POLICY REPORT

April 2019

The Romanian HIV National Program

DESCRIPTION OF A MAZE

The Global Fund

Romanian Health Observatory

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This policy report was possible with the support of the Romanian Country Coordinating Mechanism and The Global Fund to Fight AIDS, Tuberculosis and Malaria.

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Executive Summary

Significant improvements in the management of HIV/AIDS were registered in Romania in the last decade. If Romania's rate of new HIV diagnosis per 100 000 population was in 2017 lower than the European Union's average, HIV/AIDS mortality was higher than the European Union's but consistently lower than HIV/AIDS mortality in the WHO European Region.

Over **61**% of new cases of HIV infection in Romania were late diagnosis.

Nevertheless, several areas still need urgent action and careful monitoring. Over 61% of new cases of HIV infection in Romania were late diagnosis, unlike Europe which has about 48% cases on the average. Romania reported the highest number of new HIV diagnosis in young people aged under 30 years. The number of HIV diagnoses reported among MSM consistently increased in Romania in the recent years, while outbreaks of HIV among people who inject drugs were observed[1].

Moreover, at the end of 2018 repeated shortages of medicines essential for HIV/AIDS treatment were notified to the Romanian Government by an important number of non-governmental organizations active in the field. A National Strategic Plan for HIV/AIDS Management for the 2019 – 2021 period is still not approved by the Government and the present medicines procurement system is triggering red tape and creating the above-mentioned shortages.

5 pharmaceutical products from the HIV treatment reimbursement list were identified as having a price higher in Romania than in the comparison European Union countries, at the time of the analysis.

Cost-effectiveness criteria to set the evaluation indicators used for the National Program for Prevention, Monitoring and Control of HIV/AIDS infection (managed by the Ministry of Health) are not in use, while the decision-making process used for the HIV Treatment and Monitoring Program (managed by the National Health Insurance House) could be improved. The public procurement process needs to be redesigned to meet the needs of the health care system.

[1] HIV/AIDS surveillance in Europe. European Centre for Disease Prevention and Control. 2018

Five pharmaceutical products from the HIV treatment list, which are fully reimbursed to the Romanian patients, were identified at the time of the analysis as having a price higher in Romania than in the comparison countries (Czech Republic, Hungary and Netherlands). This may negatively affect the cost-efficiency of centralized public procurements for treatments intended for HIV/AIDS.

Two different public authorities are responsible for funds' allocation, monitoring and management of HIV/AIDS patients: Ministry of Health (MoH) and National Health Insurance House (NHIH). Six different directorates and healthcare institutions under the authority of the Ministry of Health have responsibilities related to public purchasing of HIV treatments and diagnosis tests. Several types of procurement are used by health authorities to purchase the needed treatments/tests, with no proof of increased efficiency.

6 different directorates under Ministry of Health's authority have overlapping responsibilities related to public purchasing of HIV treatments and diagnosis tests.

Public procurements are conducted at two different levels: at national level, by the MoH, for a limited number of medicines included in the HIV National Program, and at local level, by every hospital that implements the program. Moreover, even though the national public acquisition is carried out by the MoH, the payments of the supplier are made locally, at hospital level.

POLICY REPORT OBJECTIVES

1. To provide an overview of the HIV National program in Romania and to support a better understanding of the system for the interested public.
2. To describe the mechanism of public purchasing of HIV pharmaceuticals.
3. To provide a relationship map of all entities involved in the process.
4. To describe the specifications of the pharmaceuticals included in the reimbursement list.
5. To identify the HIV medicines included in the reimbursement list for which the price at the time of the analysis was higher than in other European Union countries.

This bureaucratic maze, with overlapping roles and unclear criteria, instead of making the whole monitoring and treatment process fast and flexible, creates more red tape, delays and, in the end, frustrations for the healthcare workers and an unacceptable decrease in the HIV/AIDS patients' quality of life.

The Policy Report's main intention is to provide a thorough description of this maze in order to increase the awareness of national/international health policy experts and of the general public with the hope that a time will come when HIV/AIDS patients' interests will prevail in front of bureaucratic inertia.

Brief Description of Pharmaceuticals' Pricing Methodology in Romania

Romania, along with other European Union countries, uses an external reference price mechanism. The pharmaceuticals' price set up in Romania cannot exceed the lowest price in a reference basket formed of 12 countries: Czech Republic, Bulgaria, Hungary, Poland, Slovakia, Austria, Belgium, Italy, Lithuania, Spain, Greece and Germany. This rule however does not apply to vaccines and plasma-derived medicines – their prices must be lower than the average of the lowest 3 prices from these 12 countries.

Additional rules for generic medicines have been introduced in Romania: the price should not exceed the "generic reference price".

The generic reference price represents 65% of the price of innovative medicine present in the market and this is set only once, usually when approving the price for the first generic medicine on the market. For biosimilars, the reference price is set up to 80% of the price of the innovative biosimilars on the market.

Reimbursed pharmaceuticals which are included in the Romanian HIV National Program are listed under C2 section of the C list of reimbursed medicines, in the "Treatment and Monitoring Program of People Infected with HIV/AIDS" subprogram.

This list contains the "anti-retroviral (ARV)" treatments and includes 29 INNs, out of which 8 are combinations; a total number of 116 pharmaceutical products of different forms, doses and packages correspond to the 29 INNs. All the details for these products are listed in Annex 1, including the manufacturer, country of origin and adverse effects.

Prices listed in the CANAMED (the official price catalogue in Romania) for the 116 pharmaceutical products, were analyzed and compared with prices in other four EU member states with populational and epidemiological profiles similar to Romania: Poland, Czech Republic, Hungary and Netherlands. The analysis was performed at the price levels valid in September 2018. The "annual" correction of prices listed in CANAMED was performed by MoH in November 2018 and came into force in January 2019. The previous "annual" correction of prices was performed in 2015. (see Info Box).

