, prison inmates and other groups at risk will be supported by both the proposed Global Fund investment and the increasing share of programme funds over the next three years from the Government.
- Controlling MDR, preventing TB infection and other airborne infections is a priority under the new NTP. Funds from the Global Fund and other donors will be used to kick-start initiatives in this area, to be taken over by the Government towards the end of the three-year period.
- Contributing to strengthening the health system based on primary health care services will be achieved through the reorganisation of TB from the Pulmonary Clinic to the IPH and the use of

a more public health-oriented approach.

- Engaging people with TB and the community through partnership; HCWs and CSOs will align and work together with communities to identify and implement the best approaches to reach key populations.

| 2.2 Counterpart Financing Requirements | | |
|---|---|---|
| **Counterpart Financing Requirements** | **Compliant?** | **If not, provide a brief justification and planned actions** |
| i. Availability of reliable data to assess compliance | ☒ Yes ☐ No | |
| ii. Minimum threshold government contribution to disease program (low income-5%, lower lower-middle income-20%, upper lower-middle income-40%, upper middle income-60%) | ☒ Yes ☐ No | |
| iii. Increasing government contribution to disease program | ☒ Yes ☐ No | |

The main financial sources for HIV and TB are derived from public sources, like the Ministry of Finance (MOF), and through public taxes and other revenues including the former Health Insurance Fund (HIF). Also there are international sources. The funding agents are:

- The MoH, who allocates the budget to public health institutions, including HIV testing sites and the Blood Centre, and the Detoxification Department at UHCMT. Government funds for HIV for 2013 amount to US$ 1,020,900 and in 2014 US$ 1,140,070;
- National Health Funds (the former Health Insurance Fund) pool financial resources from the MOF and from taxes for purchasing services such as primary care and hospital care.

HIV service providers (prevention and treatment) are; (i) the public UHCMT with public out-patient care; (ii) the National HIV/AIDS Programme within the IPH; (iii) HIV testing sites; and (iv) the Public Centre for Blood Control. TB services providers are: (i) the public University Hospital 'Shefqet Ndroqi' (UHSN); and (ii) dispensaries.

***Expenditure on HIV/AIDS and TB 2013-2014***

Data collection for 2013-2014 expenditures was based on a 'top-down' approach, and techniques for tracking sources of funds using Government financial reporting as well as the reports from various international donors' reports (such as the UN agencies, Global Fund, and so on). This enables the identification of funding sources, as well as the financial agent that allocates the budget. However, the assessment of HIV and TB expenditure is based on the 'bottom–up' approach, collecting the data from service providers for both public and international funds and providing the cost of the above health services providers in relation to HIV/AIDS and TB service delivery.

The assessment of service cost used for the proposal is based on the following:

1. Direct cost for HIV and TB service delivery include ; (i) staff salaries; (ii) cost of examinations or kits and reagents; (iii) living support; and (iv) consumable materials.
2. Indirect costs for HIV and TB service provision include: (i) utility costs (electricity, water, heating, telephone); (ii) cleaning; (iii) laundry; (iv) administration; and (v) maintenance and depreciation costs.

For 2015, HIV and TB assessed expenditure is based on the Government's mid-term planning budget. The Albanian contribution for the period thereafter is estimated on the basis of data from the National Strategic Plans for both diseases. Data on donor funds were provided directly by the

relevant UN agency and no information could be provided for future funds in-country.

On 14 January 2015, the Government formally approved the two national disease plans 2015-2019 and their accompanying budgets. The contribution of the MoH is shown in Table 6 below.

**Table 6: Government Commitment to Funding National HIV and TB Programmes, US$**

| Government Expenditure and Commitment | 2013 (Y-1) | 2014 (Y0) | 2015 (Y1) | 2016 (Y2) | 2017 (Y3) | 2018 (Y4) |
|---|---|---|---|---|---|---|
| HIV | 1,020,900 | 1,140,070 | 1,180,020 | 1,333,020 | 1,532,130 | 1,964,210 |
| TB | 631,120 | 537,003 | 620,000 | 680,200 | 749,850 | 821,050 |

*Source: Letter from Ministry of Health to the Global Fund, 29 January 2015*

***Results based solutions initiated by the government*** Contracts between Health Centers and the Health Insurance Fund (HIF) refer to PHP and are annually being renewed. The budget includes incentives from the government to improve the quality of services provided, including support for training, participation in seminars and conferences, work on the community and also financial incentives for good work, for qualification, after working hours or increase of the number of people accessing the center. Health workers (doctors and nurses) working providing services to PWHIV receive a financial bonus[42].

***Primary Health Care Package (new) 2014*** The new primary health care package (PHP) approved in 2014 by the Ministry of Health include HIV preventions and testing procedures with follow up for children, adults and pregnant women. The protocols for prevention of transmission form mother to child have been developed with support of UNFPA. Furthermore, the package institutionalizes HIV rapid test as one of the laboratory tests provided at PHC level, although the capacity of laboratory staff in health centers to perform the test needs to be raised. The present focus is on women health centers that are part of the PHC system and are able to inform, test and refer in case needed. In addition, promotion activities and community based interventions are part of the PHP and contains clear responsibilities for doctors and nurses to undertake community activities with involvement of local government and Public Health department in the regions.

The new primary health care package also includes TB specific services for adults[43]:

- management of chronic issues ( diagnosis, treatment, prevention and referral based on approved clinical practice guidelines or protocols): chronic cough and tuberculosis;
- information and education about appropriate treatment (chronic cough, tuberculosis, HTA, diabetes, etc.) ;
- information education about TB and HIV/AIDS/STI;
- evaluation, follow up and treatment of TB patient according to guidelines (as part of staff skills in primary health care);
- recommended referral: suspected tuberculosis; any complication of TB or adverse event from its treatment;
- organization of information and education within communities, in schools, families, houses, living and working places and institutions by respecting gender rights of TB and HIV/AIDS/STI (within community services).

[42] Source: VKM Nr.555 date 11.8.2011 (See Attachment 12)

[43] The PHC package does not describe these TB related services in the sections for children and older ages.

## SECTION 3: FUNDING REQUEST TO THE GLOBAL FUND

### 3.1 Programmatic Gap Analysis

The quantifiable programmatic analysis could be carried out for several defined service packages/target groups as presented in the service delivery modules. Calculations are available for PWID, Prisoners, PMTCT, TB, MDR TB, and TB/HIV. The size of the population in need as well as the country targets in the programmatic analysis refer to the National Strategy for the Prevention and Control of HIV/AIDS in Albania 2015-2019 (NSPCHA) and the National TB Strategy 2015-2019 (NTP).

Due to data not available on the total estimated population in need/at risk, programmatic gaps could not be estimated for MSM, FSW, PLWHA. In general, it is acknowledged that the programmatic gap analysis is weak in providing hard evidence for these important service packages. This is because routine and/or survey data can only partly support the analysis. For these non quantifiable programmatic gaps the analysis is mainly based on lessons learned from implemented programs (e.g. GF Rnd. 5), expertise from professionals working in the field and triangulated with other sources available.

Data underscore a large undiagnosed HIV population and an urgent need for expanded testing, while surveillance show a 2:1 male to female ratio implying that MSM and PWID activities are underreported among newly diagnosed cases (see section 1.1). Therefore, the main gaps for HIV pertain to inadequate coverage of prevention interventions for those who are at high risk, and a low uptake of HIV testing. Almost three-quarters of HIV diagnoses are made at a late stage of HIV infection with a CD4 count of less than 350, of which 52% present with a CD4 count of less than 200. The late testing in turn leads to delayed treatment. This is particularly the case among MSM, PWID, SWs and pregnant women. Although adherence data are not available for the treatment cascade, professionals confirm severe weaknesses in the continuum of care, from testing and diagnosis to treatment enrolment, retention and efficiency.

Stock-outs are reported to be frequent and drug regimens are restricted to available generics through bureaucratic processes. Treatment interruptions are reported due to stock out of antiretroviral drugs (ARV), and weak procurement and supply management (PSM) practices. Some ARVs are not available for up to three months each year, which increases the risk of the patient developing resistance to ART. Shortage of drugs has contributed to patient deaths and over a quarter of those receiving ART are already on second line regimens. In addition, monitoring of ART is not adequate due to lack of test kits for CD4 and especially viral load testing. Similarly, diagnoses and treatment of opportunistic infections (OI), i.e. hepatitis, and other viral OI) is not adequate due to shortages in kits and antimicrobials. In addition, guidelines on ART and OI need to be updated based on recent WHO recommendations, and standard operational procedures (SOP) and protocols for management of OI, case management, and referral, are missing.

While some NGOs have gained experience in GF Rnd. 5 and some NGO's are dedicated, important service capacity weaknesses and programmatic gaps remain for key populations at higher risk of HIV infection. The link between the Government and civil society organisations is underdeveloped and the country would gain from a stronger network of NGOs that is well coordinated and has targeted prevention programmes implemented by NGOs and financed and monitored by the Government.

For TB, the main programmatic gaps relate to inadequate capacity for rapid diagnosis, low and incomplete case detection (and case notification), poor contact tracing practices, poor management of TB for children, TB control not integrated in PHC and the lack of adequate human resource capacities at the central NTP level. Despite reported high treatment success rates, directly observed treatment (DOT) is hardly carried out during the follow-up treatment phase. Organisational,

technical and operational standards should guide the TB control program.
Culture and susceptibility drug tests for MDR-TB are not routinely available due to the shortage of reagents and, as a result, there are no reliable data on culture confirmation and MDR prevalence. The proportion of TB cases among pulmonary cases, confirmed by positive smear was 64%, including culture 71%, and there were two MDR cases in 2013. However, MDR patients have never been treated due to the lack of second line drugs, and lack of infrastructure and human resources capacities in the country.

While cases among the R/E community remain low, specific risk factors (see sector 1.1) reveal their vulnerability. The R/E community is not a homogeneous group with uniform HIV/STI and TB needs. This renders them particularly vulnerable, as they tend to have mixed and generally less access to information and services, and are disproportionately represented in MARP groups, including IDUs, MSM and sex workers. While there is no single IEC programme that can meet the diverse information needs of the many R/E sub-communities, specific IEC components for R/E should be incorporated in all TB and HIV/AIDS prevention, care and treatment programmes, to increase their knowledge of, and access to these programmes.

Prison inmates are at high risk of TB (and HIV) infection due to poor sanitary conditions and overcrowding. Upon release they are a potential risk for increasing the epidemic among the general population.

HIV/AIDS and its multidimensional treatment aspects are still new in Albania. Crosscutting services for PLWHA and their family members, including standardized healthcare, psychosocial, support, educational, legal and referral services, information on the disease, facilitation of financial problems for the families of the children, treatment of abandonment cases and palliative care are weak. This set of issues, which needs addressing, remains a responsibility, burden and commitment of health institutions, welfare institutions and local government bodies.

Health care workers and other professional service providers in the social sector are reported to have attitudes that negatively influence health seeking behaviour of MSM, PWID, FSW and PLWHA. User friendly and non-judging health and social care respecting human rights and gender equity is required for ultimately decreasing risk behaviour and increasing access to care. The multidisciplinary concept of case management is not applied by clinical staff at UHCMT due to several reasons: the topic is not included in undergraduate curricula and lack of 'case management' training of GP, the common mentality not to deal with "non clinical problems", the high burden of clinical work at the ambulatory clinic, and the lack of collaboration with community services.

Although government investments are made in establishing the routine data collection system for health and a data warehouse is being finalised, main gaps remain in the surveillance of HIV and TB and monitoring of patients along the treatment cascade. This weakness affects any evidence-based planning and policy making in HIV and TB in the country. Non structural solutions in the form of timely surveys, like behavioural and demographic and health surveys (e.g. IBBS, DHS) fill the gap.

### 3.2 Applicant Funding Request

The programmatic and financial gap analysis address the present needs and constraints of the national response to both the TB and HIV epidemic. The National Strategy for the Prevention and Control of HIV/AIDS in Albania 2015-2019 (NSPCHA) and the National TB Strategy 2015-2019 (NTB) together with other donor-funded projects can only partly address the identified weaknesses and gaps. This funding request is limited to the allocation amount for Albania and is therefore focused on the highest priority gaps within the national HIV and TB responses.

The proposed Concept Note is expected to partially fill the gaps. The goal of the three-year program is to contain the TB and HIV epidemics at the current low levels and reduce TB and HIV-related morbidity and mortality in Albania. Given the concentrated character of the epidemics, the focus is on who men having sex with men (MSM), people who inject drugs (PWID), sex workers

(SW), the transgender population (TG), TB infected people and their contacts, PLWHA and the sexual partners of key affected populations (KP) and PLWHA, the prison population and other vulnerable groups.

While building on the achievements and lessons learned in Global Fund Round 5 and within the framework of the National Programs on TB and HIV and existing programmatic and financial gaps and constraints, the vision for the Concept Note is to foster a long-term sustainable public health care system with continued and sustained TB and HIV prevention, treatment, care and support services increasingly integrated, institutionalised and client-centred, and scaled up through high-impact interventions in the most affected populations and epidemiological hot-spots of the country, while providing quality services that are gender sensitive and can be equitably accessed by key at risk populations.

Given Albania's status as lower-middle income country, the funding request may be for one grant period only and therefore creating sustainable solutions is a key concern in developing the Concept Note. In order to ensure sustainability and address programmatic gaps and lessons learned, the Concept Note would *not* focus on closing all the gaps in prevention activities, but would rather present a grant, which serves as a catalyst for building structures that support the link between the government and a strengthened civil society, and create structural and functional changes within the public health care system to ensures the continuation of prevention activities and the continuum of care after GF funding ends.

The Country Coordination Mechanisms (CCM) has identified seven strategic priorities to which the Programme will contribute[44]. The key strategies aim at ensuring programmatic and financial sustainability, reducing stigmatisation and discrimination and intensifying the identification and outreach of key affected populations in selected areas while ensuring continuum of care. Key to this is a client/patient tracking system that builds up from community level and is linked to a strengthened public surveillance system.

**Strategies**

**1. Ensuring programmatic and financial sustainability**

It is realised that containing the HIV and TB epidemic at current levels in Albania will not be sustained without a continued increase in public resource allocation. Therefore, a phasing out strategy will ensure that government funding will gradually replace a selection of Global Fund funded activities, while seeking support from other donors and the private sector. The transition will be supported by program approaches that aim at optimal use of the scarce resources without a risk of interruption of interventions and with equal quality. They include strengthening the health system, enabling structural and functional changes in VCT, the treatment cascade, linkages between government and NGO/CSOs, procurement and supply management, and the health surveillance system.

