

**Master plan for strengthening the HIV, tuberculosis and malaria
response in the Bolivarian Republic of Venezuela from a public health
perspective**

Update – December 2018

Introduction

The Master Plan for the strengthening of the response to HIV, tuberculosis and malaria in the Bolivarian Republic of Venezuela from a public health perspective (MP) was developed as the result of a joint PAHO/WHO and UNAIDS technical mission carried out in Caracas, Venezuela, in the days June 18-22, 2018. Representatives from the national HIV, TB and Malaria Programs, as well as health providers and civil society actively participated in its development. The Plan was subsequently presented to the national authorities who gave approval of the document, as well as to State coordinators, the Venezuelan Society of Infectious Diseases, Pulmonology, Pediatrics and Gynecology/Obstetrics.

The main objective of this addendum is to update information on purchases, donations and stocks of strategic commodities for the prevention and control of HIV, tuberculosis and malaria, as well as the situation of technical cooperation and coordination with partners and donors to support the implementation of the MP.

Summary of main gaps

The Master Plan has been instrumental to engage partners and donors and is recognized as the reference to provide a coordinated support to Venezuela to address the gaps identified based on the most up-to-date available information. Below a summary of achievements and main gaps.

- Sustained access to antiretroviral treatment will soon be resumed and ensured for most people living with HIV in the country. It is estimated that incoming donations (summarized in table 3), especially DTG-based regimens, will guarantee treatment for up to 85% of people with HIV diagnosed and linked to care for the first year of the plan. It is urgent to identify additional sources to ensure uninterrupted access to treatment for the remaining 15%, especially children with HIV. Viral load monitoring is the second most urgent gap that needs to be addressed to ensure that treatment is delivered effectively and to ensure timely switch in case of resistance and failure. Significant additional gaps persist in terms of medicines for opportunistic infections, diagnostics and HIV prevention commodities (condoms and lubricants).
- For tuberculosis, the priority is to close the gap in fixed dose combination drugs for the treatment of drug-susceptible TB (ISONIAZID 75 mg + RIFAMPICIN 150 mg+ PYRAZINAMIDE 400 mg + ETHAMBUTOL 275 mg and ISONIAZID 150 mg + RIFAMPICIN 150 mg) and diagnostics for TB (Xpert® MTB/RIF cartridges and GeneXpert® machines).
- For malaria, the priority continues to be key supplies for case management (RDTs and commodities for microscopy and medicines, including drugs to treat severe malaria), as well as vector control supplies (LLIN and insecticides), and the costs associated with the logistics of implementation the prevention and control interventions.

Progress

Within a week after carrying out the mission for the preparation of the Master Plan, the health authorities were changed and together with this decision there were new appointments in the hierarchical structure of the Ministry and its affiliated institutes, such as: the National Institute of Hygiene "Rafael Rangel" (INH), Institute of Higher Studies in Public Health "Dr. Arnaldo Gabaldón" (IAES) and the Amazonian Center for Research and Control of Tropical Diseases "Simón Bolívar" (CAICET), these centers are linked to the areas of TB, HIV and malaria.

It is important to highlight that technical cooperation actions on HIV and TB are carried out in an articulated manner between PAHO and UNAIDS.

Below, the main progresses for each disease are reported according to the recommendations agreed during the technical mission of June 2018.

HIV

Continuity of access to comprehensive care and antiretroviral treatment.

- Updated antiretroviral treatment policies in accordance with the guidelines agreed during the technical mission in June 2018 (Dec 2018). They will provide normative background for the process of transition to dolutegravir(DTG)-based regimens.
- Coordination of new incoming donations of ARVs (**See Tables 3 below**).
- Adaptation of ARV procurement plans for adults and children in accordance with the new recommendations, in particular for the procurement plan of the donation approved by the Board of the Global Fund in September 2018 (mentioned below).
- Established DTG transition criteria and development of a distribution plan in coordination with community-based monitoring by civil society.
- First shipment of 100,000 packs of DTG arrived in Venezuela (16/12). Estimated custom clearance and delivery to Central Medical Store in mid-January.
- A donation of contraceptives (implants and IUD) managed by UNFPA will facilitate access to effective and reliable contraception for women with HIV using DTG-containing regimens (information on volumes of the donation not currently available). Additional opportunities of partnership with local NGOs affiliated to International Planned Parenthood Federation (IPPF) is being explored.

Improved surveillance and strategic information on HIV.

- Orientation meetings held with HIV and STI State coordinators to present the new ART guidelines, as well as guidelines for the syndromic management of sexually transmitted infections (STI), use of rapid tests for HIV and syphilis detection. Updated analysis on the epidemiological and operational situation, as well as HIV program performance in each State. Instructions were given on the information system and surveillance of HIV and STIs in order to generate consistent information for monitoring and evaluation of the progress of the MP. The situation of HIV-TB coinfection was analyzed, with special emphasis on people in prisons

and indigenous peoples. Ongoing studies were presented: Prevalence of HIV and risky sexual behaviors in men who have sex with men (MSM) and HIV drug resistance.

- Advances in the development of the HIV drug resistance surveillance study protocol with commitment to support the study from the laboratory of the Center for Research in Infectious Diseases (CIENI) of the National Institute of Respiratory Diseases (INER) of Mexico City, regional reference center designated by WHO for the surveillance of HIV drug resistance.
- Study protocol on HIV prevalence and risky sexual behavior in men who have sex with men in 8 cities of the country submitted to the National Center for Bioethics (CENABI) and logistical organization to conduct the study.
- Field mission in the Delta Amacuro state to review the strategies to improve adherence to treatment for TB and antiretrovirals in the indigenous Warao population. Training for the ASIC health teams in Casacoima, Tucupita and Pedernales in the comprehensive approach to TB, HIV/AIDS and malaria confection, to expand the prevention, detection, diagnosis and integrated treatment of HIV, STIs, TB and malaria in primary care health services.

TB

Improve the detection and diagnosis of TB.

- Survey and census of laboratories to identify conditions of efficiency and guide the strengthening of the diagnosis, the implementation of the activities and recommendations contemplated in the Master Plan.
- Review of the situation of the bacteriology network of Tuberculosis in the country and data collection systems of laboratories.