All the prices are presented in Annex 1, while the products identified as having a price higher in Romania than in the comparison countries are listed in Table 1.

INN	Brand name	Concentration	Form	Manufacturer	Innovative /Generic	Price in Romania (RON)	Countries where the price is lower than in Romania
Lamivudinum + Zidovudinum	Lamivudina/Zidovudina Aurobindo	150/300 mg	Tablet	Aurobindo Malta	Generic	296	Netherlands
Darunavirum + Cobicistatum	Rezolsta	800/150 mg	Tablet	Janssen-Cilag Belgium	Innovative	2072	Czech Rep., Hungary, Netherlands
Emtricitabinum + Tenofovirum	Descovy	200/100 mg	Tablet	Gilead U.K.	Innovative	2824	Czech Rep., Netherlands
Emtricitabinum + Tenofovirum	Descovy	200/25 mg	Tablet	Gilead U.K.	Innovative	2824	Czech Rep., Netherlands
Elvitegravir + Cobicistat + Emtricitabine + Tenofovir	Genvoya	150/150/200/ 10 mg	Tablet	Gilead U.K.	Innovative	4066	Hungary

Table 1. HIV pharmaceuticals products included in the C2 reimbursement list for which the Romanian prices are higher than in the comparison countries (September 2018 price levels)

As stated by law, the MoH should perform an annual "correction" of the prices – all Romanian prices must be re-approved considering price variations in the 12 reference countries. If files for the revised price is not re-submitted by the market authorization holder, the product's price will not be listed in the National Medicines Prices Catalogue – CANAMED. If a product is not listed in CANAMED, it will not enter the social reimbursement system and it will not be reimbursed.

INFO BOX

Annual Correction of Pharmaceuticals Prices: a longstanding problem

Since 2009, the Romanian pharmaceutical pricing legislation states that prices for each product must be revised annually to take into account variation in prices across the reference basket. In the last decade, this annual revision was implemented only twice: in 2015 and in 2019. This lack of capacity at the Ministry of Health level generates loss of efficiency and lack of predictability.

In 2011, a progressive tax came into force on the pharmaceutical market, the "claw-back" tax, which is payed quarterly by the manufactures. The claw-back tax is paid on the consumption that exceeds the budget cap set up for pharmaceuticals in the public health care system. This also applies for medicines which are part of public purchasing at national level or by hospitals.

In July 2018, the MoH introduced a new reference price for those innovative medicines that got off-patent over time. The "innovative reference price" is also set up at 65% of the price of the innovative medicine that lost patent, while for biosimilars is 80% of the price of the innovative medicine without patent. This applies only if the generic medicine is present on the market and, therefore, a generic reference price is calculated. Because many of the innovative medicines on the market lost their patent several years ago and it was difficult for the MoH to determine the price of the innovative medicine when the first generic came to the market, the innovative medicine's manufacturer had to declare the price.

After the price of a medicine is approved by the MoH, it is published in the National Medicines Prices Catalogue – CANAMED, that also contains all the references prices.

Before the reimbursement price is set by the National Health Insurance House (NHIH), the medicine that already holds a marketing authorization in Romania goes through a series of stages, as seen in Figure 1:

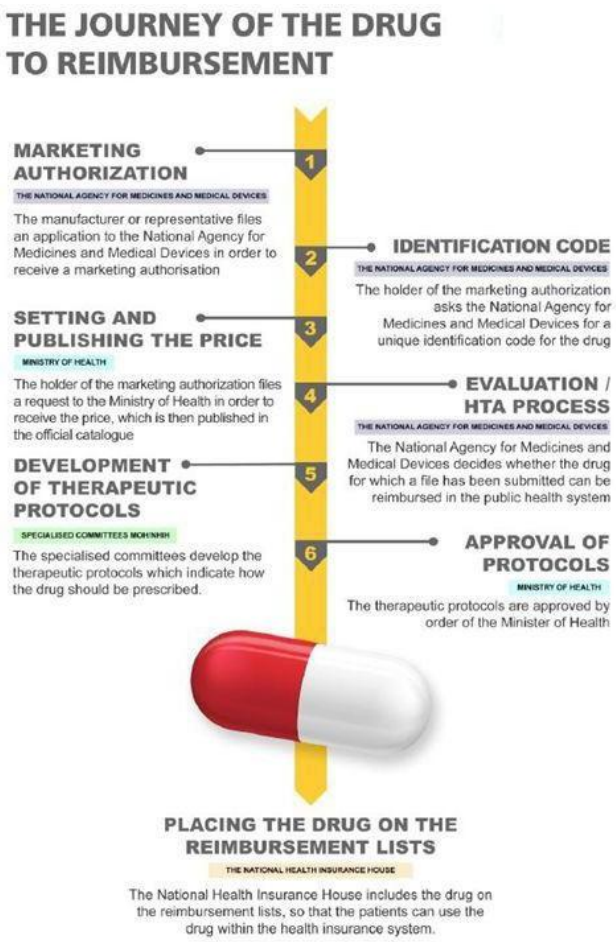

Figure 1. Stages needed for a drug to get reimbursement

Stages needed for a drug to be reimbursed in the Romanian social health insurance system:

- ⇨ The market authorization holder files and application to the National Agency for Medicines and Medical Devices;
- ⇨ The pharmaceutical product receives a unique medicine identification code (CIM), from the National Agency for Medicines and Medical Devices (ANMDM);
- ⇨ The marketing authorization holder registers the pharmaceutical's dossier to the Ministry of Health in order to obtain the price according to national regulations, which is published in the official catalog (CANAMED);
- ⇨ The pharmaceutical goes through the health technology assessment process (HTA), which analyzes its benefits and decides whether the medicine is reimbursed, by introducing it on the Medicines List according to Government Decision no. 720/2008;

- ⇨ If the decision is to reimbursed the pharmaceutical under the social health insurance system, an expert commission of physicians, within MoH and NHIH, elaborates the prescription protocols for that medicine, which is approved by order of the Minister of Health;
- ⇨ NHIH introduces the pharmaceutical on the reimbursement lists so that patients can have access to the treatment under the social health insurance system.