A ***comprehensive financial and programmatic sustainability assessment*** will be conducted in year 1 (with TA) with the aim to develop an Action Plan endorsed by the government for the medium and long term objectives of the National HIV and TB Programs, including all interventions and activities supported by the Global Fund. The plan will include measurable outputs, including evidence of significant level of budgeting from domestic resources (Ministry of Finance/MoH) for e.g. securing HIV and TB drugs, maintenance and transportation, legal outsourcing of CSO based prevention programs, surveillance and monitoring tasks, IBBS, etc.. The Action Plan will be developed by HIV and TB Program Coordinators, MoH, Ministry of Finance, CCM and other relevant stakeholders, and will serve as a framework for discussions on current and future financing arrangements to meet program objectives. Following the mid-term review (MTR) of the HIV and TB Programme which will take place in 2017, the Government plans to undertake a

[44] See also Attachment 13

Strategic Investment Case to develop a framework for sustainable financing of both the HIV and TB programmes following the end of the proposed programme's implementation.

***Transition to MoH leadership for HIV and TB prevention*** Once new legislation on social contracting is adopted (expected within 2016), MoH will take over the full responsibility of contracting and managing the sub recipients (SR). This enables the continuation of prevention and other services under government funding. In addition, it enables supporting and strengthening community systems[45], building stronger community based organisations and creating local networks with the purpose of KP identification, early HIV and TB detection and referral, improving access to treatment and fostering support and safe shelter.

***Government HIV and TB treatment support established*** Starting from year 2 MoH will establish regulations for the procurement of all TB drugs from the government budget. All first line drugs for TB have been and will be procured by the government. Second line drugs for MDR-TB treatment are required (Global Fund QA policy) to be procured through GLC/WHO. The country will explore the option of aligning the procurement of first line drugs through the same mechanism. First and second-line ARVs and OST services will be funded by the Government from the start of the GF grant. PMTCT testing/screening will become part of PHC and will be transferred to government funding during program implementation[46]. All media campaigns under GF will be continued by the Government.

Standard operational procedures, protocols and guidelines will be developed with external technical expertise from the Grant and introduced and monitored by MoH at the different tiers of the health system, including those for community outreach activities.

***Increased linkages with health reform and new strategies*** HIV and TB interventions proposed in the Grant are linked with the broader health reform and other health system supporting programs. In depth analyses and development of feasible models of services at the primary health level with the aim of reaching universal health coverage will underpin the development of the new National Health Strategy, for which in July 2015 first steps were undertaken by MOH. This aligns with responsibilities of TB dispensaries to be gradually transferred to Primary Health Care Centers, while their own role will be redefined as outpatient centers of lung diseases, regional labs and diagnostics and support to medicines delivery logistics. The table in Attachment 24 shows how TB check-up and follow-up will be supported through primary health funds and services. In support, the law on health insurance was revised to abolish payment for the visit to the GP and reduction of payment for specialized service visits independent of the insurance status of the person. The payment of care for TB patients will be reduced by 75% at the end of 2015 up to no cost at the end of 2017.

In addition, a new law on the prevention of infections and communicable diseases has been drafted, consulted broadly and aligned with EU legislation. The updated draft with inputs of academia and civil society has been submitted to the Council of Ministers for approval.

Other health system programs, which are internationally supported, include the World Bank project, the 'E-Health Albanian Nationwide Electronic Record' project by the Austrian Government, and the 'Health for All' program supported by the Swiss. The World Bank project aims at 1) improving hospital services (planning, management, legal and regulatory framework, capacity building, service quality/guidelines, National Health account), 2) expanding the HMIS/e-health system (establish and implement HMIS in regional hospitals and improve quality of data; establish health insurance information system for adequate patient handling), and 3) improving the health financing system (payment system reforms in primary and hospital care; Designing and

[45] See "Road map for the Albanian Government: Policy towards a more enabling environment. (Attachment 15)

[46] Once the demand has been created, the Ministry of Health has shown in the recent past that commodity procurement is gradually taken over by the government. For example, till 2009 the share of contraceptives provided by UNFPA, the only contraceptive donor for the public sector, has decreased and MoH allocated increasing budgets to cover the procurement of contraceptive methods. Since 2010, the MoH finances and ensures 100% of the procurement of contraceptives distributed free of charge in the public sector.

piloting pharmaceutical policies which reduce costs and improve access to affordable drugs).

The E-Health Albania project supports the e-registry of the patients, including a reference system from primary to specialized services. TB patient registration as intervention component in the GF Grant will be linked to the system. The "Health for All Project" (HAP) focuses on improving primary health services for the most vulnerable groups in the society or most disadvantage areas in the country. The project aims to cover 10 local units in the country. Implementation started in Dibra and Fier. Dibra is one of the main areas for the TB interventions and the TB Central Program Unit at IPH will seek partnership for joint activities and synergy.

***Governance and management of HIV and TB program ensured*** A sustainable solutions has been found in the governance and management structure for the TB control program. Under CCM governance the NTP will be located as Central TB Management Unit under the Infectious Disease Department of the Institute of Public Health (IPH), the structure being in line with management of other communicable disease like HIV. The attached organogram (Attachment 25) outlines the hierarchical relationships between institutes and health facilities active in the TB program in Albania.

**2. Towards less stigmatization and discrimination**

The Program will provide for the levelling out of inequalities in access to care and the quality of that care with respect to stigma and discrimination directed towards high risk and vulnerable groups. Three main target groups are approached: health and social professional service providers, peers and outreach workers, and the general population. Subjects on human rights, gender and friendly, safe and non-judgmental interaction with KPs are being included in existing curriculae and new training modules for professionals belonging to the judiciary, penitentiary, health and social sectors. Specific mainstreaming messages through national and local media channels are used to reach KPs and the general population. (see also media approach in strategy #3)

**3. Intensified outreach to key populations for early detection**

The programme intends to identify increasing numbers of PWID, MSM and SWs and test them for HIV and TB. This requires a community based, health care based and media approach.

***Community based approach*** The approach aims at building and using community networks for identifying persons at risk while offering safe and confidential shelter, information and referrals. Community based organisations for women, students, youth, and others will be identified per municipality for entering the network and serve as stationary service points. They will be the eyes and ears of the network, identifying at risk persons. The network will be coordinated by an entity to be decided. The multidisciplinary approach requires government health, social service[47] and education departments at municipality level to collaborate and coordinate.

A community based information system will be set-up and inform the network. In addition, in selected representative communities operational research will guide the implementation of the strategy. In addition, community-based organisation will receive support for their contribution to network activities and for providing shelter, VCT, medical aid, OST, DOT in case of TB and referral, and their linkage with government authorities to ensure continuation of prevention activities beyond the GF.

[47] In the overall context of governance reform, Ministry of Social Welfare and Youth (MSWY) with support from UNICEF is currently implementing the social care reform, which aims at creating a reformed system of social care services where families are helped to look after their vulnerable children and adults. For service providers the reforms mean working with central and local government planners and decision makers to provide a range of quality professional social care services that support vulnerable children and adults in their families. For beneficiaries social care reforms means predictable, systematic and practical help from government and NGOs to be cared for in their families and communities. The introduction of social care services at community level is at the core of reform and this is very much related to the MoH efforts to increase the outreach of health services to vulnerable communities and populations at risk.

***Health care based approach*** The approach will use peers and outreach workers operating from stationary service points (for PWIDs called drop-in centres) established for KPs in the community. In particular, female outreach workers will target and service females at risk, including drug users and sex workers. An already tested voucher system (in harm reduction) will be introduced (and pilot tested) encouraging clients to bring in other KPs to service providers on the basis of a scoring system.

In addition, mobile teams will reach more remote areas and hotspots. The stationary service points will service as easily accessible hubs for KPs in the neighbourhood and provide shelter and services adapted to the needs of the people at risk and capacity of the service hub. In addition, the provider initiated testing and counselling approach (PITC) is adopted for selected health centres. VCT Centres and clinics in the community or close by will be connected to the community network.

***Media approach*** National and local media will be used to influence attitudes and behaviour towards KPs both in the general population as well targeting health and social service professionals. Several channels will be addressed for repeated messages, including TV, radio, newspaper, internet, starting with training of journalist (see also strategy #2).

**4. Towards TB early diagnosis and care integrated into PHC - a patient-centred**

Based on lessons learned from the Global Fund Rnd 5 program and repeated recommendations by GLC and the 'End TB Strategy' (WHO), the NTP intends to develop an integrated, patient centered care and prevention program. The NFM Grant supports this with technical and organisation capacity building, technical assistance and infrastructural and equipment upgrades.

***Patient-centred and gradually integrated into PHC*** The approach aims to develop the current system of TB care from a vertically and hospital oriented in-patient model of care to a horizontal district and community supported patient–centred ambulant care model. The Central TB Management Unit will create an effective organisation of TB control throughout the tiers of the health system down to community level, with clear roles/standard operational procedures described for family doctors, nurses, dispensaries, epidemiologists, pulmonologists, pediatricians and the supervisor/ monitoring mechanism).

The outpatient model that includes a prominent role of TB early detection (active case finding/contact tracing and rapid testing possibilities), community treatment and its monitoring (revitalisation of the dispensary nurse model) and social support will be developed and adjusted in order to ultimately support the further development of policies and strategies, and contribute in the long run to a legislative framework on the gradual shift from in-patient to out-patient treatment in TB control, accompanied by effective infection control measures and full integration in primary health care. The change will reduce hospitalization cost, thus liberating resources that could possibly be redirected to ambulatory and patient-centred care at community level, including additional support for DOT and support for TB patients.

The patient-centred ambulant model will be accompanied by development and implementation of TB education plan for women and children in high burden areas, through CSO involvement, to reduce cultural and health knowledge access barriers. Moreover, in terms of service access, financial barriers will be legally prevented through measures based on tax-based health care to be introduced in 2017.

***Solid TB rapid testing*** The TB National Laboratory will be firmly established in a new building at UHSN and accredited by MoH and financially safeguarding its functions. NRL will be responsible for the primary diagnosis of TB by GeneXpert testing, culture, line probe assay (LPA) and drugs susceptibility testing (DST), as well as for reporting the results from central level to the peripheral level. Under the auspices of the NRL and directed by the National TB IC Guidelines the network of 9 peripheral laboratories will undergo necessary measures in order to effectuate their distribution, functioning and logistics network. for safe transport of sputum samples to NRL. NRL supervises peripheral labs by proficiency testing and on site checking.

**5. Ensuring continuum of care after early detection**

The Program will strengthen the links and referrals between testing and treatment facilities and address losses in referrals of KPs between CSO/NGOs and the health care and VCT centres through a case management approach and the strengthened surveillance system (see strategy #5).

The continuum starts with early diagnosis of HIV and TB, particularly among undeclared members of key populations. In order to increase early testing, VCT centers will be made more adapted to the specific needs of KPs in terms of client-provider interaction (friendly and non-judgmental) and collaboration with stationary service points. Furthermore, VCT center functions will be capacitated and extended, now also including health and VCT promotion. The introduction of PITC in selected health settings, including antenatal, TB and STI clinics, will further contribute to early detection. The treatment cascade will benefit from developed and revised SOPs, protocols and guidelines. Accordingly elements of the treatment cascade will be reviewed and modified to support operations (see section 3.3).

The ***case management approach*** is a new concept that needs to be developed in Albania for KPs and PLWHA. It entails non-medical and medical case management. Non-medical case management starts in the community where peers of KPs and outreach workers are trained to support clients in accessing social and medical services and other community resources according to their needs. Peers and outreach workers will be trained to identify the needs and reduce the barriers to care, through advocacy, education and follow-up with the client on admittance to testing, counselling and treatment. This is not a one–off exercise but a labour intensive regular guidance of the client/patient, requiring sufficient human resources in the community for support. Where possible, peer groups will be set-up. Special attention will be given to generate this community support through the engagement of other CSOs like youth, student and women's organisations (see also strategy #3). The medical case management aims at adherence to treatment in case patients are not capable of doing this themselves. Designated case managers from the clinic will be trained in administrative, social and psychological support areas in order to optimally manage the patient's adherence scheme. Non-medical and medical case management will be linked by means of regular coordinating meetings at municipality level organised by the network coordinator (see strategy #3).

**6. Client tracking from community upwards**

In order to generate evidence on program output, the strategy is to commence a community based information system that will be linked to the health information system and surveillance system. At community level the number of KPs identified, cases detected, counselled, tested, and referred will be collected systematically and captured in a local electronic database that is managed by the community network. A selection of this surveillance data will be shared with the health care information system, according to pre-defined indicators.

The improved surveillance system, both at community level and health facility level is indispensable for case management. In turn, case management supports data collection. The surveillance will be strengthened in a way that cases can be easily managed.

A routine data collection system will be developed for HIV and TB to strengthen program monitoring and enable data analysis at the different tiers of the system. For that matter, the data warehouse that is being finalised by IPH from government and other sources, will be supported for linking HIV and TB data sets and interrelationships with other data, and for connecting existing electronic databases using a unique identifier code.

It is expected that a move from the paper based system to electronic data management solutions contribute to the disclosure of data and enable analysis, thus generating transparency and contributing to accountability and evidence based planning and budgeting. Ultimately, the routine information system and epidemiological evidence is to ensure a targeted response. For that matter, the Programme envisages that surveillance data, population size estimates and community based

data may change the overall approach of the grant in due course.

**7. Regionalisation approach**

Albania has been divided into 36 districts and 12 prefectures, however a new administrative map has been approved recently with 61 municipalities and 12 prefectures. All HIV prevention efforts were based on districts and prefectures. However, now all prevention activities and programs related to key population groups will be implemented based on municipalities and prefectures according to HIV prevalence and risk assessment. The map on HIV prevalence in Figure 4 in section 1.1 presents the distribution of cases still per district, however based on that and several risk assessments the priority regions to address key affected populations will be as follow:

1. HIV High priority areas: Tirana, Durres, Vlora, Fier, Elbasan, Korca, Shkodra prefectures
2. HIV Medium priority areas: Lezha, Kukes, Diber, prefectures

All community interventions for HIV will be focused on these prefectures. Both high and medium priority areas will be eligible for the same service packages, but the service model can be different. For example, for MSM a stationary service point will apply in Tirana, while only outreach and mobile units are used in other districts.

The priority regions for TB programs are determined according to TB incidence ( see Figure 4 in section 1.1).

1. TB High priority areas: Kukes, Diber, Shkodra, Lezha, Tirana prefectures.
2. TB Medium priority areas: Durres, Lushnje, Elbasan, Korca, Miredita, Fier, Vlora prefectures.

The TB regionalization approach includes the development of strategies to ensure that in high burden areas active case finding and diagnosis (e.g. sustained availability of isionazid chemoproprophylaxis), contact tracing, appropriate referral and DOT are established and integrated into PHC with support from CSOs. In low to medium TB priority areas only PPD will be a requirement.

