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REPORT

access to antiretroviral therapy in countries of Balkan Peninsula

Bosnia and Herzegovina, North Macedonia, Montenegro, Romania, Serbia

Content

We would like to present our analytical study in respect of the pharmaceutical market regulation (i.e. antiretroviral drugs) in the countries of the Balkan Peninsula: North Macedonia, Serbia, Bosnia and Herzegovina, Montenegro, and Romania. Such study covering five South-East Europe countries is being conducted for the first time and is important because the Global Fund to Fight AIDS, Tuberculosis and Malaria (the «Global Fund») ends financing of HIV / AIDS program in the mentioned countries, and transition of the funding of the national HIV programmes by the means of the state budgets. The provision of ARV drugs to patients in these countries remains challenging. In 2019, the assessment made by the Global Fund showed some of the countries under study as such having a high level of HIV infection. However, the national budget, which is limited, remains the main source of funding of drugs procurement. By allocating governmental funds to the procurement of drugs, the vast majority of which are branded and therefore the prices for drugs remain high and far exceed those in Eastern Europe and Central Asia, the countries should ensure access to treatment for all HIV positive patients, taking into account the international goals, targets and commitments to end HIV epidemic declared by UNAIDS by signing 2016 United Nations Political Declaration on Ending AIDS that calls on the world to accelerate efforts towards ending the AIDS epidemic by 2030.

The study was aimed at analyzing a specified list of ARV-drugs in view of their availability and procurement procedures in 5 Balkan countries. The report analyses the issue of involvement of NGOs in activities which aim to increase ARVs access to people. It also studied the issue of transparency of procurement using appropriate electronic systems. Report envisaged analytics of the main procedural and technical requirements to the procurement and its subject matter respectively, in particular, the special aspects of taxation, marking of packing, logistics and nomenclature development.

In addition, the study also shows the specific features of other important stage in drugs supply — the state registration procedures for drugs, in particular, focuses on fast-track registration procedures and registration after winning a tender, and demonstrates special conditions for business of non-residents to sell drugs in the countries.

The report will be useful for NGOs, which purpose is to improve population health, to increase availability of medicines to HIV-infected patients, to antiretroviral drug manufacturers and suppliers, international organizations and other healthcare stakeholders.

The main purpose of this document is to facilitate efforts, which are taken by the government of South-East Europe countries to combat the HIV/AIDS epidemic.

The information is produced by the method of desk study — system analysis of statistics and secondary information from publicly available sources: laws and regulations in health care, medicines, tax of the countries under study; statistics of WHO, World Bank, UNAIDS; public procurement portals in countries under study; web-resources of state regulators, hospitals and persons responsible for the procurement of ARVs in the countries under study; web-sites of the European Center for Disease Prevention and Control of the Global Fund to Fight AIDS, Tuberculosis and Malaria and other public data.

The publication is co-authored by two organizations: CO «100% LIFE» (Zamikhovska Zoia, Dmytriiev Sergii) and Kairos Group, law firm, engaging Slobodnichenko Marina and Isaeva Olga, legal counsels of the firm in medicine and pharmacy, and published within the framework of the multi-country project «Sustainability of Services for Key Populations in Eastern Europe and Central Asia» that is coordinated by the ICF «Alliance for Public Health», in a consortium with the CO «All-Ukrainian Network of PLWH» (CO «100% Life»), the OLE «Central Asian Association of PLWH» and the Eurasian Key Populations Health Network, with the financial support of the Global Fund to Fight AIDS, Tuberculosis and Malaria.

BOSNIA AND HERZEGOVINA

3 351 527

Population, persons

25

Number of new HIV cases in 2018

350

Estimated number of people living with HIV, persons (The proportion of the population living with HIV — 0,01)

224

Number of HIV-infected people who know their status and covered by antiretroviral therapy, persons

* data as of 31.12.2018

https://data.worldbank.org/country/bosnia-and-herzegovina
http://www.fmoh.gov.ba/images/federalno_ministarstvo_zdravstva/preporucujemo/Zdravstveno_stanje_stanovnistva_2017.pdf
https://www.klix.ba/lifestyle/zdravlje/u-bosni-i-hercegovini-registrovano-350-osoba-zarazenih-hiv-virusom/171201105
https://data.worldbank.org/indicator/SH.HIV.ARTC.ZS?end=2017&locations=BA&most_recent_value_desc=false&start=2000
https://www.ecdc.europa.eu/sites/default/files/documents/HIV-annual-surveillance-report-2019.pdf