HIV National Programs in Romania

At the end of November 2018, the Ministry of Health published the draft of the Strategic National Plan for Monitoring, Control and Prevention of HIV/AIDS infection cases for 2019-2021. According to the plan, during 2008-2016 the number of patients on ARV (antiretroviral) treatment increased by 47.2% (from 7,434 in 2008 to 10,942 in 2016), which had a direct impact on the expenses: expenses with ARV treatment doubled, reaching about 60 million Euros. To cover ARV treatment and monitoring for newly diagnosed people, an annual budget increase of about 4.6 million Euros would be needed[2].

In Romania, there are two main authorities which receive and allocate budget for national health programs:

- The Ministry of Health, for the public health and prevention programs – the funds flow in from the national state budget.
- The National Health Insurance House, for the treatment programs – the main financing source is the social health insurance fund (FNUASS), but also the national state budget. The claw-back tax is returned as funds to the FNUASS.

The prevention, monitoring and control program of HIV/AIDS infection is coordinated by the Ministry of Health, that uses part of the budget for national level purchasing, through public procedures, medicines and rapid tests and ELISA tests for the diagnosis of HIV/AIDS infection. The MoH also allocates the rest of the budget directly to the hospitals, for their own public acquisitions of necessary medicines and other assets. The funds are assigned for ARV treatment and HIV testing.

[2] http://www.ms.ro/wp-content/uploads/2018/11/Anexa-la-HG-Plan-National-HIV-2019-2021.pdf (accessed in January 2019)

The National Health Insurance House reimburses the costs for the analysis and other services that are performed at the general practitioner office or in the hospitals. These are not part of the prevention program coordinated by the MoH. Also, the NHIH reimburses the costs for the curative treatment of people in hospitals with various infectious diseases, as well as for their viro-immunological monitoring, through the day-time care.

National Program for Prevention, Monitoring and Control of HIV/AIDS Infection

The National Program for Prevention, Monitoring and Control of HIV/AIDS infection aims to reduce the spread of HIV/AIDS infection by early detection of infected people, including the Most At Risk Populations (MARPS), and by reducing associated morbidity through the provision of treatment for patients living with HIV/AIDS.

Provision of technical assistance and management of the national public health programs is carried out by the 'Technical Assistance and Management Units' of the national public health programs (UATM), organized within the institutions subordinated to the Ministry of Health. In the case of the national HIV/AIDS prevention program, this unit (UATM) operates within the National Institute for Infectious Diseases - "Prof. Dr. Matei Balş".

The HIV/AIDS prevention and surveillance activity regulates that the MoH purchases rapid tests and ELISA tests for the diagnosis of HIV/AIDS infection through public procurement.

The treatment of patients with HIV/AIDS infection is managed by the Ministry of Health through centralized procurement of antiretrovirals (ARV) and anti-infectious drugs for the treatment of HIV/AIDS, HIV-related infections, and genotypic resistance testing for ARV. Medicines that can be purchased by the Ministry of Health through centralized procurement are regulated by the Order of the Ministry of Health no. 658/2013.

There is a significant difference between the public purchasing performed for diagnosis tests and medicines:

- For the diagnosis tests: a contract is signed with the winning wholesaler, that provides specific quantities of the tests, and the MoH directly pays the wholesaler for the tests received by the hospitals;
- For medicines: a framework agreement is signed with the wholesalers (a maximum of 7 suppliers/ agreement) that offered the lowest prices, and the supplier is paid directly by the hospital, who signs subsequent contracts with that wholesaler.

The medicines which are not part of the public procurement process at national level, coordinated by the MoH, are acquired by hospitals, that also have to comply with all the regulations of the Law no. 98/2016 regarding public acquisitions in Romania. Every hospital must appoint a coordinator of the HIV program at local level. The coordinator responsibilities are: to monitor the consumption and stocks of medicines; to estimate the necessary amount of medicines for the public procurements; to elaborate different reports on reaching the indicators of the program.

Nine hospitals at national level are running the Prevention, Monitoring and Control Program for HIV/AIDS patients. Each of these hospitals have several counties ascribed.

Medicines provided for outpatient treatment of HIV/AIDS patients are dispensed through closed-circuit pharmacies belonging to the healthcare units that conduct national programs for HIV/AIDS patients, based on medical prescription or medical registry. To justify the consumption of specific medicines granted under the national programs, these prescriptions are submitted to the County Public Health Directorates or directly to the UATM, together with the centralizing tally-sheet and the closed-circuit pharmacy management reports.

The medicines granted to patients, included in the national health programs for both ambulatory and hospital treatment, are provided free of charge.

ROMANIA HEALTH PROFILE

Romania has the lowest percentage of healthcare expenditure of GDP (4.1% in 2015) in Europe and has the lowest level of health spending per capita.

There are no up-to-date clinical guidelines and no feasible national disease registries – therefore impact analysis or real financial predictions are scarce or based on estimations even when the management of the most important and prevalent diseases is targeted.

Data from 2016 illustrates that the number of persons registered as living with HIV/AIDS was 14,349; over 61% of new cases of HIV infection in Romania were late diagnosis, unlike Europe which has about 48% newly-diagnosed cases on the average.

Types of Public Purchasing of HIV Medicines in Romania

According to law, the MoH can organize centralized public purchasing for the ARV treatment and public procurement of rapid tests and ELISA tests for detecting HIV/AIDS infection. Both types of procurements (Figure 2) ensure that the MoH can purchase the needed treatment/diagnosis kits at much lower prices than would have been the case if institutions/hospitals that implement the national HIV programs made purchases on their own.