Prevention, treatment and person-centered care

- Presentation of the Master Plan to heads of health services, academia and the community supporting TB control.
- Evaluation process of the integrated national tuberculosis control program and guidance on: the epidemiological and operational situation in the country and in the States, surveillance of multidrug-resistant TB, TB in people in prisons and indigenous peoples, co-infection of TB/HIV, as well as follow up on the recommendations of the reports generated in the supervisions to the states.
- Management training of PNTB for postgraduate doctors of pneumology, pediatric pulmonology and thorax surgery and integration to first level care services.

Access to information and surveillance of TB at the national level.

- Follow-up visits to the States in accordance with the epidemiological and programmatic stratification.

Improve the management of the National TB Program

- Field mission in the Delta Amacuro State to review the strategies to increase adherence to TB and antiretroviral treatment in the indigenous Warao population and train ASIC health teams to expand prevention, detection, diagnosis and integrated TB treatment and strengthen

primary care with broad participation of the community and ensuring comprehensive approach to TB, HIV and co-infection with malaria.

- Review of shortened regimens for resistant TB (introduction of new drugs).
- Update of the clinical and programmatic management guide for resistant tuberculosis.
- Clinical epidemiological follow-up of TB/RR/MDR/XDR cases.
- Updating of guidelines with the new formulations of pediatric TB/CDF medicines to be used in the country.
- Development and coordination with other health entities of an integrated care strategy for TB and respiratory diseases, with an emphasis on diphtheria.
- Strengthening of technical-administrative management competencies for members of the PNTB coordinating teams of the states.
- Coordination of donations of first-line drugs (Peru).

Malaria

- During the months following the preparation of the Master Plan, changes in the coordination of malaria actions at the national level led to the reversal of the antimalarial drug policy, contingent upon verification of the list of cases that had been implemented during the first semester of 2018, as a measure to control the sale of medicines. The Master Plan emphasized the need to correct these measures to allow people to initiate treatment in the shortest possible time from the onset of symptoms.
- In recent months, measures have been taken to guarantee the existence of permanent stocks of medicines in the municipalities and parishes to ensure the start of treatment at the time of diagnosis at the respective points of notification (they provide diagnosis and treatment). At the end of the year progress was made in the implementation of a distribution scheme of medicines to the States for a period of three months in order to maintain sufficient stock at the health unit level. After the preparation of the Master Plan, actions have been undertaken under the new malaria coordination to unify the epidemiological information. At the end of the year, with the support of PAHO, reporting formats were printed in sufficient quantities for the registration and notification of cases throughout the country. In the same way, the central level advanced in the elaboration of an application to unify the information registry with tools for on and off-line alternatives. There is also progress in the preparation of an epidemiological bulletin with updated information on the disease situation across the country. There are still important needs in improving data analysis and use to guide routine operations at local level.

Diagnosis

- At the end of December, a particularly critical situation persists, already evidenced at the time of preparation of the Master Plan, on the shortage of rapid tests and supplies for diagnosis by microscopy. Stocks of rapid tests are coming to an end at the end of December. A delivery by PAHO Strategic Fund of 200,000 rapid tests acquired by the country was done at the end of December 2018, also a donation from the emergency program of PAHO (Project ECHO II) of 30,000 units is expected for the 3rd week of January and another of 100,000 RDTs that are

expected to arrive first trimester 2019 . The needs for rapid tests estimated in the Master Plan reach 2,000,000 tests for the first year.

- The country has partially solved the needs of slides, Giemsa solution and lancets, for the diagnosis using microscopy, but there is a shortage of those materials including, immersion oil, microscope bulbs and new microscopes in the amounts foreseen when the Plan was drawn up. At the time of this update (December 2018) there is no comprehensive solution to the problems of diagnosis . Local improvements are in place at local level in Domingo Sifontes under new actions with cooperation from MSF (mainly microscopes) but gaps, including human resources for microscopy continues in according with estimations done for the second year of the Master Plan.

Medicines

- In 2018 the Bolivar State acquired antimalarials for *P. vivax* (chloroquine and primaquine) in sufficient quantities to cover the entire national territory for a year, but during the second semester there were difficulties in obtaining such medicines for the rest of the country. In the second semester there was no shortage of treatment for malaria due to *P. falciparum*, the allocation of ASU + LUM for malaria was maintained by an advance purchase by PAHO in the first semester... There is a verbal information of a UNICEF donation with ASU + LUM in December but no official information is available neither the quantities. For these reasons at the end of the year the inventory situation of antimalarial drugs is unclear. The central level is planning an inventory survey in warehouses during January 2019 to update the situation. Under the new policy established after the preparation of the Master Plan, the central level stocks the warehouses of the states for periods of three months and it is understood that in this sense there is no shortage of medicines at the moment. There are various orders of antimalarial procurement in process expected to be deliver by the beginning of the year (primaquine, chloroquine), . PAHO is in conversations with UN Foundation about possible donation of ASU+LUM, as well as a proposal presented to the Spanish government (AECID) for purchasing antimalarials. Until the inventories are updated by the central level, it is suggested to continue working with the estimates of needs made at the preparation of the Master Plan for year 2

Management

- During last months of the year, an important advance was done in order to make possible the operation of *Médecins Sans Frontières* (MSF) for malaria in the municipality of Domingo Sifontes. The actions with MSF in malaria are expected to cover operational aspects of the diagnosis, donation of microscopes, supplies, operative capacity in the field and medicines.
- Likewise, progress was made in adapting the physical space for the planning of operations in the municipality, the designation of a public health coordinator for that municipality and the preparation of an operational plan to organize diagnostic and treatment actions in the “parroquias” of El Dorado , San Isidro and Tumeremo, with the assignment of roles and the identification of more precise gaps
- Also progress made in the last months of the year with the identification of community actors linked to the mining activity, including an expression of interest in active participation in the

response to malaria. Preliminary agreements on roles in detecting and handling cases were discussed.

Vector control

- With regard to vector control, in the month of September the 149,800 LLINs donated by the United Nations Foundation through the PAHO entered the country. A Plan was prepared for its distribution. As stated in the Master Plan, this donation does not cover the need for the first year, estimated at 300,000 LLINs, to cover some 540,000 people. Actual needs are calculated at 500,000 LLINs. There is a second direct purchase management of 65,000 LLINs that would arrive in the month of December (this is being purchased with the ECHO II project). By the end of the year it is also expected a MSF support with donation of LLIN for Domingo Sifontes including support for installation and promotion of use. There are no actions in progress to solve the needs for IRS. In the case of Venezuela here they consider a mosquito net is for a single person, the criterion of 1.8 people for each mosquito net is not used.