1. SUMMARY *

Criteria	Comment
Characteristics of state registration procedures	
The law that regulates the registration of medicines	The Act of Medicinal Products and Medical Devices (Official Gazette of Bosnia and Herzegovina, No. 58/08).
Registration authority	The Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina (Agencija za lijekove i medicinska sredstva Bosne i Hercegovine).
Entities that have the right to sell medicinal products	• A medicines manufacturer registered in Bosnia and Herzegovina; • A representative of a foreign manufacturer registered in Bosnia and Herzegovina.
Entities that have the right to participate in a tender	• An economic entity authorized to sell the medicinal product. The legislation does not envisage exceptions which could allow participation of ARVs in the public procurement tender without a marketing authorization in Bosnia and Herzegovina *(see Section 2.5)*.
Packaging requirements	The availability of basic information on the medicinal product in one of the official languages of Bosnia and Herzegovina (Bosnian, Serbian, Croatian) on the outer, inner packaging and packaging leaflet (instructions to the medicines). Information on the outer and inner packaging, provided in one of the official languages of Bosnia and Herzegovina, may be also provided in foreign languages. There are no restrictions on foreign languages.
The availability of restrictive lists (for example, a list of vital medicines)	There are several lists in Bosnia and Herzegovina: • the List of medicines financed by the Solidarity Fund of the Federation of Bosnia and Herzegovina containing 13 items of ARVs, • the List of medicines with a special method of procurement (financed from the Health Insurance Fund of the Republic of Serbia) which contains 7 items of ARVs, • the Supplementary list of medicines (financed from the Health Insurance Fund of the Brcko District) containing 5 positions of ARVs. Public procurement plans may not include drugs that are not on these lists.
The availability of expeditious registration procedures	According to the Act of Medicinal Products and Medical Devices, expeditious registration procedures for medicinal products are not provided for.
VAT and tax benefits	A discounted VAT rate has not been approved for medicinal products (total VAT rate is 17%).
Availability of post-registration for medicines	In accordance with the tender documentation, the tenderer's application must include a certified copy of the decision regarding a marketing authorization granted by the Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina. Post-registration for medicines is not legally available.
Availability of special conditions for non-residents	To participate in the public procurement of ARVs, a participant must have a marketing authorization. Non-residents cannot obtain a marketing authorization without establishing a foreign representative office in Bosnia and Herzegovina.
Logistics	According to the tender documentation, the supplier selects a logistics partner.
Procedures of nomenclature formation	
Authorities responsible for the nomenclature lists formation	The nomenclature of ARV drugs is formed by infectious disease clinics based on the needs of patients registered in these healthcare facilities and according to the centralized decisions of the Solidarity Fund of the Federation of Bosnia and Herzegovina, the Health Insurance Fund of the Republic of Srpska and the Health Insurance Fund of the Brcko District.

* Information as of the second half of 2019

Opportunity for NGOs and international organizations to participate in the nomenclature formation	No relevant information has been found.
Approval terms and frequency of the nomenclature revision	The revision of the nomenclature is carried out on annual basis.
The functioning of the public procurement system	
Funding sources	Since 2005, there has been only national funding for antiretroviral therapy covered by the Solidarity Fund of the Federation of Bosnia and Herzegovina, the Health Insurance Fund of the Republic of Serbia and the Health Insurance Fund of the Brcko District.
Procuring entities	The medicines are purchased by the following institutions: • centralized, by the Solidarity Fund of the Federation of Bosnia and Herzegovina, the Health Insurance Fund of the Republic of Serbia and the Health Insurance Fund of the Brcko District; • decentralized, infectious disease clinics that treat HIV patients
Possibility to use international mechanisms/funding	The procurement of ARVs using international mechanisms is not provided by law.
Availability of transparent procedures	The Public Procurement Portal.
Availability of supply disruptions	No relevant information was found.
Procurement planning	Procurement planning is carried out for 1 year.
Statistics on the volume of procurement of ART drugs	
Purchasing prices	Specified in the tender documentation for each item.
Number of medicines purchased	Specified in the tender documentation for each item.
The total amount of procurement	Specified in the tender documentation for individual customers.
Reference to «originator/generic»	There is no information in the tender documentation.
Attitudes towards generics in the NGO/medical community	Prejudiced attitudes of both groups toward generics through stereotypes and myths about their quality and effectiveness.
Patient-centered procurement	Relevant information is not found.