In cases of centralized public purchasing of the ARV treatment, the MoH signs framework agreements suppliers (maximum of 7 suppliers/ agreement) that offered the lowest prices; the wholesaler which offered the lowest price will be the one which will provide the medicines for the first year. The framework agreements are usually signed for 2 years (the law stipulates a maximum period of 4 years); after the first year, a new biding with the wholesalers that are part of the initial agreement takes place and the wholesaler with the lowest price (can be different from the one designated to deliver to hospitals in the first year) will be the one distributing medicines to the hospitals for the second year.

The framework agreement lays down the basic grounds (especially the acquisition price) for hospitals that implement the national HIV programs to sign subsequent contracts with the suppliers. These subsequent contracts are revised by the directorate in the MoH responsible with public purchasing. The department in charge with assigning the contracts is the Investments and Acquisitions Service in the MoH.

For the public procurement of rapid tests and ELISA tests, the MoH signs direct contracts with the suppliers. The institutions/hospitals which implement the national program can receive the HIV tests by signing contracts with the County Public Health Directorate.

The MoH national public health programs/subprograms' budget is financed monthly, it is detailed for each source of funding and based on the grounded requests of the specialized institutions/hospitals that implement them, accompanied by supporting documents.

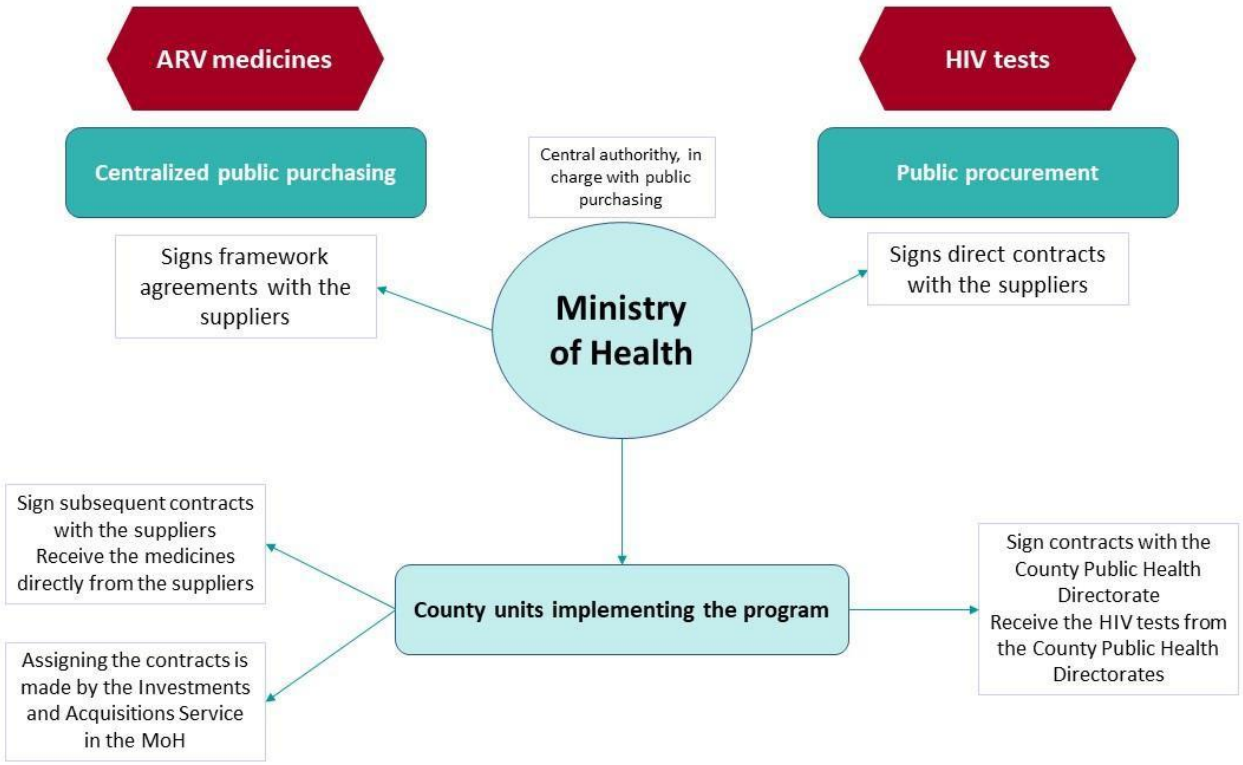

Figure 2. Types of public purchasing

The public procurement process should not last more than one month. The needed documents are: the report of necessity, the technical 'task book' (that contains all the technical details of the products to be purchased) and the announcement in the SEAP platform (the bidding online public platform).

In real life, a public acquisition procedure can last up to one year because of several barriers, the red tape and the appeals submitted usually by the suppliers that participated in the procurement process. For medicines, the process laying out the documents needed for the public procurement is more clear. For diagnosis tests, the elaboration of the technical 'task book' can be quite difficult due to significant gaps in the legislative framework regulating medical devices in Romania: no official price approved by the authorities, no complete list of all medical devices authorized in Romania (even if a national public register does exist) and no quality standards in place. Even more, not all diagnosis tests match the devices owned by the hospitals and therefore it is necessary to acquire more than one type.

A similar process takes place at local level, in hospitals, which have to run their own public purchasing for all the medicines that are not being acquired within the framework agreement by the MoH. The local coordinator of the program provides the necessary amount of medicines to be purchased and, under the supervision of the Economic Director, the Acquisitions Director and the Hospital Manager, the announcement/ invitation to bid is placed on the public bidding platform SEAP. The process is similar with the one at national level, confronting with the same issues.

As a result, delays in the acquisition process are frequent.

Who is in charge of public purchasing?

The Ministry of Health is the central health authority in Romania which, through its specialized departments and expert committees, carries out policies on health programs and finances some of them, with the possibility of carry out centralized public procurements (Figure 3).