International support

A **Regional Support Group** was formed, including representatives from multilateral organizations (PAHO/WHO, UNAIDS, Global Fund) and Venezuelan and International civil society (Acción Solidaria, RVG+, Aid for Aids, AHF, ICASO) with the main objectives of:

- Coordinating the mobilization of financial and "in kind" resources, including the donation of medicines and supplies and ensuring compliance with the prioritization and quality criteria recommended in the MP.
- Providing oversight to the implementation of the Global Fund investment case for Venezuela (mentioned below).
- Supporting the implementation of the MP, including community monitoring activities and with regular updates on stocks and needs.
- Providing a better coordination and information flow about the activities carried out by the members of the group and other actors.

Global Fund donation

Based on the Master Plan, the Global Fund Secretariat recommended that its Board of Directors approve exceptionally US \$ 5 million to help alleviate the gaps in the provision of HIV treatment in Venezuela. This request was approved by the Global Fund Board on September 24, 2018. Of the US \$ 5 million, US \$ 4.9 million will be used to purchase ARVs through the PAHO Strategic Fund, and US \$ 100,000 will be channeled through UNAIDS to support Venezuelan civil society that will oversee and monitor the delivery of antiretroviral drugs to patients.

The **ARV procurement plan of the GF donation** includes a volume of approximately 680.000 bottles of the fixed dose combination of tenofovir/lamivudine/dolutegravir (TLD) that will cover 11.8 months for 83.3% of the projected cohort of adults living with HIV on ART in 2019 once the transition to DTG-based regimens will be operationalized as per newly updated and approved ART guidelines. The first 100.000 bottles of TLD are expected to be delivered in the country by mid-January 2019. The Table 1 below illustrates the first phase of the TLD procurement plan. Once this first purchase is finalized, the remaining balance will be used to procure the additional TLD volumes (estimated 180 thousand bottles for the second phase).

Table 1. ARV procurement plan of the 2018 GF donation through the PAHO Strategic Fund.

Product		Volume	Estimated price (30 tab bottle)	Total	Estimated delivery time
TLD	First delivery (available stock)	100,000	\$5.94	\$594,000	4-6 weeks
		200,000	\$6.25	\$1,250,000	4-6 weeks

TLD	Second delivery (fresh product)	200,000	\$5.94	\$1,188,000	12 weeks
TOTAL		500,000		\$3,032,000	

A plan has been formalized between UNAIDS and civil society around the role of the community for the monitoring and oversight of the delivery of antiretrovirals to people with HIV. Meetings have been held with the Department of Programs of the Ministry of Health and the National AIDS Program to design a roadmap for the distribution and transportation of ARVs to pharmacies. Organized civil society and academia have supported the design of the DTG migration plan for eligible persons, as well as the necessary work of outreach and retention in services for people living with HIV.

While the GF donation is critical to ensure access to ARV for a large proportion of people living with HIV, it represents a fraction of the total need in the three diseases. The Global Fund hopes that this investment will catalyze additional investments, financial or in-kind, to help further alleviate the situation and ensure the continuity of lifesaving treatments for HIV, tuberculosis and malaria.

Partner and donor mobilization

Greater coordination between partners and potential donors is essential to ensure that investments are aligned to maximize impact. During the development of the investment case of the Global Fund, several conversations with partners have been held to better understand the financing landscape and the coordination mechanisms established and a round table of partners was held in the month of October with the following objectives:

1. Present the Master Plan to the partners and the current actions undertaken by the Global Fund, PAHO and UNAIDS;
2. Review current and potential investments in HIV, tuberculosis and malaria to support the people of Venezuela with other partners;
3. Evaluate the remaining gaps in the response based on the information in the Master Plan for the three diseases;
4. Coordinate a joint response and mobilize resources among partners to fill existing gaps; and
5. Establish a permanent group as a forum for long-term coordination and collaboration among partners to support the people of Venezuela.

This meeting was successful in creating momentum around the MP as the main reference for external support to Venezuela from a variety of donors and partners from bilateral- and multilateral organization. In addition, the members of the regional support group have reached out to potential donors from the private sector, mainly Pharmaceutical companies.

Current and pending donations are presented in the next session.

Situation of donations

Besides the GF donation presented above, an update on donations managed by the Pan American Health Organization and other partners in 2018 is presented in the tables below.

Table 2a - Donations made by PAHO in 2018

(only HIV, TB and malaria related commodities are included)

Medications and other commodities	2018
Artemether 20 mg/Lumefantrine 120 mg	2,520,000
EFAVIRENZ 600mg + EMTRICITABINE 200mg + TENOFOVIR 300mg FCO X 30	159,990
Ethambutol HCL 275 mg + Isoniazid 75 mg + Pirazinamide 400 mg + Rifampicine 150 mg tab	100,128
Isoniazid 150 mg + Rifampicine 150 mg TABLETS, BLISTER 28 X 24	201,600
Isoniazid 50 mg + Rifampicine 75 mg + Pirazinamide 150 mg DISPERSIBLE TABLETS, BLISTER 3 X 28	120,036
Isoniazid 50 mg + Rifampicine 75 mg DISPERSIBLE TABLETS, BLISTER 10 X 10	130,032
EMERGENCY KIT (complicated malaria + diagnostics)	20
RDTs Malaria	60,000
LEVOFLOXACIN 250MG TABLETS, BLISTER 10 X 10	375,000
LLINs	149,800
Pirazinamide 500mg Tablet	200,000
SULFAMETHOXAZOLE 200MG + TRIMETHOPRIM 40MG ORAL SOLUTION, BOTTLE/100ML	4,000

Table 2b – Consolidated donations managed by other partners in 2018.