Until now there has been little collaboration on HIV and TB prevention programs among civil society actors and health care facilities. HIV and TB services provided by civil society will be paired with health facilities and community health workers who are established in each region. The community services provided by civil society will be expanded to the areas within prefectures as per their priority described above and will seek collaboration with health care and social facilities existing in the region and the specific area (see also strategy #3).

**Objectives**

Provided these seven key strategic priorities, the following two objectives with 14 modules with specific interventions have been identified for the proposed program:

1. To ensure equitable access to high quality TB and HIV prevention, treatment, care and support with a focus on key affected populations (MSM, TG, PWID, SW and clients, PLWHA and partners, prisoners and other vulnerable people most affected by the HIV and TB epidemic);
2. To strengthen the health and community systems that enable needs-based, cost-effective and integrated interventions for key populations mostly affected by the HIV and TB epidemic.

In section 3.3 the applicant funding request is further elaborated, whereby the rational for the selection of the modules and their expected results are specified, together with further detailing the strategies and objectives as provided in the present section.

## 3.3 Modular Template

With reference to the identified strategic priorities of intensified outreach to key populations for early detection, and ensuring continuum of care and tracking key affected populations (KP) while seeking service efficiency and optimal use of resources for sustainable solutions (see section 3.2), and in response to the two objectives of the proposal, fourteen modules were selected (within budget). They can be divided into two main groups, i.e. s*ervice delivery modules* (9) and *enabling environment modules* (5). The service delivery modules generate outputs with reference to objective 1, the enabling environment modules generate output with reference to objective 2.

**Service delivery modules**

The following nine service delivery modules are selected: 1. Prevention programs for men having sex with men (MSM) and transgender persons (TG); 2. Prevention programs for people who inject drugs (PWID); 3. Prevention programs for sex workers (SW) and their clients; 4. HIV treatment, care and support; 5. PMTCT; 6. MDR-TB; 7. Prevention programs for other vulnerable populations (prisoners); 8. TB/HIV; and 9. TB care and prevention.

The general focus of the interventions in these modules is to ensure early detection and continuum of care through the delivery of effective services for KPs, thus filling the gaps of the national HIV and TB Programs as per the programmatic gap analysis.

*Service provision models* Four service provision models for prevention, treatment, care and support will be applied in different combinations, i.e. outreach, mobile units, stationary service points (SSP[48]) and facility-based service points. Throughout these models case management will be piloted and applied to the extent possible. In addition, the community-based KP detection model will become functional (see section 3.3 community based approach). In their application the models are usually combined depending on the location and characteristics of the target population.

**MSM** During the last years HIV prevention for MSM has been focused on HIV education, condom promotion and peer outreach work, but only on a limited scale, and in the capital city Tirana. Activities in this proposal aim at increasing the coverage in Tirana, expanding services to other cities, and extending program coverage of male sex workers. Throughout the programme MSM's active involvement and ownership of these responses are aimed at as they are considered crucial for success.

The proposed strategies include establishment of stationary service points (SSP) that are peer–run and will offer services to different groups of MSM. SSPs for MSM will foster a safe and client-friendly environment for MSM. The SSP in Tirana will provide individual counseling, testing for HIV and other STIs, group meetings, training sessions and social and recreational activities. In addition, the service point will serve as a basis for outreach workers and trained MSM peer educators providing referral and assistance with follow-up to facilitate initial contact with and linkage to appropriate service providers. Services will be advertised through social media.

Operational research will be applied to the establishment of a stationary service point for MSM. This is to assess the challenges and adjust the model as appropriate, and learn lessons to be applied in other districts.

Because relative strong societal stigma and discrimination are expected to hinder replication of the SSP model in districts, in three other cities to be selected from Durres, Vlora, Elbasan, Korca, Shkodra, other service models will be used, i.e. outreach and mobile team. Outreach workers, peer educators and their social network will be guided by the peer driven intervention (PDI) model[49] that is based on chain and peer referrals and that had proved its effectiveness among PWIDs in Round 5. Thus peer educators will promote reducing HIV and STI risk behaviour among MSM.

[48] In the Modular Template called NGO-based service points (NBSP)

[49] Broadhead, R, Heckathorn, D, Weakhern, D et al, Harnessing peer education networks as an instrument for AIDS prevention: results from a peer driven intervention. *Public Health Reports*. 1998;113:42–57. (Attachment 14)

Recruitment and training of peer educators among male sex workers will be given special attention. Mobile units (vans) will allow reaching MSM in places where they meet and gather, such parks, gay bars, etc. The mobile team will operate in close collaboration with the SSP, and offer a range of services including testing. Lastly, the use of websites and social media, and the use of mobile phones will enable mainstreaming of information on HIV and STI prevention, test and treatment.

Assuming a 5 % overlap, it is expected to reach around 41% of target number through SSP, 59% by outreach and mobile units and 5% by health treatment facilities. Regionalisation of interventions, to maximize case finding and increase program sensitivity, is shown as 70% of MSM are planned to be reached in Tirana, while in the districts 30%. This is based in the past experience and the consultation with MSM organizations. The same service packages will be used though.

**TG** Due to the strong societal stigma and discrimination interventions for the TG community will be implemented through the model of outreach and mobile teams. TG will be reached through activities conducted by outreach workers, peer educators and thorough their social network i.e. the PDI model: outreach workers will identify peer educators to reach TG through their social networks. For example, peer educators will be the messengers to promote reducing HIV and STI risk behavior among TG. Particular attention will be given to the recruitment and training of peer educators among the TG community and TG sex workers.

The model of mobile units will allow reaching the TG in places where they meet and gather. The mobile team will operate in close collaboration with the SSP, and offer a range of services including testing; Social media such as Facebook will focus to provide information for TG on HIV and STI prevention, testing and treatment.

Population size estimates of the TG community is planned in the first year using 'programmatic mapping'.

**PWID** The interventions targets PWIDs, including heroin injectors, non-heroin injectors, male/female injectors, young injectors, and their partners. The same regionalisation approach (70/30) as for MSM interventions is used for PWIDs. The service models described above will be applied in the same manner with an expected 48% of targeted PWIDs through SSPs, 60% through outreach and mobile units and 7% through health treatment facilities (assuming 5% overlap).

SSPs that are specifically established for PWIDs will provide comprehensive integrated services including outreach services, break the cycle interventions, contingency management[50] (voucher therapy), women's specific services, psycho-social support to PWIDs and their families, information, education and communication (IEC) on HIV and other blood-borne infections, and safer injecting drug use, access to HIV testing services, provision of wound treatment, referral to VCT, if needed, and referral to treatment for drug dependence. Furthermore, they offer capacity building for governmental service providers, advocacy and networking for harm reduction and access to services.

The packages of services fall under two main strategies: a) preventing / reducing injecting drug use; and b) reducing harm related to drug injection. The interventions will have a multidisciplinary approach, with an explicit focus on service interaction, case management and referrals. Harm-reduction services will also be provided through mobile units (vans), which will allow reaching the most hard-to-reach PWIDs in places where they meet and inject. The mobile van will operate in close collaboration with the SSPs.

[50] **Contingency management (CM)** The programs use vouchers as rewards. Clients will earn vouchers that accumulate in a type of clinic-managed bank account. voucher system (in harm reduction) will be introduced (and pilot tested) encouraging clients to bring in other KPs to service providers on the basis of a scoring system. They can request their vouchers be redeemed for a variety of retail goods and services. Each clients who introduces a new female IDU in the programs, for example, earns a voucher, and the vouchers escalate in amount as number of consecutive new clients increases, such that for the first introduced new female IDU, clients earns $5, the second $6, the third $8, and so on. The standard reward for CM clients starts from one point (equivalent to 1$) for receiving needle/syringes, up to five points (5$) for those who introduces a new female IDU client to the program. Giving the highest points will encourage IDUs using harm reduction services to bring more female injectors to the services One advantage of vouchers is that it allows for individual preferences, and clients can spend their vouchers on virtually any item. Because cash is not provided, the likelihood of clients using vouchers to purchase drugs is reduced. Other items such as : pre paid phone cards, food, fuel, clothing, will be provided.

Operational research will be applied for innovative harm reduction services for PWIDs like break the cycle intervention and contingency management.

It is expected that 10% of the clients to be reached are female injectors. Female drug users have been so far a difficult population group to reach. They are not frequently seen in the usually injecting 'hot spots' where males inject. To respond to the special needs of this group, the proposal aims to implement two strategies: a) to identify and engage female outreach workers to provide services targeting other women. It is assumed that this approach will ensure an increase in the number of female clients and their HIV testing; b) contingency management (voucher therapy), which through a scoring system will encourage clients to bring more female injectors to services provided to PWID.

These SSPs will be established gradually, starting in Year 1 with Tirana and expanding with one in Y2 and another one in Y3 in other priority cities (to be decided from Vlora, Durres, Korca, or Elbasan). This gradual expansion will allow building on experiences and lessons learned, and will avoid overburdening NGO service providers with limited institutional capacity for a rapid scale-up.

**Dual risk groups MSM/FSW injecting drugs** Effective identification and coverage of dual risk population groups i.e. MSM or FSW who inject drugs, will be ensured through the functioning of community networks (see community based approach in section 3.2) and the services of stationary service points (SSP) and mobile units. The overall strategy is to identify persons at dual risk, and while offering them safe and confidential shelter provide the services that are tailored to their immediate needs and arrange referrals if required. The strategy underscores the approach to offer a free selection of service sites that are convenient for them in terms of location, personal preferences etc. It means that a dual risk person, i.e. an injecting drugs user (MSM or FSW), can go for services to a SSP or mobile unit specific for MSM, FSW or for PWID. The SSPs and mobile units for MSM or FSW provide basic harm reduction packages (needle, syringes, other sterile equipment and IEC). For those people who need more specific treatment like OST, following a needs assessment, they will be referred to the sites offering these services. In addition, there are 2 NGOs that offer comprehensive services for both groups (MSM-PWID; FSW-PWID).

**FSW** The lessons learned from GF Round 5 and the mere fact that sex work is illegal in Albania (see Attachment 15 and 21) have been guiding the development of the interventions for FSWs for this proposal. As data on the number of sex workers is not available, one of the first activities will be to respond to this gap by mapping female sex workers to the extent possible. The community based approach using network organisation for identification and the community based data collection system will be applied. Based on newly available data the below described FSW module may need to be adapted in due course.

Apart from street-based sex workers GF funds are proposed to also focus on interventions for the supposedly larger group of young girls who are working as *self-employed sex workers in apartments and hotels and bars – without pimps* – and for whom no specific HIV-prevention programs are in place yet.

The interventions for FSWs are built on four main pillars: (1) influencing the agenda of youth and women NGOs in Albania to focus and integrate the issues of sex workers within their programmes; and supporting the establishment and capacity building of the outreach workers within these organizations, (2) conduct pilot based need assessments among the reached community to evaluate, structure and strategize outreach work and the increase of public service in country, (3) support the promotion of safe behavior and life skills through outreach work and promote/increase the request for services by the community through knowhows and knowwheres, (4) support the development of client/patient friendly health and social services in Albania with special focus on key populations including young women and with special focus on student university campuses.

In practice, the first three pillars translate into a community based approach that will be used to reach FSW. It aims at building and using community networks for identifying persons at risk while offering safe and confidential shelter and referrals. Community based organisations for women,

youth, and other entities (religious organisations, etc.) will be identified in Tirana and other cities for entering the network and serve as stationary service points. A community based information system will be set-up and inform the network. In addition, in selected representative communities operational research will guide the implementation of the strategy. In addition, community-based organisation will receive support for their contribution to network activities and for providing shelter, VCT, medical aid, OST and referral, and their linkage with government authorities to ensure continuation of prevention activity.

The interventions to reach the FSWs will be conducted through establishment of NGO based stationary service points (SSP), outreach and through mobile teams. The SSP will be established in Tirana, as the largest city and with the highest activity of sex work. The interventions include activities like establishing collaborative partnerships with "gatekeepers" (pimps, madams, taxi drivers, hotels/motels owners) to ensure adequate entry-points and support for working with FSWs.

In addition mobile teams of outreach workers for non-street-based FSWs, HIV-prevention among middle-class FSWs, who operate more independently from apartments and hotels/motels/bars, will be implemented through mobile teams Services will be tailored to meet the needs identified and include 1) HIV/STI education; 2) condom promotion and distribution; 3) VCT using rapid HIV tests; and referral to services including STI diagnosis and treatment. The first mobile teams will be established in Tirana and replicate in other major cities to be selected s, (e.g. Vlora, Durres, Korca, Shkodra, Elbasan and Fier). FSW peer volunteers will be recruited among former and active FSWs, and receive training in outreach and education activities.

Operational research will be applied for specific service models for FSW in order to monitor effectiveness of the intervention and make necessary intervention adjustments.

**PMTCT** There is currently no antenatal screening for HIV, hepatitis or syphilis in Albania. All MTC cases are identified in the high risk areas Tirana, Durres, Vlora, Lezha prefectures but also in middle priority areas: Shkodra, Kukes, Diber, Fier, Elbasan, Korca prefectures. Funding is requested to support introduction of provider-initiated testing and counselling in antenatal care settings across the country, including the preparation of standards for PITC and treatment. Services will be promoted for pregnant women HIV testing by campaigns and other means, thus also addressing stigma and discrimination

**Prisoners** Education on TB and HIV prevention in prison will be provided by peer educators and professional prison staff, using IEC materials and through interpersonal communication. Prisoners will also be educated on post-release programmes and harm-reduction services outside prisons. To ensure adequate and continuous HIV prevention services in prisons, socio-medical and other staff of prisons in Tirana (3 prisons), Durres, Fier, Berat, Lezha and Peqin will be trained in HIV counselling and testing, TB and HIV education and other aspects. Voluntary HIV counselling and testing will be available to all prisoners.

The TB control program in prisons will be drafted and implemented in close cooperation with the NTP and the health care system of prisons, including the Ministry of Justice. The control program under the GF grant includes conducting active screening of (new) prison inmates by TST, clinical, radiological and bacteriological examinations as appropriate, and sputum test with geneXpert will be carried out. After the TB diagnosis has been confirmed the prisoner is referred to the prison hospital in Tirana for treatment. In the hospital DOT is given by the prison health staff. After smear conversion the prisoners are discharged from the hospital. In case when Rifampicin-resistance is detected, it will be confirmed by culture, DST and LPA. In terms of technical capacity, socio-medical prison staff will continue with the training activities that were initiated during GF Rnd 5. Reporting of TB cases in the prisons is part of the national surveillance system.