The specialized departments of the Ministry of Health in charge with the proper conduct of the national programs are the General Directorate for Medical Assistance and Public Health (DGAMSP) and the National Health Program Agency (ANPS), which collaborate and request information from the UATM on the need for tests and ARV medicines. The UATM obtains information from the County Public Health Directorates, which in turn asks data from the specialized institutions/hospitals implementing the project at the local level.

The specialized committee within the MoH is in charge with developing a report of needs, that takes into consideration the medical guidelines and has to include the needed medicines and medical devices, as well as the quantity for each and an estimated budget. The needed quantity of medicines and diagnosis tests takes into consideration the consumption for the last year and the available stocks in hospitals. Ministerial Order no. 377/2017 stipulates that at the end of the year, in the case of the National Program for Prevention, Monitoring and Control of HIV/AIDS infection, hospitals have to ensure a buffer stock of products for 3 additional months. Therefore, the public procurement has to take into consideration the need for 1 year and 3 months but also the fact that the framework agreement is signed for 2 years.

The Public Procurement Directorate within the MoH has an important role since it is responsible with the support of the other two departments, for the bidding announcement and establishing specifications for centralized public procurement (directly influencing the criteria that represents the basis for the winning bid) – which is usually carried out through an open public tender. Another committee is set up for developing the awarding documentation – the technical 'tasks books' are developed by three national experts and the other documents needed for the announcement in SEAP are developed by representatives of the Public Procurement Directorate in the MoH. The technical 'tasks books' have to be revised by two independent experts, different from the three experts that originally developed the documents.

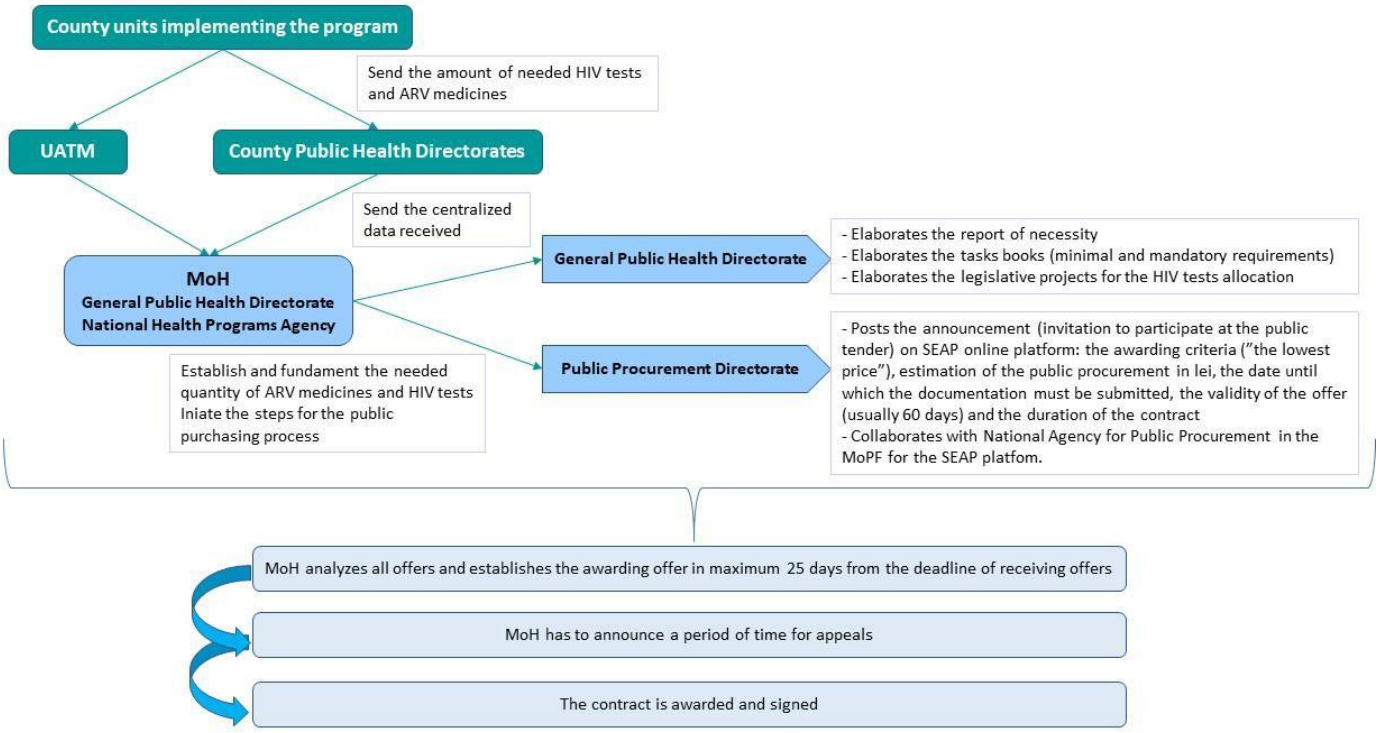

Figure 3. Mechanism of public purchasing: relational map

The Romanian law stipulates that pharmaceuticals must be distributed only by wholesalers; therefore, the market authorization holder cannot sign framework agreements (and neither participate in a public procurement procedure) or direct contracts to provide medicines; this would be possible only if the market authorization holder can demonstrate the ability to deliver to hospitals, having in place their own distribution system.

Within the Ministry of Public Finance, the National Agency for Public Procurement (ANAP) functions as a regulator and monitor of the public procurements carried out by the contracting institutions/authorities in Romania. ANAP also manages the SEAP online platform – the Electronic Public Procurement System - designed to make the public procurement process more transparent and efficient.