2. STATE PROCEDURE OF MEDICINAL PRODUCTS REGISTRATION

2.1. General information

Registration of medicinal products in Bosnia and Herzegovina is carried out in accordance with the Act of Medicinal Products and Medical Devices[1] Official Gazette of Bosnia and Herzegovina, No. 58/08, hereinafter — the Medicinal Products Act).

According to Article 7 of this Act, the Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina *(Agencije za lijekove i medicinska sredstva Bosne i Hercegovine)* is responsible for granting marketing authorization, its extension, withdrawal or amendment.

According to Article 23 of the Medicinal Products Act, the Agency includes the Commission for Medicines *(Komisija za lijekove)* which evaluates the documentation on the quality, safety and efficacy of the medicinal product submitted for obtaining a marketing authorization, renewal or amendment thereof.

According to Article 31 of the Act of Medicinal Products and Medical Devices, the medicinal product may be marketed in the territory of Bosnia and Herzegovina, provided that the economic entity has a marketing or import authorization.

Composition	15 people.
Formation of the Commission	The Director of the Agency for Medicinal Products and Medical Devices appoints participants. The Ministries of Health proposes 7 persons; the Health Department of the Brcko District proposes 1 person[2].
Possible participants	Health experts with experience relevant to the activities of the Commission.
Term of office	Four years with the possibility of re-election for the second term.

Information block	**Content**
Administrative part	• Information on the manufacturer of the medicinal product, place of manufacture; • Information on the applicant or future holder of the trade license; • Summary characteristic of the product; • Instructions for the patient; • Proposal for packaging of the medicinal product; • A list of countries the medicinal product has marketing authorization; • Expert opinions containing an assessment of the quality, safety and efficacy of the medicinal product.
Analytical part	• Data on the qualitative and quantitative composition of the medicinal product; • A description of the manufacturing process; • Quality control of the manufacturing process; • Quality control of the finished product; • Data on the environmental safety assessment of the medicinal product.
Pharmaco-toxicological part	• Pharmacodynamic and pharmacokinetic characteristics of the medicinal product; • Data on toxicity and reproductive function effects; • Data on embryonic and perinatal toxicity; • Data on mutagenic and carcinogenic potential. • Data on tolerability.
Clinical part	• Information on clinical trials and their results; • Clinical and pharmacological data; • Bioavailability and bioequivalence data (if applicable); • Clinical safety and efficacy data; • Information about exceptional testing circumstances; • Data on using the medicinal product after marketing authorization in other countries.

1. http://www.fmoh.gov.ba/index.php/zakoni-i-strategije/zakoni/zakon-o-lijekovima-i-medicinskim-sredstvima
2. Bosnia and Herzegovina is a parliamentary republic consisting of the Federation of Bosnia and Herzegovina, the Republic of Srpska and the Brcko District.

Authorization for sale

According to Article 29 of the Act of Medicinal Products and Medical Devices, the medicinal product may be placed on the market if it has obtained a marketing authorization (a trade license) from the Agency for Medicinal Products and Medical Devices.

To obtain a marketing permit, the submitted application, under Article 33 of the Act of Medicinal Products and Medical Devices, must contain the following information.

According to Article 34 of the Act of Medicinal Products and Medical Devices, the applicant is not required to submit his/her own pharmacotoxicological and clinical trial results under one of the following conditions:

- A medicinal product is similar to medicine which has a marketing authorization in Bosnia and Herzegovina and its owner agrees in writing with reference to its documentation;
- Information about pharmacotoxicological and clinical data is publicly available, and the safety and efficacy of the components of the medicinal product has been proved and/or its active substance has been used for at least 10 years as a medicinal product in Bosnia and Herzegovina, the EU or other countries with the same standards of quality, safety and efficacy requirements;
- A medicinal product is similar to medicine that has already been authorized for at least 8 years in Bosnia and Herzegovina, the EU or other countries that have the same standards of quality, safety and efficacy requirements. The Agency may only authorize the sale of a generic medicinal product after the expiry of a period of 10 years from the date of authorization of the original (reference) medicinal product.

According to Article 37 of this Act, having obtained a conclusion on the authenticity of the documentation and the Commission's assessment of the quality, safety and efficacy of the medicinal product, the Agency shall decide (no later than 210 days after receiving a complete application for a marketing authorization) to grant a marketing authorization or to reject the application.

A marketing authorization for a medicinal product is granted for a period of 5 years

Import authorization

There are no exceptions in the legislation under which ARVs could be submitted to the public procurement tender without a marketing authorization in Bosnia and Herzegovina *(see Section 2.5)*.