**Roma and Egyptian (R/E) Community** The R/E community (in areas including Tirana, Elbasan, Korce, Fier, Gjirokaster and Berat) is not a homogeneous group with uniform HIV/STI-service needs, but is characterized by specific socio-cultural characteristics, and affected by widespread marginalization, stigma and discrimination by the general population, as well as in specific settings such as health-care services. This renders them particularly vulnerable, as they

have less access to information and services, while members of the Roma community are disproportionately represented in MARP groups, including IDUs, MSM and sex workers. Interventions envisaged will all refer and analyse the numerous recent studies on the R/E community conducted by the EU, UNDP and others (see Attachment 26 for references). The following interventions will also link with existing or forthcoming programs[51] for R/E communities as much as possible.

1. *IEC strategy* A single IEC programme that can meet the diverse information needs of the many R/E sub-communities would not suffice. Therefore, specific IEC components for R/E will be incorporated in all HIV/AIDS prevention, care and treatment programmes, to increase their knowledge of, and access to these programmes. As such an IEC strategy for R/E and also other minorities will be developed that will systematically map and address the specific information needs of these communities. This involves the segmentation of IEC messages, and special attention for communication channels that can reach the R/E community. The strategy will specifically focus on facilitating access to, and client-friendliness of services to the Roma community.

2. *Capacity building* R/E NGOs that will work in the HIV/AIDS field will be trained as well as health professionals working in Roma communities;

3. *Community outreach* will take place through engaging R/E NGOs, local leaders, R/E mediators, and community workers for health related issues (HIV and TB) around the country. The R/E mediator and health staff will work as community teams. Also Health Center staff in and close to R/E communities will be trained and active screening will be carried out in these communities performing PPD/TST and rapid HIV test .

**Continuum of care – VCT, treatment, care and support** Due to lack of data measuring the percentage of people who are missing in each step of the cascade of HIV testing, care and treatment service is not possible. Moreover, the estimated number of PLWHA is missing. Efforts will be done to conduct these estimations in the first year of the program. In the meantime, the following measures are taken to improve the continuum of care and mitigate the risk of suboptimal quality of services:

*1. HIV testing – community based* An approach to achieve high coverage of testing and linkage to care particularly among key affected population will be community based testing. Community based testing include provision of testing in fixed sites (stationary service points for PWIDs, MSM), through mobile outreach in Hot Spots of KPs, and special testing campaigns and events (e.g. for university students). Awareness for HIV testing will be increased through outreach, social network, community and social media, social events and provide information where to get the testing services. Finger pin-prick blood testing with same hour result will be promoted to encourage early diagnosis and treatment. The confirmation test (Western Blot) is done at the Institute of Public Health. While blood tests are sent by SSP or mobile unit health care workers, the follow up and feedback on test results will be done by trained staff (psychologist, social worker). The turnaround time for the results is 24-48 hours.

Furthermore, VCT services will be made more friendly and non-judging services, reducing stigma and discrimination for KPs. The collaboration of NGO/CSOs and VCT/Health facilities will be strengthened through capacity building at both sites. For NGO/CSOs this means training for outreach workers on pre and post-test counseling, to do testing in selected sites, and become familiar with referral guidelines for KPs. Thus, outreach workers and peers will increasingly facilitate the process to link KPs to stationary service points (NGO-based) and more of these stationary service points will be conducting testing. PITC will be adopted as a new approach. Operational research will be applied to assess operational challenges and successes in the linking between KPs and VCTs. Also psycho social interventions will be subject to operational research.

*2. HIV diagnosis – linkage to care (enrollment in care)* Persons who are identified to be infected

[51] UNDP will start in December 2015 the implementation of a new EU funded programme under IPA 2014 titled: "Economic and Social Empowerment for Roma and Egyptians - a booster for social inclusion" (ESERE).

with HIV, viral hepatitis, STIs, or TB will be referred and linked actively to medical care. The non-medical case management approach will be applied (see section 3.2). Persons will be referred, following a needs assessment process, for medical treatment, care, and supportive services. Assistance with follow-up will facilitate initial contact with and linkage to appropriate service providers

Unfortunately, data are not collected on retention from the time of diagnosis to linkage to care, i.e. the number people lost in transition from testing to pre ART care. However HIV care is offered only at UHCMT for all the newly diagnosed cases (all the confirmatory test are performed at IPH). The data from IPH and UHCMT show that almost all cases (more than 90%) are referred to UHCMT (ambulatory clinic and pediatric hospital). Interventions include strengthening the linkage between testing services and UHCMT; introducing standard procedures to ensure that the people who test positive are linked to and retained in services through treatment monitoring; set-up electronic data bases and improve coordination between IPH, NAP and UHCMT; intensify collaboration with network of CSOs and key populations for referral and adherence; increase the availability of Point of Care diagnostics; improve access to ambulatory clinic (friendly hours, receptions, UHCMT case management services, incl. SMS reminding messages, contact with communities and families following HIV status disclosure, etc.), reduction of stigma and discrimination within health care settings.

*3. Antiretroviral therapy (retention in care*): Although data on patients starting ART is known (e.g. 65 cases in 2014), the percentage of those registered at the ambulatory clinic at UHCMT and retained in care is missing. The Program will ensure that the required will be collected and an electronic database will be established and made ready for linking with other data collection systems where necessary, starting the first year. Other interventions include revising the criteria for admission to therapy. The newly WHO guidelines on ART will be introduced in 2015 based on WHO expert team recommendations. These guidelines will increase the number of cases starting ART earlier. In general, the interventions will aim at increasing the number of persons retained on treatment, through improving monitoring of ART according to WHO guidelines, continuous monitoring of CD4, viral load (VL), and genotype resistance test. As a consequence, in-service training for staff of ambulatory clinic, training of ID specialist and nurses on HIV case management, friendly approaches, will be strengthened. In addition, pre-service training will be reviewed for introduction of case management topics in the curricula of undergraduate and post graduate curricula of doctors, nurses and social workers. Furthermore, intervention activities include IEC activities for patients and relatives on treatment.

*4. Efficacy of ART* As indicated in section 3.1 on the programmatic gaps weak procurement and supply management (PSM) limits ART monitoring and causes treatment interruptions. The strategy is to improve schemes of ART through introduction of fixed dose combination schemes and improve PSM (see PSM module) and built capacity of clinical pharmacists. Furthermore, as mentioned above, introduce evidence based monitoring and planning (incl. electronic database), early diagnosis of failure of therapy (clinical, immunological and virological), improve capacities of diagnostics and scale up testing for VL and CD4 based on new WHO guidelines, introduce of resistance testing, but also strengthening CSOs and interventions to support PLWHA in care and support.

**TB care and prevention**

***TB case detection and diagnosis*** *Active case finding/Contact tracing* One of the main lessons from GF Rnd 5. is that active case finding among close contacts of TB patients and populations considered at high risk, including the Roma population, prisoners etc. should be made financially sustainable and thoroughly embedded in the health care system, particularly in primary health care, and supported by health insurance. In addition, active screening of staff in specific TB health care settings will require attention. Therefore, two main strategies will be applied. One is to re-instate active case finding, starting with high burden areas and health settings. For this, GF financial means will be used again. The second strategy is to establish a system of active case finding that is integrated into the health system at primary care and higher care levels in such a way that it is gradually and ultimately fully financed and programmatically supported and coordinated by the

government by the end of the GF Grant in 2018.

To this end, endeavours to remove existing legal barriers that still exist for non-insured TB patients and active screening of high risk populations (TB contacts, Roma, prisoners and PLWHA) will be accompanied by the development of national protocols for active case finding and use of isoniazid for chemoprophylaxis (as part of the TB National Guidelines) for family contacts (including children) and high risk groups. The procurement of tuberculin will be ensured and made available for adults and paediatric formulations for children. The LTBI register will be activated and linked to the electronic TB database. Health education for patients and contacts will be introduced again, while dispensary nurses will be trained. Operational research on active case finding in high burden areas that assesses the model of dispensary nurses as 'patrons of the case finding/contact tracing system' will guide its embedment into primary health care and inform the possible intervention scale-up by the government.

*TB National Reference Laboratory (NRL) and peripheral network* The TB laboratory of the general hospital UHSN has been appointed as NRL by MoH. The NRL will be located at the new premises of the UHSN. The mission of NRL is to ensure that all suspected TB cases have universal access to high quality TB, MDR-TB and HIV-related TB diagnosis. The movement to the new building at the hospital compound will require some civil work and IC engineering design measures (with technical assistance from WHO) to ensure an ideal workflow of the laboratory and proper infection control. Upon development of the IC plan for NRL the required administrative, environmental and respiratory protection measures will be implemented.

Under the auspices of the NRL and directed by the National TB IC Guidelines the network of 9 peripheral laboratories will be reviewed and necessary measures will be taken to ensure the rationale distribution of labs and their adequate workload (with possible closure of some inefficient ones), and strengthen logistics for safe transport of sputum samples to NRL. The NRL also works closely with the Infectious Disease and Pediatric Departments at UHCMT.

From every TB suspect in a primary health center, three consecutive sputum samples will be collected and sent to the dispensary by the family doctor or nurse using WHO recommended packaging (UN 3373). However, the NTP will consider using microscopy of two consecutive sputum specimens instead of three only after assessment of the programme and the logistical and operational implications at country level and if positive it will be supported by a carefully phased implementation plan. This consideration is based WHO policy guidance: most patients with smear-positive TB are identified by examination of the first two sputum specimens and this approach would allow initiation of anti-TB treatment on the same day, which would contribute to lowering patient-related costs and might reduce patient loss in the diagnostic pathway.

At the dispensary, if there is a laboratory, direct smear examination will be performed; afterwards the same samples will be sent to the NRL in Tirana within 24 hours of receipt by a private courier company under contract using UN 3373. If there is not a laboratory at the dispensary, the sputum sample will be sent directly to NRL. Sputum containers and UN 3373 packaging will be purchased and sent to dispensaries and health centers once per year and adequate training on their use will take place. In year 3 the government takes over.

NRL will be responsible for the primary diagnosis of TB by GeneXpert testing, culture, line probe assay (LPA) and drugs susceptibility testing (DST), as well as for reporting the results from central level to the peripheral level. GeneXpert will be covered by GF for the full 3 years of the program. The peripheral laboratory will be responsible for sputum smear examination for the monitoring of therapy. NRL supervises peripheral labs by proficiency testing and on site checking. Proficiency testing for smear microscopy will be performed by sending (annually) the peripheral labs a set of prepared slides to be stained and examined by Ziehl Neelsen microscopy. The prepared sets of slides will be purchased annually from a well known agency such as UKNEQAS or InStand e.V.

Collaboration with the SRL in Milan, Italy for external quality control of DST (confirmation of resistance and 20% of susceptible strains) will be ensured, first by GF and in the last year the activity will be included in the regular quality assurance activities conducted by the government.

The GF Grant will support all necessary work to ensure the implementation of IC engineering alongside maintenance of the old and new lab equipment in the first year only.

Once accredited as the TB NRL, an earmarked government budget (either independent of the hospital or a certain amount safeguarded in the hospital budget) will enable the NRL to service and maintain its laboratory equipment and support the safe transport of sputum samples to NRL. MoH ensures that even if labs come under public-private partnership arrangements, the NRL will be protected.

*Testing of latent TB infection* LTBI diagnosis will have a two steps approach: 1) the initial screening will be conducted with the tuberculin skin test (TST), and 2) in case TST is suspected to be not reliable, Tb blood tests or interferon-gamma release assay (IGRA) will be used. The potential advantages of IGRA over TST include: i) higher sensitivity, ii) higher specificity (less influence by BCG vaccination and NTM infection), iii) less influence by technical problems, and iv) the requirement of only one visit. IGRA tests measure CMIR (cell mediated immune response) to peptide antigens such as ESAT-6, CFP-10 and TB7.7. These antigens are absent from all BCG strains and most of NTMs.

Step two is proposed to be performed for individuals with HIV (100 tests per year for UHCMT) and 50 tests per year are anticipated for UHSN where TST performs poorly. For immuno-compromised cases like HIV it is shown that IGRA are at least as sensitive as TST and that a significant discordance exists between TST and IGRA results due to the failure of TST. A good example is the 70 to 100 new cases of HIV that are diagnosed in Albania every year. The majority of them are late and very late presenters (with CD4 levels below 350 and 200 cell/ul). Among these cases the false negative rate of TST is very high due to allergy related to immune-depression. Therefore IGRA testing will be used to diagnose LTBI among these HIV patients. In total 150 (100+50) tests per year will be ordered and the IGRA test equipment that is expected to increase the diagnostic capacities at the NRL, will be purchased in the first year with GF funds. The cost of maintaining the tests after GF ($6000 per year) will be sustained by MoH.

***Towards integrated TB services in primary health care*** During GF Rnd 5 interventions were designed to increase TB control at the primary health care level. They were not or could only be partly successful for reasons including the lack of structure and organization, legal barriers, lack of funding and support, etc. For an overview of lessons learned and rational for TB control integrated in PHC see Attachments 27. The NTP 2015-2019 clearly describes that 'with the constant decline in TB incidence, the existing "vertical" system for its control has become insufficient. TB activities must necessarily be included in the primary health care service.' It is realised that integration of TB control within the PHC system is not a sinecure and cannot be accomplished overnight. Re-organisation of the TB control program not only relates to larger health reform efforts by the government, but also requires:

- *Development of a detailed National Action Plan on TB Integration into PHC Strategic Plan by* the National TB Programme (at the Institute of Public Health) (Jul 2015 – Mar 2016);
- *Adaptation of the legal framework* A promising start has been the inclusion of TB control in the primary health care package (see for functions CN Section 2.2). The National TB Programme will review and propose adjustments including child and older age services (Nov 2015 – Mar 2016). The legal framework will be reviewed by National TB Programme as for the following regulations (see NTP, page 47/48): 'mandatory reporting of TB cases by doctors and laboratories (Jan 2016 – Jun 2016); mandatory supervised treatment for pulmonary TB cases (Jan 2016 – Jun 2016); mandatory close contact tracing (Jan 2016 – Jun 2016); free of charge service and treatment for all patient categories (Jan 2017); coverage of expenses by the health insurance (Jan 2017); granting invalidity as of the start of treatment for TB patients and not after six months, regardless of the age (Jan 2017); restriction of Rifampicin in the ambulatory pharmaceutical market (Apr 2017), and the issue of patients that interrupt or refuse the treatment (Jan 2016 – Jun 2016).'
- *Adaptation of guidelines, standard operational procedures, protocols for TB integration into PHC,* including case detection and contact tracing, referral, DOT, and social support; registration, database and monitoring mechanism (Jul 2016-Dec 2016);
- *Re-structuring of the TB organisation/functions at the de-central level and link them to regional and national level* (TORs for family doctor, nurse, dispensary, pulmonologist, district

epidemiologist and others), organogram (incl. TB Central Management Unit at IPH, MoH (/PMU), district and local entities), standard operational procedures for directive and reporting lines. For example, the role of the dispensary requires a re-assessment as it is currently floating between hospital and primary health care (Jan 2016-Dec 2016);

- *Inclusion of the functions of a community network of organisations and individuals*, which requires the development and implementation of a TB de-central/outpatient/ambulant model with a community component (Jan 2017 – Dec 2017). Envisaged is a pilot of the outpatient model in high burden areas, such as Shkodra region; the pilot includes organizational set-up, cascade training of health staff, involvement of the community network - including TB community treatment and social support, intervention specific operational research, supervision and monitoring mechanism. It furthermore involves evaluation of the pilot to inform scale up, sustainability and the transition plan (Jan 2018 – Jun 2018). The outpatient model will be developed and adjusted in order to ultimately support the further development of policies and strategies, and contribute in the long run to a legislative framework on the gradual shift from in-patient to out-patient treatment in TB control and full integration in primary health care. Ultimately a scale up and transition to 100% government coverage/funding is foreseen (Jun 2018);
- *(re-)Defining public-private partnership within primary health care (Jul 2015 – Mar 2016)*

***Removal of financial barriers to comprehensive diagnostic TB services*** on TB screening, testing and initial consultations. A proposal on primary health care services to be free of charge for all Albanian citizens (insured and uninsured) from the Health Insurance Fund went through the Council of Ministers and is presently being discussed in Parliament. Ratification is expected in 3 months time. As the country health care financing mechanism will move from national health insurance to general taxation in 2017, in the future health insurance will not be the determinant factor for out-of pocket expenditure anymore. Instead, government decisions on service costs for the patient will be determinant. It is expected that all TB services will become free of charge by then.