The Government recently established a new entity with a role in public procurement, named the National Office for Centralized Acquisitions (ONAC). This Office is a Directorate within the Ministry of Public Finance and conducts the centralized purchasing on behalf of contracting authorities for products and services, including pharmaceuticals. In addition, ONAC also monitors the centralized framework agreements or centralized procurement contracts. Contracting authorities have the obligation to purchase the products and services bid for in a centralized system through ONAC, an office which started its activities only during 2019.

Steps in the Public Purchasing Process

The following activities take place in the public procurement process:

- ⇨ The National Health Program Agency (ANPS) collaborates with the General Directorate for Medical Assistance and Public Health (DGAMSP) in order to establish and provide the evidence needed to set the quantity of ARV medicines and HIV tests, according to the estimates received from the County Public Health Directorates and UATM.
- ⇨ In case of the diagnosis test, the General Directorate for Medical Assistance and Public Health (DGAMSP) collaborates with the Public Procurement Directorate for the acquisition and coordinates the storage and distribution of these tests.
    - The General Directorate for Medical Assistance and Public Health (DGAMSP), with the consultation of the specialized committee in the MoH, elaborates the report of necessity that provides grounds for initiating the public purchasing procedures;
    - DGAMSP also coordinates the activities for the public purchasing procedures:
        - To elaborate the technical 'tasks books' and approve them internally in the MoH; the technical 'tasks books' contain the minimal and mandatory requirements needed for a supplier to be allowed to take part in the public procurement process;

- To monitor the public purchasing contracts;
- To approve the documents for the HIV tests received by the receiving committee of the MoH;
- To elaborate the legislative projects for the HIV tests allocation and approving them by the Minister of Health;
- To elaborate and sign the paperwork for the expenses in order to pay for the purchased tests with prior approval by the financial departments of the MoH.

⇨ After the needs report is developed, the Public Procurement Directorate is responsible for publishing the invitation to participate at the public tender on the SEAP online platform. For this to happen, the technical 'tasks book' has to be developed by a committee of three national experts and the awarding documentation must be developed by a representative of the Acquisition services in the MoH. The announcement in SEAP must contain at least the awarding criteria ("the lowest price"), estimation of the minimum and maximum quantities, estimation of the public procurement in lei (RON), the deadline for the submission of the documentation, the validity of the offer (usually 60 days) and the duration of the contract. Each type of medicine (INN and concentration) represents a batch in the public acquisition procedure – for each batch, the estimated quantity (minimum and maximum) must be published. The minimum and maximum estimated value of the public acquisition for each batch is also published.

⇨ Before the actual electronic biding takes place, all interested suppliers may request more information or ask for details on the documentations posted in SEAP. If there are aspects related to the technical data, the three national experts that elaborated the technical 'tasks book' must provide an answer.

⇨ The MoH announces all the details for the electronic biding to take place. The supplier offering the lowest price per each batch is the one to deliver for one year the products to the hospitals.

⇨ The framework agreement is signed for 2 years with the suppliers that offered the lowest prices (maximum of 7 suppliers/ agreement).

Each hospital has to sign subsequent contracts with the winning supplier. At the end of each month, if necessary, the hospital has to send all the bills to the County Public Health Directorate, in order to receive funds from the MoH to pay the supplier.

Criteria Set-Up for Public Purchasing

The "lowest price" is the standard awarding criteria used by the MoH in centralized public procurements. In the case of PN-HIV, the purchase price may not exceed the reimbursement price (which in this case is similar with the price listed in CANAMED), approved by joint order of the Minister of Health and the President of the National Health Insurance House. The reimbursed price for the national program is calculated taken into consideration the wholesaler price listed in CANAMED.

The law specifies that until the MoH finalizes the centralized public procurement, the units that implement the national program can purchase for themselves the needed medicines, in compliance with public procurement legislation, at a purchase price that may not exceed the approved reimbursement price (which in this case is similar with the price listed in CANAMED) set up by the National Health Insurance House.

The detailed specifications for every national program, as well as each specific budget, are approved by a Ministerial Order for a period of two years. During these two years, changes can be made regarding the budget, taking into consideration that the state budget is approved annually and there is also an annual rectification.

The entire process for establishing the allocated budget for the HIV National Pogram is presented in the next section.

Setting the budget: the power map

The departments in the MoH involved in setting the national programs budget are:

- the National Health Program Agency (ANPS), that collaborates with the General Directorate for Medical Assistance and Public Health (DGAMSP) and gathers data from the UATM and the County Public Health Directorates. ANPS takes into consideration the consumption data and the available stocks in elaborating the proposed budget. ANPS sends the proposed budget to the General Budget Directorate in the MoH that centralizes all needed funds for the activity of the MoH.
- the General Budget and Finance Directorate fills in a document with the proposed annual budget for the MoH and sends it to the Ministry of Public Finance.