Medicine/ commodity	AID FOR AIDS	UNAIDS*	AID FOR AIDS	PALESTINA (to be confirmed)	UNICEF	HAITI DONATION GF
ABC 300 mg tab. X FCO 60		24951	4270			
ABC 600 mg / 3TC 300 mg x 30		151215	70622			
ABC 60mg / 3TC 30mg dispersable FCO		138199				
ABC oral sol.20 mg/ml /BOT-240ml					3426	
ARTEMETHER 20 mgs+ LUMEFANTRINE 120 mgs tab. PAC 30					475	
ARTEMETHER 40 mgs+ LUMEFANTRINE 240 mgs tab. 12BL	73760					
ARTEMETHER 20 mgs+ LUMEFANTRINE 120 mgs tab. 12BL	2356					

ARTEMETHER 20 mgs+ LUMEFANTRINE 120 mgs tab. 24BL	386335					
ARTEMETHER 40 mgs+ LUMEFANTRINE 240 mgs tab. 12BL	900					
ARTESUNATO pdr /inj 60 mgs box 1					10000	
ATV 300 mg/RTV 100mg X 30 TAB				16435		29,261
COLORQUINA BASE 150 mg pack 100 tab					21000	
EFV 200 mgX 90 CAPS				3872	216	
EFV 600mg x 30	243	20403				
TDF 300 mg X 30 TAB				13963		
AZT/ 3TC dispersable x 60 infantil		29481				
3TC 150 mg x 60 TAB	5144	49611	23913	26550		
3TC 150 mg/AZT 300 mg x 60 TAB		95272	73878	71898		
3TC sol oral 10 mg x 100ml					2256	
LPV 100 mg /RTV 25 mg x 60 TAB				4812	3444	
LPV 200 mg/RTV 50 mg x 120	9600	43021			40	
LPV/RTV oral sol.80+20 mg/ml/BOT-160ml					1596	
PRIMAQUINA base tab. 7,5 mgs PAC 1000					2984	
QUININA iny 300mgs box 10					180	
RAL 400 mg x 60 COMP				11620		
RTV 100mg tab x 30	4968					
SULFATO QUININA tab 300 mgs PAC 100					850	
TDF/3TC/EFV tab	294	72800				
TDF/3TC tab	2266					
AZT 100 mg tab.10 X 10		1883				
AZT 300 mg / 3TC 150 mg / ABC 300 mg tabletas x 60		6835				
AZT 300 mg x 60 TAB				5682		
AZT IV,10 mg/ml,inf.,20ml					60	

AZT oral sol.10 mg/ml/BOT-240ml					1080	
Reagents						
BIOLINE MALARIA SB KIT 25					7200	
BIOLINE SYPHILIS KIT					500	

*AID for AIDS donations delivered through UNAIDS

Table 3. Consolidated donations (in country, confirmed and pending) to cover the estimated needs for antiretroviral treatment during the first year of the Master Plan (2019).

ARV	Unit (per pack)	Aid for Aids (in country)	UNICEF (in country)	Global Fund (confirmed)	Merck (confirmed)	Mylan (pending)	Brazil (pending)	Total
TDF 300MG / 3TC 300MG / DTG 50MG	30 TB			680,000		12603		692,603
ABC 600MG / 3TC 300MG	30 TB	70,622						70,622
AZT 300MG / 3TC 150MG	60 TB	73,878						73,878
DTG 50MG	30 TB						14400	14,400
TDF 300MG / FTC 200MG	30 TB					67	14400	14,467
LPV 200MG / RTV 50MG	120 TB					1919		1,919
TDF 300MG / FTC 200MG / EFV 600MG	30 TB					18530		18,530
RAL 400MG	60 TB				3879			3,879
RTV 100MG	30 TB					9085		9,085
ABC 60MG / 3TC 30MG	60 TB					19665		19,665
LPV 100MG / RTV 25 MG	60 TB					3400		3,400
RAL 100MG	60 TB				1950			1,950
AZT 50MG/5ML	240 ML		1080					1,080

Table 4. Consolidated donations to cover the estimated needs for TB during the first year of the Master Plan (2019).

Medications and other commodities	Unit	Spain (confirmed)	PAHO (confirmed)
ISONIACIDA 150 mg + RIFAMPICINA 150 mg CDF	Tablet	150,000	100,000
PIRAZINAMIDA 500 mg	Tablet	180,000	
ETHAMBUTOL 400 mg	Tablet	83,000	
ISONIACIDA 75 mg+ RIFAMPICINA 150 mg+ PIRAZINAMIDA 400 mg+ ETHAMBUTOL 275 mg CDF	Tablet	200,000	400,000
AMIKACIN 500mg /2ml	Vial	3,000	
MOXIFLOXACINA 400 mg	Tablet	18,000	
BEDAQUILINE 100 mg	Tablet	1,692	
CLOFAZIMINE 100 mg	Tablet	18,000	
LINEZOLID 600mg	Tablet	1,000	
GeneXpert®	Machine	2	
Xpert® MTB/RIF cartridges	Cartridge	2,000	

Status of inventories (updated to September 2018)

At the moment of this update no information on current stocks of antiretroviral and antimalarial drugs were available.

Table 4. Availability of TB drugs (September 2018).

N°	Medicine	Unit	Stocks (Sep 2018)	Procurement (Strategic Fund) in process
1	ISONIACIDA 150 mg + RIFAMPICINA 150 mg CDF	Tablet	241,920	1,526,112
2	PIRAZINAMIDA 500 mg	Tablet	16,000	200,000
3	ISONIACIDA 300 mg	Tablet	32,300	1,000,000
4	ISONIACIDA 100 mg	Tablet	150,800	800,000
5	RIFAMPICINA 300 mg	Tablet	105,600	
6	ETHAMBUTOL 400 mg	Tablet	13,200	300,000
7	RIFAMPICINA SYRUP 100 mg/5 mL, 60 ml bottle	Bottle		
8	RIFAMPICINA 75 mg + ISONIACIDA 50 mg CDF	Disp. tablet	61,488	

9	RIFAMPICINA 75 mg + ISONIACIDA 50 mg + PIRAZINAMIDA 150 mg CDF	Disp. tablet	54,768	
10	ISONIACIDA 75 mg+ RIFAMPICINA 150 mg+ PIRAZINAMIDA 400 mg+ ETHAMBUTOL 275 mg CDF	Tablet	2,016	1,499,904
11	AMIKACIN 500mg /2ml	Vial	8,940	3,000
12	MOXIFLOXACINA 400 mg*	Tablet		
13	ETHIONAMIDE 250 mg	Tablet	21,800	25,000
14	BEDAQUILINE 100 mg*	Tablet	-	
15	CLOFAZIMINE 100 mg *	Tablet	-	
16	CICLOSERINA 250 mgs	Capsule	16,300	
17	LINEZOLID 600mg	Tablet	-	1,500
18	PAS ACID SACHET = 4g aminosalicylic acid	Sachet	-	2,010
19	LEVOFLOXACINA 250 mg	Tablet	2,790	
20	LEVOFLOXACINA 500 mg	Tablet	6,590	