***TB services for children and women*** Given the recent increase in prevalence among children, and the present relative poor state of TB management for children in the country, the focus of the interventions will be on improved management and operations through development and use of National Guidelines for the management of TB in children, including LTBI management and contact tracing, capacity building of pediatricians and nurses at the Pediatric Ward at the University Hospital ' Mother Theresa ' and regional hospitals and establishing proper links with pulmonologists, the purchase and adequate distribution of tuberculin managed by the MOH drug supply system (initially paid by GF), and a rigorous supervisory system on the use of drugs and guidelines and SOPs. The efforts are complemented by community based education activities on TB (see also CSS section) in order to influence women's hesitant attitude to access health care due to stigmatization.

**MDR-TB**

***MDR-TB Unit at University Hospital 'Shefqet Ndroqi' (UHSN)*** This former lung hospital in Tirana will establish a separate isolated unit for the treatment of MDR-TB cases in year 1. WHO will technically support the physical design of the unit in order to function according to international standards on MDR TB treatment and infection control (IC). The reconstruction will be financed under the UHSN budget and additionally supported by GF in terms of infrastructural adaptions, ventilation system, UV lamps and maintenance start-up. Maintenance will be covered by UHSN from year 2. The choice is for a less expensive mechanical ventilation system that does not require high running costs after the government takes over maintenance.

The MDR-TB unit will be staffed by two pulmonologists from UHSN, who will be trained abroad on MDR-TB case management, drugs side effects and infection control under the GF Grant. MDR-TB case management capacities of the MDR-TB unit staff will be further developed by increasing their clinical competences through adherence to protocols, international technical assistance, and support in the use of available international tools to manage difficult-to-treat resistant cases (online ERS/WHO Consilium). It furthermore entails coaching of the newly established national MDR-TB

Consilium (including ordering drugs after ERS/WHO Consilium advice), and proper infection control measures. The MDR-TB Unit in collaboration with NRL, IPH, MoH and technical assistance will develop the National Guidelines on MDR-TB.

***MDR-TB case detection and diagnosis*** Early detection of MDR-TB cases will be introduced through rapid diagnostics, foreseen in a new to be developed national diagnostic algorithm (with technical assistance), where GeneXpert (purchased with GF Grant) will be performed to all smear positive and negative cases, to all retreatment cases and other high-risk categories. MDR-TB patients' contacts will also be screened as part of the case detection strategy. A MDR-TB register will be developed, which will link with a central electronic TB registration system. The LMIS at NRL will be developed.

***MDR-TB treatment*** Second-line treatment for MDR-TB patients will be provided (by the GF Grant in 2017, MoH from 2018 onwards) with social support, adverse drug effects will be managed, and clinical and laboratory monitoring of treatment response will be conducted with support of the GF Grant. Treatment of MDR-TB patients from Albania in Peja Hospital in Kosovo will end in 2016 where after UHSN in Tirana will start MDR-TB treatment.

In the meantime, the Central TB Management Unit will coordinate the treatment and follow-up of patients in Peja Hospital and monitor progress. The Central TB Management Unit will coordinate treatment of MDR TB cases with the respective district dispensary (doctor and nurse). In the continuation phase, each month until completion of treatment the MDR-TB patient takes the SLD in Peja Hospital (only in Y1) and continue treatment through the dispensary in Albania. Dispensary (patronage) nurse will continue providing DOT, based on her TORs to be developed. (see Community MDR-TB below).

Drug calculations for designing the treatment protocol will be supported by the ERS/WHO online Consilium. Uninterrupted drug supply with second line drugs will be ensured by procurement of these drugs through GDF/GLC mechanisms. Guidelines for managing adverse side effects under MDR-TB treatment will be translated and the ancillary drugs will be procured to ensure proper management of these adverse effects. Furthermore, incentives to MDR-TB patients will be distributed from the beginning of MDR-TB treatment in the form of food and hygienic packages every month.

***Community MDR-TB care and treatment*** Supervised second-line treatment for MDR-TB patients with DOT will be provided at local/community level, including social support. The continuation of treatment in the out-patient setting requires the development of a community service delivery system based on DOT providers/treatment supporters, whereby dispensary nurses will play a pivotal role. Dispensary (patronage) nurses, particularly in higher TB burden areas, will be identified and trained. Thus, the GF Grant will support the reliable provision of DOT, monitoring outpatient treatment adherence, together with the appropriate management of side effects, and social support and transportation incentives. The dispensary (patronage) nurse will receive incentives (financial) during the outpatient's phase of the treatment. The financial support for the nurses will be during the three years, (3 nurses /year based on the estimated number of 3 MDR TB patients per year) and government will take over after the end of the GF programme. A supervisory mechanisms for all DOT providers will be set-up by MoH.

**TB prevention - infection control**

Three GLC assessments (2010, 2013 and 2015) have indicated the need for infection control measures in health facilities and hospitals in general and specifically for TB prevention. The NTP 2015-2019 re-iterates the requirements for administrative control, environmental control and respiratory protection measures.

MoH considers the CN proposal as final financial support to help raise the standard of infection control particularly for TB in the country. Therefore, responding to the long lasting need for the consistent application of infection control measures at all TB health facilities (health centers/dispensaries and regional and central hospitals), concrete steps will be taken to develop and implement facility-based infection control plans (inpatients and outpatients). The facility plans will closely follow the National TB Infection Control Guidelines and standard operational procedures that will be developed in year 1. These guidelines will be built on the newly drafted 'Infection

Disease Law'[52] for which endorsement by the government is pending.

Infection control measures will include administrative, environmental and respiratory protection measures. This includes the separation/isolation of the different categories of TB patients, such as infectious vs. non-infectious; MDR TB patients vs. sensitive TB, etc. IC measures will also be applied to health care workers for occupational disease protection and screening; the latter guided by a clear HCW screening policy that will be developed. Furthermore, family members and visitors are required to use masks and respirators during their visits to TB patients at the hospitals/dispensaries, and a patient/contacts education plan on IC measures (cough etiquette, etc.) will be developed and implemented.

With an explicit focus by the GF Grant on increasing the capacity of facility health workers, the health facility infection control plans seek for sustainable solutions while introducing quality measures and supervision. MoH supports these efforts and increasingly adopts ownership through taking over IC maintenance in year 2, IC supervisory visits and patient/contacts education in year 3.

**Procurement of TB drugs and pediatric formulations**

Small scale procurement due to few patients have withheld local manufacturers so far to register TB drugs and pediatric formulations. MoH with support from the Global Fund and GDF will encourage manufacturers to register their products in Albania. However, it is important to note a back-up provision as per the Law No. 105/ 2014 "On the medicines and pharmaceutical service":

1. The authorized medicines (registered ones) can be imported by the authorized importers as assigned by the companies that hold the marketing authorization, after being equipped with the import authorization on the basis of the published Register of Medicines from the National Center of Medicines and Medical Devices (an Agency under the Ministry of Health).
2. The import of unauthorized (unregistered) medicines can be carried out through a special authorization by the Minister of Health, case by case. This is a back-up provision, in case any medicines fail to be registered.

All first line drugs (FLD) for TB have been and will be procured by the government. Second line drugs (SLD) for MDR-TB treatment are not available yet in Albania. They will be required (Global Fund QA policy) to be procured through GDF. The country will explore the option of aligning the procurement of FLD through the same mechanism, i.e. establish a legal mechanism of direct procurement from GDF.

Starting from year 2, MoH will regulate and ensure the procurement of *all* TB drugs from the government budget. See Attachment 28 for procurement details by MoH. For SDL this would mean the procurement for at least 3 MDR-TB cases per year. Paediatric formulations and chemoprophylaxis (Isionazid 100 and 300mg) will be procured through GDF. Import licensing will be facilitated by MoH.

For procurement and supply chain management (PSCM) issues on oversight and quantification of FLD/SLD drugs etc., LMIS and other health system strengthening interventions, please see the section on PSCM below in this section 3.3.

**HIV/TB**

Section 1.3 and Table 3 highlight the need for a joint TB/HIV approach and contains five crosscutting areas for collaboration between the HIV and TB National Programs. An array of interventions are proposed for these identified areas in Table 3, which include, among others, the operationalization of a TB/HIV Technical Expert Group, the development of National TB/HIV guidelines, the provision of provider-initiated HIV testing and counselling (PITC) for people diagnosed with TB in TB treatment settings, the provision of appropriate TB screening for PLWHA through rapid diagnostic test using geneXpert, introduction of isoniazid preventative treatment among PLWHA, TB infection control measures in HIV treatment settings and capacity building of

[52] Existing regulation includes the Minister of Health Order Nr. 105, dated 2 December 1998 which specifies actions to be taken in the fight against tuberculosis with regard to implementation of the Law Nr. 7761, dated 19 October 1993 "For prevention and fight against infectious diseases and also implementation of the WHO DOTS strategy in Albania".

health staff at hospitals and regional dispensaries on TB/HIV based on the National TB/HIV guidelines.

**Enabling environment modules**

The following 5 modules are selected: 1. community systems strengthening (CSS) 2. human resource development; 3. procurement and supply chain management (PSM); 4. monitoring and evaluation; and 5. programme management.

***Community systems strengthening (CSS)*** Community systems in the CN are observed as being inextricably linked to the Albanian public health care system and as such its strengthening is regarded an essential factor for a more effective epidemic response. Foremost, the strengthening of community systems is to achieve improved detection and health outcomes for KPs and PLWHA, their partners and TB patients.

Strengthening of the community system will allow improving access to existing health care services, thus enabling services that are more tailored to the needs of specific risk groups. But even more important, it will provide an opportunity to reach the most marginalized and hidden populations, that is, key affected people who may not be visible to existing stationary service points and health facilities due to geographic, social or other factors. As such it will generate the basis for identification of persons at risk and early diagnosis of HIV and TB infections. Moreover, it will support gender equity and rights of risk populations and PLWHA, and will enable an environment that allows sustainability of the national HIV and TB response.

The main principle offered for all the activities on community system strengthening is to join the efforts of different communities for containing the HIV/AIDS and TB epidemic in the country. Two main strategies guide the CSS activities:

*Strategy 1 'Institutional capacity building, planning and leadership development in the community sector':* This first strategy aims at building the capacity of key CSOs working in HIV and TB. This entails organizational strengthening, management and leadership, financial management, human resources, technical skills and a mentoring system, as deemed necessary for building the potential of these organization in contributing to the containment of the epidemics, while working with a growing number of smaller CSOs in the future. CSOs have already been mapped[53] and linkages will be established with the Civil Society Support program supported by the European Union[54].

*Strategy 2 'Social mobilization, building community linkages, collaboration and coordination':* This entails the establishment of the community network (see also section 3.2 Strategy #2 sub 'community based approach') that links CSOs being youth, women, student or other community groups of organizations, and aims at early identification (and referral) of key at risk persons in the community (FSWs, MSM, PWIDs, TB suspects) among the general population (student groups, youth groups, women's groups, men's organisations, but also community health workers/volunteers (e.g. providing DOT), etc.). Network coordinators, operating at the municipality level and recruited from social service offices, health clinics, dispensaries (e.g. for TB dispensary (patronage) nurse), NGOs or other entities to be decided, will set-up the linkages with CSOs in selected communities.

[53] *CSO Mapping* A mapping of civil society organizations (CSO) has been conducted and describes the sector of activity, the field of activity, and the geographical coverage of activity. The mapping is expected to contribute to synergy and efficiency in joint programming and will be instrumental in organizing developing the community based approach that aims at building and using community networks for identifying persons at risk while offering safe and confidential shelter, information and referrals. It furthermore will inform the set-up of the TB community treatment model and social support component. (see Attachment 29)

[54] *Linkage with EU Civil Society Support in Albania* In order to further improve efficiency, CSS interventions will link with EU Civil Society Support, a European Union program in Albania that "strengthens civil society focusing on two main pillars: 1) achieving an environment that is conducive to civil society activities and 2) building the capacity of CSOs to be effective and accountable to independent actors." Specific support will entail CSOs capacity building in eligible sectors including: justice, rule of law, good governance, environment, but also support to vulnerable groups (Roma, socially marginalized, LGBTI, victims of trafficking and other disadvantaged categories) in access to basic services, and gender equality. (see Attachment 30)

CSOs will be made aware and trained on their role as 'eyes and ears' of civil society. The network coordinator assures functionality and monitoring of the system.

The second strategy furthermore includes a) strengthening the relationship between the government and CSO by finding inter-sectoral and common fields of collaboration in HIV and TB programs, and b) strengthening public-private partnership. It is expected that in the near future, probably in 2016, legislation will be ratified that allows non governmental organization to be contracted by the government.

Both strategies are expected to highly contribute to the creation of a sustainable environment for the continuation of preventive services for HIV and TB patients after GF funding ends.