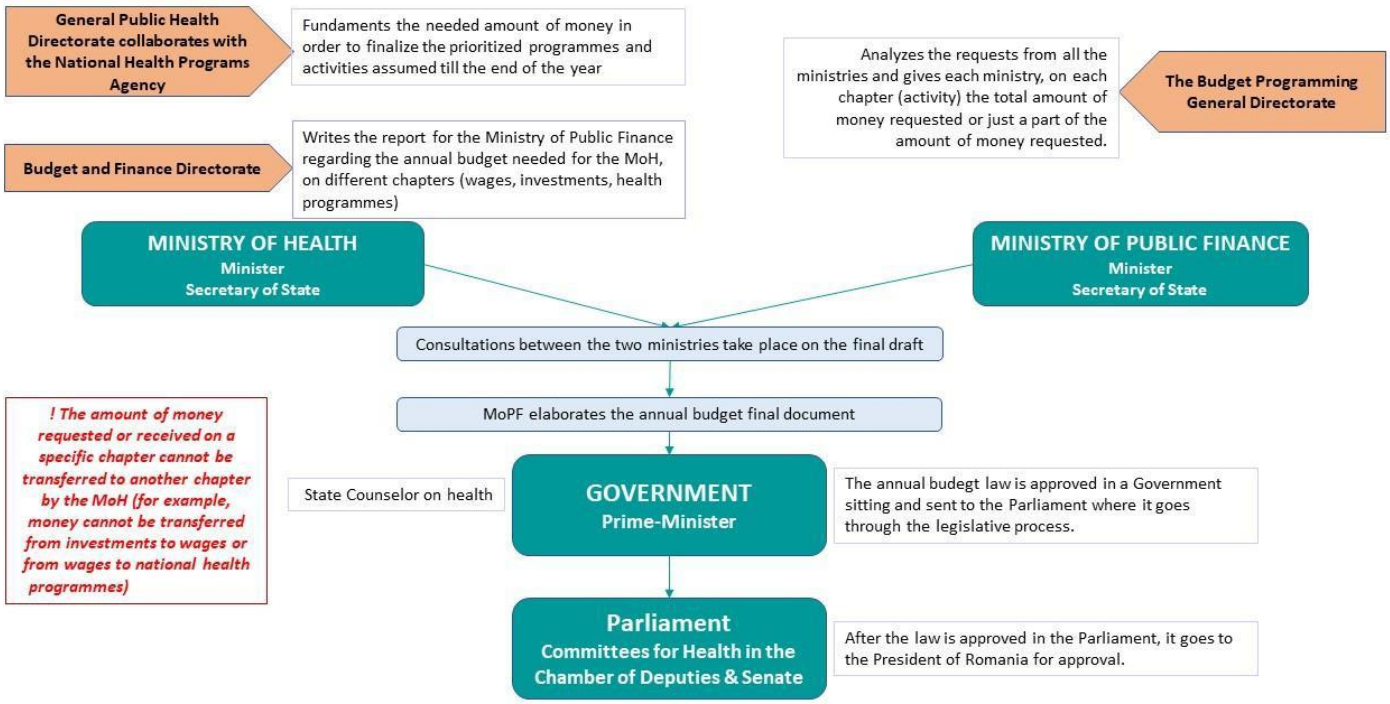

Figure 4. Authorities involved in setting the budget for HIV Program

According to the available funds for the current year, the Ministry of Public Finance through the Budget Programming General Directorate, analyzes the requests from all the ministries. It then gives each ministry, based on each chapter (activity), the total amount or part of the amount of funds requested.

Consultations between the two ministries (MoH and the Ministry of Public Finance) take place on the final draft of the annually established budget, and the Ministry of Public Finance develops the final legislative act that shall be approved by the Government and the Parliament.

Once or twice a year, a budget rectification is carried out. The process is similar to that used for the specific budget set-up. Nevertheless, strong arguments must be made by each directorate in the MoH to prioritize activities underfunded for the rest of the year in order to receive additional funds. Despite the arguments, the Ministry of Public Finance can decide not to allocate to the MoH additional funds for the underfunded activity. Usually, the MoH receives additional funds after the budget rectification, but the amount is often too small to cover all the needs for the national programs.

Specific indicators and budget allocation for the National Program for Prevention, Monitoring and Control of HIV/AIDS infection

For each activity, the program developed by the MoH provides a series of indicators, as follows:

Prevention and monitoring activity:
> rapid HIV tests: 170,000 tests, of which 120,000 tests made for pregnant women; > HIV ELISA tests (1+2): 200,000 tests, of which 120,000 tests for pregnant women; > estimated average cost/ rapid HIV testing: 4.70 RON; > estimated average cost/ HIV ELSA test (1+2): 9,50 RON;
Ensuring treatment for HIV/AIDS patients:
> number of individuals who have received post-exposure prophylaxis: 400; > number of HIV/AIDS patients receiving ARV treatment: 10200 patients; > number of HIV/AIDS patients receiving prophylaxis with non-ARVs: 500 patients; > number of HIV/AIDS patients in therapeutic failure beneficiaries of the genotypic resistance ARV test: 3,500 tests.
> estimated average ARV cost/person who has received post-exposure prophylaxis: 688 RON; > estimated average cost per HIV/AIDS patient receiving ARV treatment/year: 27500 RON; > estimated average cost per HIV/AIDS patient receiving prophylactic non-ARV treatment/year: 2000 RON; > estimated average cost/genotypic resistance test for ARV: 1300 RON.

The budget set up for the prevention program in 2017 and 2018 (RON)

2017			
National public health program	State budget	MoH incomes	**Total**
National Program for prevention, monitoring and control of HIV/AIDS infection	137.373	170.784	**308.157**

2018						
National Public Health Program	State budget		MoH incomes		**Total**	
	Engagement credits	Budgetary credits	Engagement credits	Budgetary credits	**Engagement credits**	**Budgetary credits**
National Program for Prevention, Monitoring and Control of HIV/AIDS Infection	113.998	113.998	226.158	189.078	**340.156**	**303.076**

URGENT POLICY ACTIONS TO BE IMPLEMENTED

ACTION 1. To assign a detailed budget and approve the Strategic National Plan for Monitoring, Control and Prevention of HIV/AIDS Infection for 2019 – 2021.

ACTION 2. To initiate an integrated HIV program, from medicines to services.

Responsibilities should not be splitted between so many actors, since this leads to lower accountability, increased red tape and delays.

ACTION 3. To reduce the excessive red tape in public procurement and provide more flexible tools to strengthen MoH or NHIH ability to negotiate.

The excessive tightness of SEAP announcement and documentation rules generates significant delays in the public purchasing of medicines/tests. Direct negotiations with market authorization holders, especially when only one product is available on the market, should be considered.

ACTION 4. To pay suppliers at central level.

Today, even though the MoH is in charge with the national public acquisition for the HIV program, the actual payment to the awarded supplier is made at local level, by the hospital. Since budgetary credits can be allocated only quarterly, this interferes with timely billing by the hospitals. Delays in paying suppliers are common, which might cause delays in delivering the products.