***These medicines are newly introduced for the treatment of MDR TB.**

Update of needs and gaps

HIV

In September 2018 progress was made with the updating of the national antiretroviral treatment policy in accordance with the agreements of the technical mission and the new WHO recommendations on antiretroviral treatment published in July 2018.¹ The tables below reflect the expected needs of antiretrovirals for the implementation of the new guidelines in adults (Table 5a) and children (Table 5b) with updates regarding the amounts included in the MP and taking into account the incoming donations for 2019 (Table 3). Table 6a and 6b show the estimated financial gap in ARVs for adults and children. Table 7 a consolidated situation of the gap in ARVs highlighting priority drugs for which there are currently no confirmed or pending donations. The estimated volumes of antiretrovirals will have to be updated periodically during 2019 depending on the incoming donations and the regimens in use.

Tables 5a. Estimated gaps in antiretrovirals for adults (expressed in packs) over the three years of the Master Plan.

Item	Unit (packs)	Dosis	Need Year 1 (2019)*	Need Year 2 (2020)	Need Year 3 (2021)
TDF 300MG / 3TC 300MG / DTG 50MG	30 TAB	30	173,151	711,529	729,887
ABC 600MG / 3TC 300MG**	30 TAB	30	0	39,816	40,853
DTG 50MG	30 TAB	30	26,116	33,380	34,318
TDF 300MG / FTC 200MG	30 TAB	30	75,996	62,594	64,286
LPV 200MG / RTV 50MG	120 TAB	120	70,656	59,658	61,209
ATV 300MG / RTV 100MG	30 TAB	30	42,733	35,128	36,041
AZT 300MG /3TC 150MG**	60 TAB	60	0	21,951	22,525
TDF 300MG / FTC 200MG / EFV 600MG	30 TAB	30	0	15,235	15,634
DRV 600MG	60 TAB	60	24,053	19,865	20,469
RAL 400MG	60 TAB	60	0	3,204	3,301
ETV 100MG	30 TAB	120	3,879	3,204	3,301
AZT 10MG/ML	1 VIAL	5	0	2,880	3,225
RTV 100MG	30 TAB	30	39,020	33,321	34,335

* The estimated amounts for year 1 (2019) take into account confirmed and expected donations (Table 3) and correspond to 12 months +3 months of buffer stock.

**Sufficient stocks available in country for year 1 (2019).

¹ Document available at: <http://www.who.int/hiv/pub/guidelines/ARV2018update/en/>

Table 5b – Estimated gaps in antiretrovirals for children (expressed in packs) over the three years of the Master Plan.

Item	Unit (packs)	Need Year 1 (2019)*	Need Year 2 (2020)	Need Year 3 (2021)
ABC 60MG / 3TC 30MG	60 TAB DISP	-	15,376	15,038
LPV 40MG / RTV 10MG	120 PELLETS	9,720	7,776	7,776
AZT 60MG / 3TC 30MG	60 TAB DISP	900	720	720
LPV 100MG / RTV 25 MG	60 TAB	3,425	5,187	4,928
TDF 300MG / FTC 200MG	30 TAB	2,760	2,098	1,993
DRV 75 MG	480 TAB	2,055	1,562	1,484
RAL 100MG	60 TAB MAST	-	1,560	1,560
AZT 50MG/5ML (240ML)	240 ml	-	400	400
NVP 10MG/ML (100ML)	100ml	100	100	100
RTV 25MG	60 TAB	2,055	1,562	1,484
DTG 50MG	30 TAB	2,025	1,539	1,462
ATV 200MG	60 TAB	750	570	542
RTV 100 MG	30 TAB	750	570	542

* The estimated amounts for year 1 (2019) take into account confirmed and expected donations (Table 3) and correspond to 12 months +3 months of buffer stock.

Table 6a – Estimated financial gap in ARVs for adults for the 3 years of the MP (in US \$)

Item	Unit (bottle)	Total cost year 1 (2019)	Total cost Year 2 (2020)	Total cost year 3 (2021)
TDF 300MG / 3TC 300MG / DTG 50MG	30 TAB	\$1,402,523	\$5,763,385	\$5,912,085
ABC 600MG / 3TC 300MG	30 TAB	\$0	\$597,237	\$612,797
DTG 50MG	30 TAB	\$115,016	\$147,005	\$151,136
TDF 300MG / FTC 200MG	30 TAB	\$478,772	\$394,343	\$405,001
LPV 200MG / RTV 50MG	120 TAB	\$1,526,168	\$1,288,623	\$1,322,115
ATV 300MG / RTV 100MG	30 TAB	\$794,837	\$653,380	\$670,365
AZT 300MG /3TC 150MG	60 TAB	\$0	\$138,291	\$141,910
TDF 300MG / FTC 200MG / EFV 600MG	30 TAB	\$0	\$127,973	\$131,322
DRV 600MG	60 TAB	\$2,020,410	\$1,668,638	\$1,719,379
RAL 400MG	60 TAB	\$0	\$211,656	\$218,092
ETV 100MG	30 TAB	\$1,955,235	\$1,614,811	\$1,663,915
AZT 10MG/ML	1 VIAL	\$0	\$31,104	\$34,830
RTV 100MG	30 TAB	\$191,978	\$163,942	\$168,927
TOTAL		\$8,484,939	\$12,800,387	\$13,151,874

Note: costs include freight, insurance and administration costs

Table 6b – Estimated financial gap in ARVs for children for the 3 years of the MP (in US \$)