***Human resource management and development*** Human resource management and development aims at reaching the diverse spectrum of service and care providers, managers and specialists in the TB and HIV related field of service provision at the different levels of the health system, from NGOs staff, health care personnel at health and VCT centers, professional at the district and regional health system, as well as specialists at regional dispensaries and providers of tertiary care at district, regional hospitals, UHCMT and National Reference Laboratory for TB, thus including nurses, family doctors, infectionists, pediatricians, epidemiologists, pneumologists and lab technicians. Not only staff in the health sector but also professionals in social and judiciary sectors, like police and penitentiary staff are target of the capacity strengthening endeavour included in the Program. As such the approach identifies the engagement of the public and the private sector.

*NTP Capacity at Central level* TB program coordination by the Central TB Management Unit will be under the Institute of Public Health (IPH) and as such is financed by IPH. The Central TB Management Unit at IPH is responsible for TB program coordination & surveillance and has the following staff assigned: TB Program coordinator, epidemiologist and M&E staff (Attachment 31). The Central TB Management Unit perform all its public health duties as per all communicable diseases control programs at IPH. The TB control program is assisted by a TB clinical coordinator and TB laboratory coordinator both at the University Hospital 'Shefqet Ndroqi' (UHSN). The attached organogram (Attachment 25) outlines the hierarchical relationships between institutes and health facilities active in the TB program in Albania. Central TB Management Unit staff at IPH will be trained internal and international, in organization and management as well as TB technical issues. Where GF funds are used for staffing or training during the 3-year program, these will be taken over by IPH upon ending of the program.

*Quality assurance TB program* Supervision and mentoring at all 3 levels (national, regional and district) is planned to be conducted by the NTP supervisory team of 3-4 people (NTP Manager, laboratory expert, epidemiologist and ad hoq members based on the needs). Each TB health facility, including paediatric wards and the penitentiary system, will be supervised once per year and health centers in higher TB burden areas will receive supervisory visits twice per year. The total number of supervisory visits planned per year is 42. The WHO modified supervisory check list will be used. The supervisory visits will be financed from the GF Grant during the 3 years of the GF Programme and will be covered thereafter by MoH. The Transition Plan will clearly state the sustainability in terms programmatic follow-up and financial support.

*HR distribution strategy* In order to rationalize the distribution of skilled human resources in accordance with the burden of the disease and the need, a two-pronged approach has been developed that benefits the TB control programme: 1. With reference to the post-graduate 4-year clinical training (and residency) in lung diseases, infectious diseases, pediatrics, microbiology and public health (epidemiology) that started in 2014 at the UHCMT on a yearly basis, contractual arrangements between Ministry of Health and the resident medical doctors (MD) are under revision in order to ensure that specialized MD serve in district, regional or university hospitals as needed. 2. Financial incentives (triple of the actual average salary of a district/regional Hospital MD) for MDs serving in understaffed regions of the country have been decided by a Government Decree in July 2015. The implementation of this Government Decree will help in alleviating the current shortage in some specialties in district/regional hospitals.

*HRH capacity building* Training on TB case management, infection control and DOT will be coordinated by the Central TB Management Unit and provided to epidemiologists, paediatricians, dispensary nurses, family doctors and nurses at health centers. In addition, CSOs, community organisations and TB treatment supporters will be trained as part of the strategy towards an 'outpatient model'.

The Institute of Continued Education will ensure accreditation of the training (after receiving the training manual, list of trainers and plan of trainings). Credits will be provided to the training topic. Credits earned through the continuous medical education (CME) system will be better linked to the practice of each medical professional. CME courses will be extended. The HIV and TB accredited training will be an incentive for all health institution in the future to perform refresher training and new training for the ones not trained under the Program.

Human rights based approaches/perspectives will be included in the development of training materials for the TB and HIV programs. Considering the stigma and discrimination present among service providers related to HIV and TB, the activities will become the forum to change not only the technical skills, but the attitudes as well. This becomes particularly relevant for TB services, because - following the approved regulatory framework as described elsewhere - the majority of the training activities target providers that will be engaged in service delivery for the first time.

All education and training activities will be designed with a view on structural changes and institutionalisation, thus ensuring a more sustainable environment that can deliver the conditions for continued education in the field of HIV and TB. The recently approved decision by the government[55] that legitimizes a dedicated separated budget line to health care institution that can be utilized for continuous education activities of the respective health staff, adds to this.

***Monitoring and evaluation*** The programmatic gap analysis and experiences to date in terms of monitoring and planning of HIV and TB interventions in Albania make clear that the information systems on health and health care in general and HIV and TB in particular are not sufficient. This applies to the collection, analysis and reporting on the epidemics among the general and key at risk populations, as well as on testing, the treatment cascade, and care and support activities. In order to adopt an approach of capacity building in routine and non-routine data collection for both HIV and TB, several interconnected interventions are proposed.

*KP size estimates* Of highest importance to the further investments in interventions, for both HIV and TB, is the estimation of population sizes, denominators to the indicators. To this end, programmatic mapping[56] of key/high risk populations i.e. MSM, PWID and FSW, and selected groups at higher risk of TB and HIV will be applied (e.g. the Roma and Egyptian populations) in year 1.

Programmatic mapping reflects a renewed focus on the need for an informed local response to local epidemics. Programmatic mapping is a research method that analysis and documents where key populations can be reached, whether services are available and accessible to key populations in these locations, the typology and size estimation of KPs and where there are gaps in program services for KPs. Results will be used to review proposed interventions and adapt these if necessary.

*Facility based HMIS* Also of high importance is the strengthening of the health facility based management information system (HMIS) and hospital monitoring systems, especially the development of HIV and TB monitoring indicators, data collection and flow, analysis and reporting protocols and guidelines, adequate follow-up and supervision at all levels. It also includes the training of health care providers on issues from data capture to information management and reporting. The intervention under the GF grant will be developed in synergy with current activities on HMIS strengthening and finalisation of the data warehouse at MoH.

[55] Since this year (2015) PHC has the right to use 1% of the budget for continuous education activities of respective health staff, as per the contract for health center financing of health services in primary health care: No, 101,. 4.02.2015. See also Attachment 11 and 17 on the Basic Package and Contract at Primary Health Care – revised for 2015 (Albanian language).

[56] Source: 'Using Programmatic Mapping to Improve Program Access and Coverage for Key Populations. Guidelines for Countries.' [no date]

It is regarded necessary to replace the current paper-based notification forms with an electronic database/reporting system for new HIV diagnosis and TB diagnosis, as it will have the following advantages: a) reporting will be more timely and comprehensive, b) reporting will be more complete due to mandatory fields to fill in, and c) databases can be inter-linked (e.g. VCT and clinical data/TB registry and case management) for improved monitoring and analysis of e.g. enrollment and adherence to treatment. A Unique Identifier Code (UIC) has been developed that enables sharing socio-demographic an risk behavior information that is recorder at SSP and mobile unit level. GF support to this activity supports the digital e-health application (Nationwide Electronic Health Records)[57] that is being established by MoH. This new project will aim to establish an electronic patient forms and will create the patient electronic health history.[58]

*Program M&E capacity building for evidence based planning* Program monitoring will be through measurement of coverage, quality and cost-effectiveness of services by all implementers, with special attention to quality of services. The GF grant will support the following two steps: a) the development and adoption of national quality standards for key HIV services (STIs are already covered). Medical standards will be based on international (WHO) standards, while other service standards for non-medical programmes – e.g. for harm reduction – will be established in agreement with key local implementers and other stakeholders. b) based on these standards, standardized M&E tools will be developed and implemented. The latter involves strengthening the M&E capacity of implementing partners, thus training on using the M&E standards and tools and common MIS software, also including data collection and processing, analysis and data use for programme planning. The network of community based organisations for the mapping and early identification of KPs (as described under CSS) will have community based data collection system, which will be part of the programme M&E system.

*Strengthening Second-Generation Surveillance of HIV/STI* A follow-up IBBS study will be conducted among current KPs (PWID, MSM, SW and Roma) in Y1 and Y3 IBBS data will be incorporated as part of the overall national HIV/STI surveillance and M&E system. he current IBBS protocol will be expanded to include additional STIs (incl. HBV, HCV, syphilis and chlamydia) and strengthen more in-depth data analysis.

***Procurement and supply chain management***

The MoH recognizes the profound weaknesses of the PSM in the country, as the system is hampered by uncontrolled import, distribution and sale of medicines, the presence of counterfeit medicines, uncontrolled medicine price increases raising the costs of healthcare, and the likelihoods of medicines moving from subsidized towards retail channels, products being sold by the unit, multiple requests for reimbursement by pharmacists, and taxes on medicines not being paid. In addition, independent parallel supply systems were created for HIV and TB drugs and commodities, not contributing to sustainable integrated solutions for planning and procurement.

The MoH is adamant to resolve the problems and is working on a project since November 2014 that will establish a track and trace system for drugs, expected ready for introduction by mid 2016[59]. The system aims at creating transparency and accountability in PSM[60]. The medical supply chain for HIV and TB will need to become part of the system and independent previously set-up chains for

[57] Law number 69/2014 on 3.07.2014, http://www.parlament.al/web/pub/ligj_nr_69_dt_3_7_2014_18459_1.pdf

[58] The MoH's new Department of Technology and Information aims to address existing challenges and improve the system through created other linkage with this electronic backbone, such as health facilities, health force, e-prescription, track & trace, HMIS for hospitals. The framework development plan will allow the system to be ready within a cascade timeframe, starting health facilities and health force by June 2015, track & trace by end 2015, e-prescription by end mind 2016, e-health by mid 2017, HMIS by end 2019. Different donors are supporting MoH bringing to a close reality this e-project. WHO is providing some Technical Assistance, Albanian Government, World Bank and Austrian Government are facilitating funds and TA to make IT applications part of the health facilities daily routine.

[59] Currently the track and trace system is being discussed with the Min. Of Finance, negotiations are on going with Customs Authorities and a pilot is carried out in Durres on prescriptions validity.

[60] Among others, the track and trace system project aims to securely identify authorized products, allow inspectors to control the status and legality of any box at any stage of its distribution or sales process, make visible and identify the intended distribution channel of the medicine, provide to the patient tools to have a control mark to authenticate and verify, providing the reference sales price. In addition, the system will ensure that any box gets reimbursed only once by HIF.

HIV and TB drugs and commodities will need to be integrated.

In March 2015 a consultant team from WHO conducted an assessment[61]. Based on this assessment and ongoing PSM reforms (track and trace system) the present PSM Module was developed. Two main strategies are applied: 1. Technical support to the national PSM reform efforts in the field of HIV and TB, and 2. Technical support to PSM at UHCMT in the field of HIV and TB.

Regarding the national PSM on HIV and TB technical assistance will provided for the establishment of a PSM HIV/TB Oversight Committee, the establishment and functioning of the Product Selection and Forecasting Technical Committee (PSFTC), including development of terms of reference, standard operational procedures for needs-based quantification, forecasting, and costing for TB first and second line drugs, tuberculine, ARV drugs and HIV test kits, reagents, other health-products (gloves, masks, etc.) and other services, and collaboration with other agencies, and the set-up of control mechanisms for procurement contracts on TB first and second line drugs, ARV drugs, HIV test kits and reagents, etc. Furthermore, technical assistance through the GF Grant will be provided to support the track and trace system for HIV and TB drugs throughout the supply system, thus building a robust LMIS including stock monitoring and evidence based and timely procurement. Also the GF grant will technically assist the comprehensive assessment of the existing laboratories in order to assess current infrastructure and equipment, test kits and reagents, and human resource capacity.

Supported by MoH, UHCMT will have a new facility for pharmaceutical service by the end of 2016. The GF grant will provide TA for strengthening PMS, supporting the re-organisation of the management and distribution system at UHCMT and train stock keepers and pharmacists accordingly. The managers responsible for monitoring patient data and those responsible for monitoring the supply of TB drugs and ARVs drugs will work together with MoH experts to strengthen HMIS by identifying common data elements and developing methods in which data can be recorded and shared on HIV patients (see also M&E module in this section 3.3).

## 3.4 Focus on Key Populations and/or Highest Impact Interventions

By means of the Concept Note the funding request for Albania, categorized as a lower-middle income country, focuses at least half of the budget (54%) directly on underserved and most at risk populations and/or higher impact interventions. The request is structured around 14 modules encompassing 9 service delivery modules and 5 enabling environment modules..

The general focus of the interventions in the modules is to early diagnose HIV and TB and ensure the continuum of care through the delivery of effective services for most at risk populations filling the gaps of the national HIV and TB Programs as per the programmatic gap analysis.

The service interventions are all focused on most-at-risk populations. Hundred per cent of the HIV prevention activities are targeted for PWID, MSM, FSW and prisoners and are provided through a choice of highest impact prevention models applied through the regionalization strategy. Active TB screening is among TB contacts, PLWHA, prisoners and Roma/Egyptians.

The TB care and prevention intervention as well as MDR-TB and TB/HIV interventions focus on TB patients in the regions with a high burden of TB and HIV and TB/HIV co-infections. PWID, SW, PLWHA, TB contacts, Roma and prisoners are the key groups for interventions.

The enabling environment modules (community systems strengthening, health systems strengthening) are aiming at protecting the human rights of the most-at-risk groups and provide for advocacy for access to high quality services for those groups. The expected outcomes from the interventions under these modules would enable sustainable services for these most-at-risk groups.

[61] Lazarus, Jeff at al. DRAFT Report April 2015 'HIV Programme Review in Albania: Antiretroviral therapy and procurement and supply management'. (see Attachment 16)

## SECTION 4: IMPLEMENTATION ARRANGEMENTS AND RISK ASSESSMENT

### 4.1 Overview of Implementation Arrangements[62]

**a. The reason why the proposed implementation arrangement does not reflect a dual-track financing arrangement**

In 2007, the Global Fund Board approved the recommended, routine use of dual-track financing as a set of measures under the heading of "Strengthening the Role of Civil Society and the Private Sector in the Global Fund's Work." The nature of the goal, objectives and activities of this proposal requires a network of civil society and CBOs working in tandem with the government to implement them successfully. However, in the case of Albania dual-track financing is not proposed for this funding request.

Civil society has played a critical role within every step of the processes of this Concept Note: a broad range of civil society and communities has been involved in its development and will continue to be involved in programme implementation through the delivery of specific interventions for key populations (see details in Section 3). However, the CCM also recognises the somewhat weak organisational and institutional capacity of many CSOs in Albania, most of which have only emerged in recent years after 50 years of strict communist rule. CSOs played a key role as SRs in Global Fund Round 5, and efforts have been made to strengthen the organisational and institutional capacity of CSOs – not only to scale up service delivery beyond their current capacity, but also to allow them to take on larger management responsibilities, including their potential role as a PR for Global Fund programmes. Although repeated and explicit efforts were made to encourage CSOs to become co-PRs, little or no interest has been expressed by CSOs to fulfil this role.

Accordingly, there will only be one PR for this programme, who has been selected through an open call for applicants and a transparent process of assessment and endorsement by the CCM.