ACTION 5. To clarify conditions used in the framework agreements.

The current framework agreements signed with the suppliers are lacking in detail on what happens if the awarded supplier cannot deliver the products or if it is not able to satisfy the provisions of the contract.

GENERAL RECOMMENDATIONS

ON PREVENTION

In line with the WHO prevention policy on HIV, Romanian Government should focus on providing more financing sources for prevention, mainly for essential health sector interventions and essential strategies for an enabling environment.

Essential Health Sector Prevention Interventions should be aimed at:

1. The establishment of a strong supply chain for the distribution of condoms, test kits, etc. Trained individuals, educational materials, and the use of technology should be employed in sharing information on the right way to use available stock.
2. Establishing voluntary testing and counselling centres, helpline, or system for MARPS ensuring that no member of the vulnerable community is left behind in terms of access to prevention. The idea is to ensure that vulnerable populations have the same level of access to testing and prevention services as the rest of the population.
3. Establishing media-focused health campaigns for harm reduction interventions for drug users.
4. Generating IEC materials which would promote a re-orientation, behavioural interventions, and achieve desired change.
5. Providing constant voluntary HIV testing and counselling services at health centres and boosting complementary testing services on strategic dates (eg. RMNCH Week, World AIDS Day/Week, Immunisation Days, etc).
6. Making readily available Pre-exposure prophylaxis (PrEP) and Post-exposure prophylaxis (PEP) for eligible people from key populations on a voluntary basis. Healthcare workers who treat and manage PLHIV should also be factored in during the provision of PrEP for needle prick incident and prevention purposes.

Prevention aimed at providing an enabling environment should:

- Establish laws which fight against stigmatization, provides support for persons of varying sexual orientations and many other vulnerable groups.

ON FUNDING

The high rate of new cases of HIV infections diagnosed in a late stage should serve as a wake-up call to every official who plays a strategic role in managing HIV/AIDS in Romania. The red tape in the system should be urgently cut and clear criteria based on cost-effectiveness principles should be used in the HIV Programs designing process. Too many directorates and health agencies have overlapping activities creating in the system an environment of institutional adversity and unclear responsibilities.

It has become imperative that the Romanian government, the Romanian Parliament and/or budget managers devise ways of boosting funding for the provision of screening rapid tests and ELISA kits. This should also cover drug provision and psychosocial support for affected persons. An emergency response committee should be set up to boost early detection rates and encourage enrollment in care.

ON RESEARCH

HIV infections reduction cannot be achieved adequately and on time without the inclusion of the academic milieu. Across the world, there have been studies that have supported international agencies, donor bodies and countries in taking strategic steps towards combating HIV infections and its attendant sequalae. There is a growing need to encourage, boost and commission studies within the Romanian local context in this regard. These studies can be focused on funding mechanisms, prevention, treatment, data management or any other branch of HIV programming.

There will be no better source of information to guide responsible agencies that oversee care and support of Persons Living with HIV (PLHIVs), than outcome of research conducted within the Romanian public health space. Civil society organizations, donor agencies and the Romanian Government should encourage such a strategy, within stipulated ethical guidelines, to yield guiding information that would lead to a better outcome for the direct beneficiaries of HIV care and support as well as the Romanian country at large.

SPECIFIC RECOMMENDATIONS

Using a Combined Request and Requisition Form (CRIRF) system. CRIRF is a centralized form system, implemented across the country, used to curate numbers of tests and drugs supplied/used and the quantities needed for reimbursements. Details of other drugs recommended by international guidelines for the treatment of opportunistic infections that come with HIV should be included in CRIRF. In addition, other materials used in the treatment, care and support within the hospital setting will be included and monitored. Apart from being centralized, there is the need to establish an electronic platform for inputting request and requisition data. This is key as it enables authorities responsible for procuring to reconcile what is on the platform and what is sent to them as paperwork. This boosts accountability, accounts for usage, wastes, and strengthens projections of needs to prevent stock-outs.

Establishing more peer-to-peer networks and strengthening patients organizations. Great successes have been recorded in countries where there has been peer-to-peer networking among vulnerable populations; this means one-on-one engagement and encouragement circles done by affected persons in an informal way and without strict oversight from medical personnel. These networks have helped in ensuring retention on treatment for those who have tested positive and has also helped in contact tracing of partners of persons who are already infected. In addition, these

networks have also played a role in guiding governance policies regarding their care and support. In the area of pharmacovigilance, the peer-to-peer groups have been known to partake in reviews of drug-drug reactions and this guides HIV drug procurement and dispensing. Patients organizations are already playing an important role in Romania and their activities should be actively supported by designing new financing tools and increasing access to public funds.

Encouraging more players in HIV Management. Due to cash constraints, many countries have been known to welcome support from non governmental organizations or members of the private sector in providing support in the area of HIV /AIDS. As part of their Corporate Social Responsibilities (CSR), local private bodies should be encouraged to donate more funds to the NGO sector, provide non-drug/medicinal needs of patients in centers where they receive screening, treatment, care and support. CSR activities in the Romanian healthcare system are already present, but more is needed.

Decentralizing Screening Points. In order to pick up more positive cases and early too, it is key that civil society organizations and healthcare workers be involved in decentralizing testing points. This should be based on the premise that due to cultural limitations, cash constraints and poor information, many of the vulnerable members of the society will not go seeking screening opportunities on their own except if this is brought close to them. While this is being carried out, it is imperative that the test supply chain system is adjusted to factor in out-of-hospital testing sites and that confidentiality of every individual is maintained.

Update Trainings. It is important that all key staff responsible for data management, prevention/screening, treatment and overall management of HIV patients undergo periodic trainings according to an updated WHO manual and standards. In addition to this, step-down of information garnered by those trained should be carried out to ensure a decentralization of knowledge learnt. It also helps prevent and/or guard against cases of staff attrition.