Item	Unit (bottle)	Total cost year 1 (2019)	Total cost Year 2 (2020)	Total cost year 3 (2021)
ABC 60MG / 3TC 30MG	60 TAB DISP	\$ -	\$ 76,573	\$ 74,890
LPV 40MG / RTV 10MG	120 PELLETS	\$ 223,949	\$ 179,159	\$ 179,159
AZT 60MG / 3TC 30MG	60 TAB DISP	\$ 2,052	\$ 1,642	\$ 1,642
LPV 100MG / RTV 25 MG	60 TAB	\$ 119,190	\$ 180,508	\$ 171,482
TDF 300MG / FTC 200MG	30 TAB	\$ 17,388	\$ 13,215	\$ 12,554
DRV 75 MG	480 TAB	\$ 932,148	\$ 708,432	\$ 673,011
RAL 100MG	60 TAB mast	\$ -	\$ 141,972	\$ 141,972
AZT 50MG/5ML (240ML)	240 ml	\$ -	\$ 1,032	\$ 1,032
NVP 10MG/ML (100ML)	100ml	\$ 156	\$ 156	\$ 156
RTV 25MG	60 TAB	\$ 10,111	\$ 7,684	\$ 7,300
DTG 50MG	30 TAB	\$ 8,918	\$ 6,778	\$ 6,439
ATV 200MG	60 TAB	\$ 16,200	\$ 12,312	\$ 11,696
RTV 100 MG	30 TAB	\$ 3,690	\$ 2,804	\$ 2,664
TOTAL		\$ 1,333,802	\$ 1,332,268	\$ 1,283,998

Note: costs include freight, insurance and administration costs

Table 7. Consolidated ARV gap (Year 1 – 2019; 12 months + 3 buffer stock).

population	ARV	Unit (per pack)	Need (12 m + 3 m buffer stock)	Available + incoming	Gap	% gap (year 1)
a	ATV 300MG / RTV 100MG	30 TB	42733	0	42733	100%
a	DRV 600MG	60 TB	24053	0	24053	100%
a	ETV 100MG	30 TB	3879	0	3879	100%
p	LPV 40MG / RTV 10MG	120 PELLETS	9720	0	9720	100%
p	AZT 60MG / 3TC 30MG	60 DISP TB	900	0	900	100%
p	DRV 75 MG	480 TB	2055	0	2055	100%
p	RTV 25MG	60 TB	2055	0	2055	100%
p	ATV 200MG	60 TB	750	0	750	100%
p	NVP 10MG/ML	100 ML	100	0	100	100%
p	AZT 10MG/ML	VIAL	2535	0	2535	100%
a	LPV 200MG / RTV 50MG	120 TB	72575	1919	70656	97%
a	TDF 300MG / FTC 200MG	30 TB	78823	14467	64356	82%
a/p	RTV 100MG	30 TB	48855	9085	39770	81%
a/p	DTG 50MG	30 TB	42541	14400	28141	66%
p	LPV 100MG / RTV 25 MG	60 TB	6825	3400	3425	50%
a	TDF 300MG / 3TC 300MG / DTG 50MG	30 TB	865754	692603	173151	20%
a	ABC 600MG / 3TC 300MG	30 TB	48433	70622	0	0%

a	AZT 300MG / 3TC 150MG	60 TB	26698	73878	0	0%
a	TDF 300MG / FTC 200MG / EFV 600MG	30 TB	18530	18530	0	0%
a	RAL 400MG	60 TB	3879	3879	0	0%
p	ABC 60MG / 3TC 30MG	60 DISP TB	19665	19665	0	0%
p	RAL 100MG	60 CHEW TB	1950	1950	0	0%
p	AZT 50MG/5ML	240 ML	400	1080	0	0%

Note: a (adults); p(pediatric); a/p (consolidated adults/pediatric).

In addition, gaps in medicines for opportunist infections still persist (table 8), as well as approximately 2M USD estimated for micronutrients, proteins and formula.

Table 8. Gap in medicines for opportunistic infections.

Item	Product	Farmaceutical form	Presentation	Annual need	Annual cost (US\$)
1	Folinic acid	TAB	15 mg tab x10	100,000	\$210,000.00
2	Itraconazol	CAP	100 mg cap x28	126,000	\$20,160.00
3	Ganciclovir	VIAL	500 mg	1,200	\$57,600.00
4	Pirimetamine	TAB	25 mg x10	208,000	\$20,800.00
5	Trimetroprin/Sulfametoxazol	TAB	800/160 mg x10	120,000	\$3,600.00
6	Trimetroprin/Sulfametoxazol	ORAL	200 mg/40 mg	3,800	\$14,516.00
7	Valaciclovir	TAB	500 mg x10	20,000	\$24,600.00
8	Valganciclovir	TAB	450 mg x60	30,000	\$810,000.00
9	Fluconazol	TAB	200mg x100	100,000	\$15,000.00
10	Fluconazol	VIAL	400mg/200ml	3,000	\$21,270.00
13	Amfotericine B liposomal	VIAL	50mg	8,000	\$144,000.00
14	Flucitosine	VIAL	2.5g/250ml	1,500	\$420,433.20
15	Doxorubicine	VIAL	50mg/25ml	300	\$1,062.00
16	Penicilina Benzatinica 2.4 MUI	VIAL	2.4MUI	3,000	\$10,260.00
17	Penicilina Cristalina 1.0 MUI	VIAL	1.0MUI	900	\$3,600.00
				TOTAL	\$1,776,901.20
				TOTAL with freight and insurance	\$2,132,281.44

The gap in diagnostics continues to be critical and unattended (Table 9), especially reagents for HIV viral load monitoring.

Table 9. Needs in diagnostics for HIV diagnosis and treatment monitoring for year 1 (2019).

Item	Volume (tests)	Estimated cost (USD)
Rapid HIV test kits	300,000	525,000
HIV ELISA (3rd and 4th gen; blood banks)	220,000	175,000
Viral load (1)	84,000	2,800,000
GeneXpert (Viral load)(2)	4 GX4 + 8000 tests	257,000
DNA PCR HIV	672	22,000
CD4(3)	75,000	1,000,000
HIV resistance test(4)	500	50,000
Others (e.g. hepatitis, OIs)		42,000
Total		4,871,000

Note: (1)COBAS AmpliPrep/Taqman HIV-1 (Roche) capacity installed and in operating condition in 6 labs (+2 machines not yet installed); (2)for decentralized access in States with lower needs and logistic issues to ship samples and integrated use with TB; (3)BDFACSCount; (4) Equipment for Trugene at INH/ In House at IVIC.