Two applications for PR were submitted to the CCM Selection Committee; UNFPA/Nesmark Foundation and the MoH/UNDP Albania. The expression of interest from UNFPA/Nesmark was disqualified as it did not meet the Call for Proposals criteria and no supporting documentation was attached. Accordingly, following review, recommendation and endorsement of the application by the CCM, it was agreed that the MoH is the PR responsible for the overall programme management and achievement of results.

**Selection of MoH as Principle Recipient** The following arguments rationalize the selection of the Ministry of Health as PR as compared to the Institute on Public Health (PR in Rnd. 5):

*MoH's position to coordinate the health sector* MoH is the coordination body for all the public health entities and is responsible for monitoring the quality of services delivered through public and private health facilities in country. Different reporting documents outlined the importance of an improved quality in coordination and collaboration among health entities. During the previous grant period when IPH was the PR, the delegation of roles and responsibilities with other health facilities were artificial, limited only to the grant implementation and not sustainable. Ad hoc solutions were found to enable the grant implementation without building new models of implementation that could be sustained and used in the longer run. MoH is and has been the only leading and coordinating institution which is responsible for guiding and supporting the planning, implementation and monitoring of the health entities including UHCMT, IPH, HIF as part of its

[62] The overall institutional context for the Concept Note and the management arrangements is the national reform of public administration and services delivery. All line ministries, including the Ministry of Health and its respective institutions, participate in the Government's overall reform of its public administration system including but not limited to public financial management, civil service reform and professionalization; and, reform of services delivery. The fight against corruption is contextualized in the efforts to modernize public services delivery through institutionalizing innovations towards good governance.

structural composition and governance mechanisms. Nowadays the MoH is the government institution that is committed to undertake the structural health sector reform on transition towards Universal Health Coverage.

*MoH's mandate to endorse policy and ensure program synergy* As a policy making institution and at the same time as the ultimate responsible entity for NSP implementation, MoH (i) ensures to keep HIV and TB on the country agenda; (ii) has the authority to allocate incremental funding for HIV and TB from the state budget; (iii) coordinate the work of all health institutions under its jurisdiction to ensure synergies for greater impact and outreach and better multidimensional services to PLWHA and key populations.

MoH is also the authority that can enter into specific agreements with line ministries making sure social and educational policies, strategies and laws take into consideration HIV issues and address them respectively. The IPH, as the implementer of the specific public health activities in country does not have the mandate to establish a regulatory framework needed to fully implement the HIV NSP. This is one of the reasons why TB issues are being handled outside of the IPH. During the implementation of the first grant, the IPH did not manage to endorse cooperation protocols that are so much needed for addressing the complexities of HIV related work.

The new law on infection disease, which will be approved by Albanian Parliament at the end 2015 (in line with EU regulations and Directives) will address this bottleneck and the Department of Public Health at MoH will have the authority and will be responsible to facilitate and ensure the collaboration not only on HIV and TB, but on the whole range of infection disease policies in the country, including other public agencies such as Custom Directorate, Border Police Directorate, Food and Safety Agency, etc.

*MoH's position to align and harmonise M&E systems* Monitoring and evaluation was one of the weak points of the first grant implementation. The M&E structures were not able to collect or update regularly all the needed data and produce analytical reports that would advise country planning and policies. The indicators identified for monitoring are based on survey data and not on formal country reporting systems which routinely collect and elaborate the information. It is important to mention that the health entities have closed internal reporting systems and have not been able to align with each other. IPH has not been able to influence the reporting process of various health institutions or to enforce the use of different indicators and data sources that needed to be reported by different entities. The MoH has formalized a new structure that should be able to take forward the institution's commitment to upgrade the data collection and information systems. The country is moving towards a greater use of technology, to the benefit of the health system and its programmers' (see also section 3.3 M&E Module).

*MoH position to steer PSM* PSM systems managed by the IPH lagged behind when it came to services for people living with HIV. While the national public procurement systems has been moving ahead step by step and e-procurement is established throughout the government, the procurement of ARV treatment and health utilities related did not become part of the new reformed system The IPH as the previous PR facilitated the procurement of such health products independently from the UHCMT. As such not sustainable processes were envisioned and undertaken on planning and procuring the ARV. The procurement was not aligned with UHCMT causing thus delays in planning and delivery timing.

MoH is committed to set up a Product Selection and Forecasting Committee by July 2015 to identify if the current ART lines are consistent with the WHO Consolidated Guidelines (2013) in order to optimise ART (see also section 3.3 Module PSM). This Committee will be in charge to conduct accurate product selection and forecasting exercises. In order to mitigate the risks in terms of delays or stock-out during the procurement process, regular meeting will be organized. MoH will support UHCMT pharmacy to be renovated and extend following the International Good Storage of Essential Medicines practices, as by end of 2016.

**b. If More Than One PR Is Nominated, How Co-Ordination Will Occur Between PR(S)**

**for The Same Disease and Across the Two Diseases**

Not applicable.

**c. The Type of Sub-Recipient Management Arrangements Likely to Be Put Into Place and Whether Sub-Recipients Have Been Identified**

***PR Management Arrangements***

The Ministry of Health is the sole Principal Recipient and as such would be responsible for programme management, financial management, SR management (government), supply chain management and M&E. The MoH current structures will need to be enhanced to take on this additional role and therefore staff will be contracted to strengthen its existing units to manage the GF programme as the PR. To ensure sustainability, the positions required for implementation of national programmes in the long term will transition from the GF to government funding. In the area of SR management, because of current legislation constraint, in the first year the MoH will be contracting only governmental SRs. The NGO SRs will be contracted and managed by UNDP in year 1 of the grant and this function will be taken over by the MoH as soon as the legislation is changed (expected year 2 of the grant).

UNDP will enter into a cost sharing agreement with the MoH and at MoH request the GF will disburse funds for UNDP implemented activities directly to UNDP. In light of mentioned constraints, UNDP will be managing NGO SRs in year 1 of the programme. Also, UNDP will support the Ministry to access international market and procure quality assured pharmaceuticals and health products at competitive prices through its existing contracts. As part of the capacity development planning it will be determined what would be a sustainable and cost-effective solution for international procurement of PHP post GF grant. If the government will take over, then transfer of this function, including required capacity development, will be included in the CD plan. The third component implemented by UNDP will be capacity development. After the CD plan is elaborated (expected 2nd quarter 2016) the activities in the CD plan will be implemented by UNDP using various methods. Part of it will be UNDP contracted capacity development officers to support the Ministry staff in daily implementation of the grant. While the Ministry staff will have the decision making capacity for the implementation, UNDP capacity development officers will provide them on the job training for a limited time. Other CD activities include support to revise the legislation, revise the SOPs, introduce new procedures etc. For implementation of the NGO SR management (limited time), PHP procurement and implementation of the CD activities UNDP will engage limited number of staff which will be scaled down over time, as its role is reduced. The capacity support will complement other efforts to strengthen government systems including the MoH management capacity of donor support. The capacity development plan will be firmly grounded in strengthening national institutions to increase program impact and enable the MoH to effectively manage the programme post GF support.

Monthly coordinating meetings will be held by the PMU with MoH and UNDP senior management and regular meetings will be conducted with SRs and technical partners (once every two months). A quarterly meeting will be dedicated to reviewing and providing feedback on progress, and six-monthly meetings will be designated to review Global Fund Management Letters and examine and refine implementation arrangements.

Annual review meetings will be held after receipt of SR audit reports to prepare and submit Annual Commitment and Disbursements Decision requests to the Global Fund. The PR, supported by the PMU, will prepare reports to the Global Fund as per the requirements of the grant agreement and the CCM.

Given the strategic importance of capacity development and taking over of full management of the grant by the MoH,, strengthening national systems and structures for the implementation of National Programs and Global Fund grants is critical. In this context, the Ministry of Health and the other SRs facilitated by UNDP will jointly engage in a capacity development approach to strengthen the National Programs and grant related functions and integrate them into national structures and

systems. This will be supported by the Global Fund and delivered in collaboration with other technical and UN partners.

The primary purpose of the systematic approach to capacity development is to strengthen the implementation systems, procedures and skills of national entities. This helps to build greater country ownership, mitigate the risks and improve the performance of the Global Fund grants. The achievement of the capacity development results, including the revision and utilization of Standard Operating Procedures (SOPs) and accounting systems, prepares MoH for the transition and fully taking over the PR role. The investment in the development of functional capacities of national entities helps to ensure the sustainability of Global Fund grant as well as use the built capacities for implementing future health system strengthening programs.

To be able to develop a detailed Capacity Development and Transition Plan, a detailed plan of activities for the period November-February is presented below as agreed between MoH and UNDP.

**Priority Activities to Finalize the Capacity Development and Transition Plan**

| # | Activity | Deadline |
|---|---|---|
| 1 | Agree with the MoH (and disease programmes) the plan and timeline for CD. | November |
| 2 | MoH and national programmes to agree the division of responsibilities post GF financing. | Early December |
| 3 | UNDP (GF PT) to undertake initial mission for scoping and facilitate self-assessment of the current level of capacity of the MoH and possibly two disease programmes. | December |
| | UNDP (GF PT) to undertake mission to facilitate workshop for capacity development plan development by the MoH | January |
| 4 | First draft of the CD plan shared with the national institution(s). | January |
| 5 | Feedback on the first version of the CD plan provided to UNDP. | January |
| 6 | Second version of the CD plan shared by UNDP | January |
| | CO to facilitate a meeting with national institution(s) to have the CD plan adopted and transition plan developed and endorsed. | February |
| 7 | CD/ transition plan provided to the GF for grant making | February |
| 8 | Implementation of the first phase of the prioritized Capacity Development and Transition Action Plan, to strengthen nation systems. | Before grant start (if pre-allocation of grant funds approved) or after grant start |

***SR Management Arrangements***

The proposal foresees use of two types of SRs for the implementation of the GF grant:: public institutions under the jurisdiction of the Ministry of Health and civil society organizations. A mapping of public and CS SRs has been developed showing the range of institutions' and organizations that will be involved in the project implementation (see Attachment 22).

A phased approach will be adopted for SR management dividing thus the roles and responsibilities between the MoH and UNDP as outlined in 4.3.2 below.

The management of public SRs will be conducted by the Ministry of Health which will be responsible for planning and monitoring and reporting throughout the implementation of GF.

Civil society in Albania has evolved in some areas since the implementation of the previous Global Fund programme under Round 5, which engaged a number of community and NGO SRs. The SRs involved in the health sector include national NGOs with proven experience and capacity and having demonstrated expertise. As far as possible, there will be no change in SRs compared to implementation arrangements under the previous grant; however, this will be subject to satisfactory capacity assessments, approved programme activities, value for money and the willingness of SRs to continue in their designated function.

It is likely that the SRs and SSRs will be selected from among the following organisations:

- Stop AIDS and Aksion Plus, who would support the delivery of the harm reduction including MMT components;

- ALGA, who remains an important outreach organisation for LGBT persons and MSM;
- The LGBT Alliance, who also works prominently in the prevention of transmission of HIV and other STIs among its communities;
- The PLWHA organisation, People Living with HIV/AIDS in Albania, is likely to continue its work on supporting and following up on HIV positive persons as well as advocating for the rights of PLWHA and their family members; and
- The Alliance on AIDS, only established in the past two years, focuses mainly on advocacy and awareness-raising.

All proposed NGO SRs will comply with the UNDP standard procedure of Request for Proposals, including those potential SRs identified above and other prospective SRs as necessary**.**

UNDP will conduct capacity assessments of the proposed SRs prior to the signing of SR Grant Agreements and transfer of funds. The assessments of SRs' capacity will be annexed to the SR Agreements, or included in the SR Annual Work Plans.

UNDP will work to build the skills of the MoH to be able to take over NGO SRS after the law is adapted, so a smooth transition to MoH management of all SRs is ensured.

The PR will undertake eoutine monitoring and evaluation of governmental SR activities will provide a strong evidence-base to inform decision-making and propose changes to programming as well as appraise SR funding requests. During the time UNDP is managing the NGO SRs it will regularly provide the SR reports and outcomes of the verification to the MoH.

The completeness and accuracy of accounting data will be monitored and assessments will be made of management efficiency, adequate separation of responsibilities, safeguarding of liabilities and assets, transparency of transactions, authorisation within the range of respective authority, documentation of transactions processing and the reconciliation of accounts.

**d. Coordination Between the Nominated PR and its Respective Sub-recipients**

The MoH, as the PR has the overall responsibility of programme management and coordination among SRs, be them public SRs or NGO SRs, Based on feedback from SRs and performance reviews by MoH staff overseeing public SR Management and UNDP for NGO SRs, SR will receive capacity building on a regular and ongoing basis as appropriate. The NGO SR Coordinators will regularly monitor GF Grant activities and provide written reports to UNDP who will consolidate the reports for the MoH to submit to the Global Fund.

In addition, as outlined in Section 4.1C above, regular coordination meetings will be held among MoH, UNDP, all SRs and technical partners to review progress in grant implementation, SR performance (through reviewing their quarterly reports and audit findings) and agree any corrective measures as required.

**e. Active Participation of Representatives of Representatives of Women's Organisations, People Living with HIV and TB and Other Key Populations in Programme Implementation**

Key populations will be involved in many different ways in programme implementation:

Many CSOs representing key populations will be directly involved through their role as implementing partners or SRs.

There will be ongoing stakeholder consultations throughout the life of the programme. A Roadmap for Stakeholder Consultations through round tables and other fora will be developed through negotiations with the SRs and other key CSOs who are not acting as SRs.

The MoH will work with the CCM and implementing partners to ensure that activities to obtain this vital feedback, and provide another type of checks and balances, will be built into regular and ongoing M&E activities.

| 4.2 Ensuring Implementation Efficiencies |
|---|
| **Complete this question only if the CCM is overseeing other Global Fund grants.** |
| Not applicable |

| 4.3 Minimum Standards for Principal Recipient (PR) and Program Delivery | | | |
|---|---|---|---|
| PR Name | MoH | Sector | HIV and TB |
| Does this PR currently manage a Global Fund grant for this disease component or a stand-alone cross-cutting HSS grant? | | | Yes |
| Minimum Standards | | CCM Assessment | |
| **1.** The PR demonstrates effective management structures and planning | | The PR, the Ministry of Health of Albania has employed 100 professionals and officials (based on the law for civil servants) to enable the programmatic planning, implementing and monitoring its priorities. The structure of the Ministry reflects the mandate of the institution as well the aim of our institution to perform effectively and also show transparency of the processes. (the organogram of the Ministry attached)<br>While the Ministry as a national institution is based in Tirane, it is able to fulfil and implement its mandate on the ground through line institutions which have clear specific roles to play at national and local level. Through this institutions the Ministry is able to provide equitable access to quality services (primary health structures, clinics, labs and regional hospitals). Further, the Ministry plans policies and interventions, promotes monitors and evaluates the trends of public health (Institute of Public Health and Regional Health Departments).<br>The national coverage of services and monitoring has added value on the way the national and local authorities interact which assures a reflection of the regional/local priorities and special needs.<br>Project/programme management is well organized within specific sectors and reflects the strategic priorities of the country. Officials and professionals are hired based on the law for civil servants and they have specific tasks and clear reporting lines.<br>PSM management is organized in two departments, that of Investments Planning and Procurement that support their activity on the law on Public Procurement Nr.9643 date 20.11.2006<br>Financial management is based on the law on "Management of public budget in the Republic of Albania" Nr.9936 date 26.6.2008.<br>The Ministry of Health is the sole Principal Recipient and as such would be responsible for programme management, financial management, SR management (Gov't), supply chain management and M&E.<br>Because of the legal constraints at this point UNDP will provide temporary support to the PR for the implementation of the following components:<br>• Managing NGO SRs in year 1 of the programme. (until approval of new legislation)<br>• Supporting the Ministry to access international market and procure quality assured pharmaceuticals and health products at competitive prices through its existing contracts.<br>• Supporting MoH in the capacity development by implementing the CD plan of the program, including on the job support for newly recruited MoH staff who will be managing the GF grant and national programmes going forward. | |

| | |
|---|---|
| | Through this approach, the following results can be expected:<br>• The presence of professional and capable staff in the MoH capable of facilitating Grant implementation.<br>• Strengthened capacity of the national HIV and TB programmes to effectively and efficiently manage the Grant.<br>• The transfer of Global Fund-supported activities to government plans and budgets.<br>UNDP systems are designed to ensure transparency, accountability, cost effectiveness and value-for-money. Those systems will be used in the above mentioned areas of temporary support where national counterpart institutional capacities require improvement.<br>For each of identified areas where MoH currently needs UNDP support a detailed plan with timelines will be developed before the grant making period specifying when MoH will gradually take over responsibilities from UNDP. |
| **2.** The PR has the capacity and systems for effective management and oversight of SRs (and relevant SSRs) | MoH will be managing the public SRs throughout the project implementation.<br>The MoH does not routinely involve NGOs in health service delivery and the practice of central government institutions of engaging NGOs for service provision is missing in Albania. While there is overall agreement that this is a deficiency that impedes development, participatory processes and quality provision of services, national partners have committed to amend existing legislation. At this stage, and as anticipated by the beginning of the grant, the process is not complete and does not allow for the line Ministries to contract NGOs or outsource services to civil society organizations. While there is commitment on the part of the Albanian government to introduce changes in the national legislation for the moment this process is not legally regulated. Hence, until the legal impediments have been surpassed, UNDP will support the MoH, using its own robust systems to ensure that resources are available to identify, assess and contract civil society SRs and, once engaged, to oversee their work. Additionally, UNDP will collaborate with the MoH to ensure that the potential risks associated with working with SRs are identified and addressed. Commensurately, based on an understanding of the particular needs and challenges of CSOs, UNDP will assist the Ministry to support the NGO SRs in implementing effective and sustainable programmes. UNDP rules and regulation will be used for NGO for SR management and coordination. A phasing out approach will be adopted for the implementation of this part of program, i.e. NGO SR management. Once new legislation is adopted, MoH will take over the full responsibility of contracting and managing the civil society SRs. Upon the approval of new legislation (expected within 2016) the MoH will pilot contracting SR to see if there are any bottlenecks in the process of contracting, funds transfer and reporting. After the process is confirmed as working (i.e. after the first contracted SR successfully receive the second disbursement upon MoH review and approval of their reports), the management of all other NGO SRs will be transferred to the MoH. |
| **3.** The internal control system of the Principal Recipient is effective to prevent and detect misuse or fraud | Albania's financial audit system is based on a Public Internal Financial Control System which contains a well-structured, comprehensive and consolidated control system with a well-developed methodology, administrative procedures and Internal Audit (IA) aiming to achieve management objectives based on principles of transparency, legality, efficiency and effectiveness.<br>The Public Internal Financial Control System has three components:<br>• Sound financial management and control systems (FMC), the primary responsibility of managers in each unit of public expenditure;<br>• Independent and objective IA to support management and provide |

| | |
|---|---|
| | reasonable assurance that control systems are established in accordance with rules and standards, according to sound financial management principles; and<br>• Central Harmonisation Units (CHU) in the Ministry of Finance (MOF) to design and implement a methodology to harmonise and standardise the systems for FMC and IA.<br>UNDP's internal control system (ICS) is effective in preventing and detecting misuse or fraud. All UNDP operations are implemented in line with Programme and Operations Policies and Procedures which entails a level of control according to the internal control framework. The ICS ensures consistent adherence to policies and procedures, and compliance with its grant agreement with the Global Fund. . |
| **4.** The PR's financial management system is effective and accurate | The public accounting system enables managers to timely make payments, track and report on the implementation of the work plan in a timely manner, in 'real' time.<br>The MoH has a Finance Department with finance and accounting functions both at Ministry headquarters and every dependent institution. The Ministry has sufficient capacity to make payments, disburse funds to government SRs, monitor the budget, manage the cash flow and report to the GF. However, as mentioned because of the current legislative constraints, this system has not been designed to work with civil society service providers.<br>The new legislation on CS contracting will regulate further this area influencing the improvement of financial system management and reporting. Part of UNDP CD plan (pending confirmation from the MoH capacity assessment) will be to develop the systems for financial management of NGOs. |
| **5.** Central and regional warehouse have capacity, and are aligned with good storage practices to ensure adequate condition, integrity and security of health products | The MoH is responsible for the PSM of drugs, health utilities and equipment in all areas other than HIV and TB, and as such, it has a legal framework and operating standards. Under the envisaged programme, it is expected that only a modest volume of health commodities will be procured. The national storage and warehousing facilities will be used for the commodities procured under the Grant.<br>Moreover, in response to issues raised through Global Fund Management Letters, the MoH has improved conditions at various warehousing facilities – notably, the Durres MMT centre have been improved and there is now a secure storage case in the centre. PSM strengthening has also been included within the new national HIV strategy. |
| **6.** The distribution systems and transportation arrangements are efficient to ensure continued and secured supply of health products to end users to avoid treatment and/or programme disruptions | Supply chain management is provided by the Ministry to its health facilities and under the forthcoming Grant this will include provision of OST, medicines and health equipment to implementing NGOs. Experiences gained during the Round 5 grant implementation have contributed to the establishment of procurement procedures, monitoring and reporting from NGOs to the MoH, and vice versa. However, although specific guidelines exist, hospitals still have to contend with a lack of drugs or equipment which impacts on their ability to provide services. Steps have been taken in the past to improve the systems, especially with procurement of ARVs supported by UNICEF. Although some progress has been made, the PSM sector is weak and requires further strengthening.<br>Cognizant of the comments in Global Fund Management Letters related to procurement issues (for example, the need for a more systematic approach to quantifying ARV needs to avoid stock-outs, and methadone management), the MoH is using the previous Global Fund-supported system assessment and mechanisms for addressing system gaps to design a new PSM approach. A WHO technical assistance mission advised on treatment guidelines and PSM practices in September 2014. The MoH plans to establish an online computer tracking software tool in the University Hospital Pharmacy which will allow |

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| | for timely planning, including updating of the hospital drug inventory to prevent stock-outs. Finally, technical assistance will be sought to assist the MoH to develop a consolidated Procurement Supply Management framework.<br>UNDP will support the Ministry to access international market and procure quality assured pharmaceuticals and health products at competitive prices through its existing contracts. As part of the capacity development planning it will be determined what would be a sustainable and cost-effective solution for international procurement of PHP post GF grant. |
| **7.** Data-collection capacity and tools are in place to monitor programme performance | In May 2014, a standardised format and methodology for collecting and reporting health indicators was approved by the Government. For the first time ever, the reporting format includes reporting from private health facilities.<br>The country is moving towards a greater use of technology, to the benefit of the health system and its programmes. The Ministry is establishing a digital database and reporting software. The MoH's new Department of Technology and Information aims to address existing challenges and improve the system through the use of web-based reporting.<br>Ministry of Health is being supported by Government of Austria and the World Bank to build a consolidated system of patient record and from the World Bank on building a heath information management system. These are strategic interventions will improve data collection capacity of MoH and will create information platforms that can monitor program progress and performance. |
| **8.** A functional routine reporting system with reasonable coverage is in place to report programme performance timely and accurately | The Ministry of Health has an established routine reporting within its public health institutions. The system is based on the best practices from the region and reflects the country specificities.<br>In December 2004, a Monitoring and Evaluation Reference Group (MERG) was established composed of specialists in the field of HIV/AIDS including people from different institutions, such as IPH, MoH, and academic institutions. Roles of the MERG include developing a set of indicators for the national HIV/AIDS M&E system, data collection and analysis and data dissemination (NAP, 2004a). The MERG developed a preliminary set of indicators (NAP, 2004b) for use within a national M&E system.<br>The supervision and monitoring component of the TB programme is based on a system of visits from the central to the peripheral level, performed irregularly, with limited feed back to the visited units. At the same time, the TB surveillance is based on aggregated data reported from the 30 peripheral units to the central level (Ministry of Health) and the data are merged at this level.<br>Outside the public health system, data on key populations people reached with targeted interventions will be provided by CSO SRs. This quarterly reporting requirement is included in the standard UNDP-SR agreement. Until the NGO SRs are fully integrated under the MoH activities, UNDP will receive quarterly reports from the NGO SRs and after verification report the result to MoH. MoH will collate and analyze the information, submit reports to the GF and if required take corrective actions based on the programme performance. |
| **9.** Implementers have capacity to comply with quality requirements and to monitor product quality throughout the in-country supply | The PR has strong quality assurance systems in place. Ministry of Health has established the National Center for Drugs Control as the only entity responsible to guarantee the quality, efficiency and unified prices for drags in Albania. The National Centre for Drugs Control, on the chain of drug management, is responsible to monitor, inform and raise awareness of health professionals as well as clients on drugs quality, respecting the principles of transparency, non discrimination, equality and competiveness.<br>The National Centre for Drugs Control is governed by law nr.105 date 2014 "On drugs and pharmaceutical services". The centre fulfils its responsibilities |

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| chain | through professional staff, experiences and well positioned within the chain of procurement. The center operated in close cooperation with other entities such as Institute of Public Health, taxation offices, health inspectorate, hospitals etc.<br>For the health products procured by UNDP, the established procurement systems ensure the supply of quality-assured products. A Quality Assurance Plan will be developed to ensure that all aspects of quality assurance will be monitored, and it will cover the following areas of product selection, international transport, transit, reception, quality control, central storage, peripheral storage, distribution, waste management, pharmacovigilance, rational use and development of capacities. Quality control will be performed at receipt of the medicines in country and along the supply chain. The national medicines regulatory authority will be the key national partner in this area. For items procured by UNDP, some parts of the QAP will be responsibility of UNDP, while after receipt in the country, the remaining steps will be responsibility of the MoH with the support of National Center for Drugs Control. |

## 4.4 Current or Anticipated Risks to Program Delivery and PR(s) Performance

### a. Risks to Program Delivery and PR performance

Albania is a small country which does not encounter geographical issues to impact the programme implementation. From legal and structural framework we should mention that Albania Government has undertaken health reform aiming for universal coverage in the near future.

MoH will be supported by UNDP in relation to the new grant risk assessment to Programme delivery. UNDP is well aware of the changes being made under the New Funding Model and Global Fund's new programme modules and risk management tools like the Grant Risk Assessment and Action Planning Tool which will also be utilized as necessary.

### b. Proposed risk mitigation measures

MoH will be supported by UNDP to improve and enforce the risk mitigation measures. UNDP already has well established systems on risk mitigation and also capacities to properly address the bottlenecks. Part of overall risk mitigation is engaging UNDP to support the MoH in the first stages of the grant.

Albania is a small country able to reach all areas within 24 hours. Anyhow there are some situation which could create difficulties in service provision of services: aggravated weather conditions in winter may isolate some mountainous areas for short period of time up to 1 month. Also flooding, as happen late last year, may affect the services for shorter periods. The government has developed the emergency plan with responsibilities delegated to the prefecture level. The reproductive health is part of the emergency plan based on the standards of UNFPA.

A contingency plan will be developed as part of the programme to identify any other risk linked with specificities of the programme implementation, key populations and government priorities

In developing the concept note a number risks have been identified that relate to the following issues:

*Lack of capacity to manage and coordinate the needs of both programs and align them with overall health reform* - Strong governance mechanisms of health system are fundamental for the achievement of the objectives contained in the country's policy documents. The leading coordination role of the MoH to ensure synergies of the two national programs as well as to reinforce accountability mechanisms from all partners in this endeavour is vital for ensuring the achievement of impact results. The programme will put in place due governance structures and coordination mechanisms from the very start of programme implementation so that the above risk is addressed. Coordination with the other ongoing programs in support of improvement of health system in Albania (from Austria and the World Bank) will be ensured to address overall governance and coordination risks (see strategy #1, section 3.2).

*Changes in the political environment to lower the importance of HIV and TB* . While the MoH is engaged in an ambitious reform agenda of the health system which is crucial for the achievement of identified results in the areas of HIV and TB, changes in the political environment and priority setting could influence the realization of the National Strategies of TB and HIV. The CCM with the support of key Government, civil society and development partners, will undertake continuous advocacy to ensure wide political commitment towards the fight against HIV and TB to mitigate this risk as well as effective engagement of civil society in decision-making process.

*Lack of sound partnerships among state and non-state institutions and civil society*. Successful implementation will require a multi-sectoral response involving partners from all government institutions and civil society. Any significant lack of commitment or capacity to partner and implement jointly will seriously affect the achievement of identified results. The program will support the development of a partnership framework and capacity support. The capacity support plan will be developed to address the capacity needs of partner institutions and CS to network, coordinate and deliver on the outcome. Its continuous update will ensure addressing the gaps throughout the grant implementation phase.

*Low level of development of results based management systems in the country* - Lack of proper reporting structure, weak analytical capabilities alongside with quality assurance of reported data, will negatively affect the evidence based planning and implementation of the national plans of TB and HIV. To mitigate these risks the new M&E framework has been developed to support the implementation of national plans and to coordinate monitoring by stakeholders. It clearly outlines reporting structures and hierarchies; provides indicators on results-based management and outlines responsibility of each partner. UNDP will support the implementation of RBM principles throughout the program implementation.

An initial risk log has been prepared (Attachment 23) , which will be regularly updated on a quarterly basis.