Finally, as previously mentioned, US \$ 100,000 of the GF donation will be channeled through UNAIDS to support Venezuelan civil society that will be in charge of monitoring the delivery of antiretroviral drugs to patients and this value is subtracted from the health system strengthening component of the MP.

In the table below, remaining gaps in HIV prevention commodities and health system strengthening interventions.

Table 10. Other HIV prevention, health system strengthening and surveillance gaps for the first year of the MP (2019).

Item	Estimated need (USD)
Condoms (masculine and feminine) and lubricants	5.5M
Human resource training (lab, HIV surveillance, human rights approach, etc.)	50K
Quality control programs	10k
Health promotion, prevention and treatment literacy material	10k
HIVDR surveillance	40k

TUBERCULOSIS

The following table (Table 11) reflects the updated needs for anti-TB drugs for the 3 years of the MP, with updates regarding the amounts included in the MP and taking into account the stocks and the incoming donations and procurement. The estimation of needs is made as of September 2018, with year 1 being the period from September 2018 to September 2019 and so on for year 2 and 3. Table 12 shows the estimated financial gap in anti-TB drugs. Table 13 shows a consolidated situation of the gap in anti-TB drugs.

Table 11. Estimated gap in anti-TB drugs for the 3 years of the Master Plan

N°	Medicine	Unit	Needs year 1* (sept 2018 - sept 2019)	Needs year 2 (sept 2019-sept 2020)	Needs year 3 (sept 2020-sept 2021)
1	ISONIACIDA 150 mg + RIFAMPICINA 150 mg CDF	Tablet	465,968	2,808,000	3,650,400
2	PIRAZINAMIDA 500 mg	Tablet	104,000	500,000	600,000
3	ISONIACIDA 300 mg **	Tablet	-	1,000,000	1,300,000
4	ISONIACIDA 100 mg **	Tablet	-	800,000	1,000,000
5	RIFAMPICINA 300 mg	Tablet	294,400	400,000	500,000
6	ETHAMBUTOL 400 mg	Tablet	3,800	400,000	500,000
7	RIFAMPICINA SYRUP 100 mg/5 mL Frasco 60 ml ***	bottle	1,000	1,000	1,000
8	RIFAMPICINA 75 mg + ISONIACIDA 50 mg CDF	Disp. Tablet	68,512	130,000	140,000
9	RIFAMPICINA 75 mg + ISONIACIDA 50 mg + PIRAZINAMIDA 150 mg CDF	Disp. Tablet	65,232	120,000	130,000
10	ISONIACIDA 75 mg+RIFAMPICINA 150 mg+ PIRAZINAMIDA 400 mg+ETHAMBUTOL 275 mg CDF	Tablet	198,080	2,600,000	3,380,000
11	AMIKACIN 500mg /2ml	vial	21,060	16,800	28,200
12	MOXIFLOXACINA 400 mg **	Tablet	-	19,000	34,300
13	ETHIONAMIDE 250 mg **	Tablet	-	50,000	131,400
14	BEDAQUILINE 100 mg	Tablet	-	5,640	8,648
15	CLOFAZIMINE 100 mg	Tablet	2,075	32,800	32,000
16	CICLOSERINA 250 mgs **	Capsule	-	5,000	5,000
17	LINEZOLID 600mg	Tablet	-	5,500	9,500
18	PAS ACID SACHET = 4g aminosalicylic acid ****	Sachet	1,990	-	-

* The calculation of needs is made as of September 2018. The estimated amounts for year 1 (September 2018 to September 2019) take into account the stocks and the incoming donations and procurement.

**Sufficient stocks available for year 1 (2019).

*** Product difficult to acquire, not included in the Strategic Fund of PAHO or in the GDF. Donation/alternative will be found.

**** The estimated need for this drug is to complete the treatment of patients who are currently using it and subsequently it will be discontinued.

Table 12 – Estimated financial gap in anti-TB drugs for the 3 years of the MP (in US \$)

N°	Medicines	Unit	Total cost year 1 (sept 2018-sept 2019)	Total costs year 2 (sept 2019-sept 2020)	Total costs year 3 (sept 2020-sept 2021)
1	ISONIACIDA 150 mg + RIFAMPICINA 150 mg CDF	Tablet	20,264	122,113	158,747
2	PIRAZINAMIDA 500 mg	Tablet	3,877	18,638	22,365
3	ISONIACIDA 300 mg	Tablet	-	43,488	56,534
4	ISONIACIDA 100 mg	Tablet	-	13,419	16,774

5	RIFAMPICINA 300 mg	Tablet	32,921	44,730	55,913
6	ETHAMBUTOL 400 mg	Tablet	142	14,910	18,638
7	RIFAMPICINA SYRUP 100 mg/5 mL Fraso 60 ml	Bottle	2,485	2,485	2,485
8	RIFAMPICINA 75 mg + ISONIACIDA 50 mg CDF	Disp. Tablet	3,065	5,815	6,262
9	RIFAMPICINA 75 mg + ISONIACIDA 50 mg + PIRAZINAMIDA 150 mg CDF	Disp. Tablet	4,863	8,946	9,692
10	ISONIACIDA 75 mg+ RIFAMPICINA 150 mg+ PIRAZINAMIDA 400 mg+ETHAMBUTOL 275 mg CDF	Tablet	17,228	226,135	293,976
11	AMIKACIN 500mg /2ml	Vial	16,195	12,919	21,685
12	MOXIFLOXACINA 400 mg	Tablet	-	9,207	16,621
13	ETHIONAMIDE 250 mg	Tablet	-	3,976	10,449
14	BEDAQUILINE 100 mg	Tablet	-	14,912	22,866
15	CLOFAZIMINE 100 mg	Tablet	2,533	40,037	39,060
16	CICLOSERINA 250 mgs	Capsule	-	1,665	1,665
17	LINEZOLID 600mg	Tablet	-	37,586	64.921
18	PAS ACID SACHET = 4g aminosalicylec acid	Sachet	3,297	-	-
TOTAL ESTIMATED COST (USD)			106,868	620,979	818,650

Note: costs include freight, insurance and administration costs

Table 13. Consolidated anti-TB drug gap (Year 1 – sept 2018 to sept 2019).

Medicine	Unit	Total need year 1 (sept 2018 - sept 2019)	Availability year 1*	Gap	% gap
RIFAMPICINA SYRUP 100 mg/5 mL Bottle 60 ml	Bottle	1,000	-	1,000	100%
RIFAMPICINA 300 mg	Tablet	400,000	105,600	294,400	74%
AMIKACIN 500mg /2ml	Vial	36,000	14,940	21,060	59%
RIFAMPICINA 75 mg + ISONIACIDA 50 mg + PIRAZINAMIDA 150 mg CDF	Disper. Tablet	120,000	54,768	65,232	54%
RIFAMPICINA 75 mg + ISONIACIDA 50 mg CDF	Disper. Tablet	130,000	61,488	68,512	53%
PAS ACID SACHET = 4g aminosalicylec acid	Sachet	4,000	2,010	1,990	50%
PIRAZINAMIDA 500 mg	Tablet	500,000	396,000	104,000	21%
ISONIACIDA 150 mg + RIFAMPICINA 150 mg CDF	Tablet	2,484,000	2,018,032	465,968	19%
CLOFAZIMINE 100 mg	Tablet	20,075	18,000	2,075	10%
ISONIACIDA 75 mg + RIFAMPICINA 150 mg+ PIRAZINAMIDA 400 mg + ETHAMBUTOL 275 mg CDF	Tablet	2,300,000	2,101,920	198,080	9%
ETHAMBUTOL 400 mg	Tablet	400,000	396,200	3,800	1%
ISONIACIDA 300 mg	Tablet	1,000,000	1,032,300		0%
ISONIACIDA 100 mg	Tablet	800,000	950,800		0%

MOXIFLOXACINA 400 mg	Tablet	18,000	18,000	0%
ETHIONAMIDE 250 mg	Tablet		46,800	0%
BEDAQUILINE 100 mg	Tablet	1,692	1,692	0%
CICLOSERINA 250 mgs	Capsule		16,300	0%
LINEZOLID 600mg	Tablet	2,000	2,500	0%

* Stocks and incoming donations and procurement.

** Product difficult to acquire, not included in the Strategic Fund of PAHO or in the GDF. Donation/alternative will be sought.

Table 14 shows the gap in diagnostics for TB.

Table 14. Needs in diagnostics for TB.

Item	Year 1 (USD)	Year 2 (USD)	Year 3 (USD)
Gene Xpert® (4 modules, UPS, 3 years warranty): 12 for year 1* and 14 for years 2 and 3	351,024	409,528	409,528
GeneXpert® calibration kits: 14 per year	7,560	7,560	7,560
Xpert® MTB/Rif cartridges: 37,000 for year 1*, 39,000 years 2 and 3	444,000	468,000	468,000
Other items (LED fluorescence microscopes, autoclaves, etc.)	73,880		
TOTAL	876,464	885,088	885,088

Note: costs include freight, insurance and administration costs

* The estimated amounts for year 1 take into account incoming donations.

Malaria

Table 6 - Malaria component (revised tables for year 1)

Area: Medicines	Year 1 (2019) (estimated value in US\$)	Year 2 (2020) (estimated value in US\$)	Year 3 (2021) (estimated value in US\$)
Drug procurement (Year 1 is without Bolívar for cases of P. vivax, and Year 2 considers the whole country, but with a 40% reduction in malaria incidence nationally)	389,844.01	689,759.16	464,359.20
Procure drugs to treat severe malaria and comorbidities and medical supplies	234,549.97	164,184.98	110,532.50
Transport, insurance and other	93,659.09	128,091.62	114,978.34
TOTAL ESTIMATED COST (USD)	718,053.08	982,035.76	689,870.04
Area: Prevention	Year 1 (2019) (estimated value in US\$)	Year 2 (2020) (estimated value in US\$)	Year 3 (2021) (estimated value in US\$)
Procurement LLINs	3,355,000.00	1,800,000.00	900,000.00
Procurement insecticide for IRS	320,000.00	320,000.00	160,000.00
Procurement Hudson pumps	120,000.00	0.00	0.00
Procurement protection equipment	32,550.00	0.00	0.00

Transportation, logistics and supervision in the field	1,503,720.00	0.00	0.00
Transport, insurance and other	498,000.00	318,000.00	135,000.00
TOTAL ESTIMATED COST (USD)	5,829,270.00	2,438,000.00	1,195,000.00

Update of the Master Plan budget

Table 7 – Grand total of updated PM (December 2018)

COMPONENT	2019 (estimated value US\$)	2020 (estimated value US\$)	2021 (estimated value US\$)
HIV			
Medicines	\$13,939,915	\$18,049,366	\$18,265,300
Diagnostics	\$4,882,259	\$7,567,632	\$7,779,575
Prevention	\$5,479,200	\$5,479,200	\$5,479,200
Health System Strengthening	\$108,650	\$173,700	\$158,700
Surveillance	\$50,000	\$10,000	\$10,000
TOTAL VIH	\$24,460,024	\$31,279,898	\$31,692,775
TB			
Medicines	\$106,868	\$620,979	\$818,650
Diagnostics	\$876,464	\$885,088	\$885,088
Prevention	\$4,800	\$7,800	\$4,800
Health System Strengthening	\$1,005,580	\$45,900	\$45,900
Surveillance	\$26,200	\$15,000	\$10,000
TOTAL TB	\$2,019,912	\$1,574,767	\$1,764,438
Malaria			
Medicines	\$718,053	\$982,036	\$689,870
Diagnostics	\$2,031,075	\$1,364,044	\$849,627
Prevention	\$5,829,270	\$2,438,000	\$1,195,000
Health System Strengthening	\$256,000	\$185,000	\$160,000
Surveillance	\$890,900	\$830,900	\$506,700
TOTAL MALARIA	\$9,725,298	\$5,799,980	\$3,401,197
TOTAL			
Medicines	14,764,837	19,652,381	19,773,820
Diagnostics	7,871,018	9,816,764	9,514,289
Prevention	11,313,270	7,925,000	6,679,000
Health System Strengthening	1,370,230	404,600	364,600
Surveillance	967,100	855,900	526,700
TOTAL (by área)	36,286,454	38,654,645	36,858,410

TOTAL VIH	\$87,432,697
TOTAL TB	\$5,359,117
TOTAL Malaria	\$18,926,475
TOTAL MASTER PLAN (3 years)	\$111,718,289