However, there are a number of cases in which the medicinal product may be imported into Bosnia and Herzegovina without tendering.

In accordance with Article 66 of the Act of Medicinal Products and Medical Devices, the competent ministries of Bosnia and Herzegovina may, as an exception, authorize the import of the medicinal product, which has no marketing authorization in Bosnia and Herzegovina, under one of the following conditions:

- Urgent import for individual treatment at the request of a healthcare institution;
- Urgent import of a limited number of medicines to protect public health at the request of a healthcare institution;
- Urgent import of humanitarian medicines;
- Import of medicinal products for scientific research.

These conditions apply only to one-time imports even if all the permitted number of medicines was not imported at one time.

Marking and instruction

According to section 71 of the Act of Medicinal Products and Medical Devices, the requirements for packaging of medicines marketed in the country are as follows:

- The availability of basic medicinal product information in one of the official languages of Bosnia and Herzegovina (Bosnian, Serbian, Croatian) on the outer and inner packaging;
- The availability of instruction for patients in one of the official languages, describing the main characteristics of the product, unless the necessary information is already presented on the outer packaging;
- The availability of the following basic information about the medicinal product on the outer packaging: the name and INN, the quantitative and qualitative composition of the active substance, pharmaceutical form, dosage, packing size, data on the manufacturer and the trade license holder, method of use, storage conditions, expiration date, the batch number, the trade license number and other necessary identification codes, various warnings, etc.;
- The availability of the following basic information on the inner packaging: the name and INN, the quantitative and qualitative composition of the active substance, pharmaceutical form, dosage, data on the trade license holder, expiration date, the batch number and other data, if the size of the package allows;
- The availability of the following basic information in the leaflet (instructions): the name and INN, the quantitative and qualitative composition of the active substance, pharmaceutical form, dosage, packing size, data on the manufacturer and the trade license holder, method of use, indications for use, contradictions, precautions, side effects, storage conditions, expiration term, etc.

Information on the outer and inner packaging provided in one of the official languages of Bosnia and Herzegovina may also be provided in one or more foreign languages. There are no restrictions on foreign languages.

2.2. Restrictive lists

The Decision on the List of medicines covered by the Solidarity Fund of the Federation of Bosnia and Herzegovina[3], adopted on 27.06.2019, contains a list of 13 antiretroviral drugs. Public procurement plans may not include drugs that are not on this List.

3. http://www.fedzzo.com.ba/bs/preuzmi-dokument/odluka-o-listi-lijekova-fonda-solidarnosti-05-07-2019g/795

Table 2.2.1 — Antiretroviral drugs from the List of medicines covered by the Solidarity Fund of the Federation of Bosnia and Herzegovina

ATC Code	INN	Pharmaceutical form and dosage
J05AE06	lopinavir+ritonavir	Tablets, 200mg+50mg Oral solution, 400mg+100mg/5 ml
J05AF01	zidovudin	Capsules, 300mg, 100mg Oral solution or syrup, 50mg/5 ml infusion solution, 10mg/ml
J05AF05	lamivudin	Tablets, 100mg Oral solution, 5mg/ml
J05AF06	abacavir	Tablets, 300mg Oral solution, 100mg/5ml
J05AR01	zidovudin+lamivudin	Tablets, 300mg+150mg
J05AR02	abakavir+lamivudin	Tablets, 600mg+300mg
J05AG01	nevirapin	Tablets, 200mg Oral solution, 50mg/5ml
J05AG03	efavirenz	Tablets, 50mg, 200mg, 600mg Oral solution, 150mg/5ml
J05AR03	tenofovir disoproksil+ emtricitabine	Tablets, 245mg+200mg
J05AR08	emricitabin+ tenofovir+rilpivirin	Tablets, 200mg+25mg+245mg
J05AF07	tenofovir disoproksil	Tablets, 245mg
J05AX08	raltegravir	Tablets, 400mg
J05AX12	dolutegravir	Tablets, 50mg

The Decision on the List of medicines with special procurement method (covered by the Health Insurance Fund of Republika Srpska), adopted on 29.12.2015 (as amended), contains a list of 7 antiretroviral drugs. Public procurement plans may not include drugs that are not on this List.

Table 2.2.2 — Antiretroviral drugs from the List of medicines covered by the Health Insurance Fund of the Republic of Srpska[4]

ATC Code	INN	Pharmaceutical form and dosage
J05AF01	zidovudin	Capsules, 100mg
J05AG01	nevirapin	Tablets, 200mg
J05AG03	efavirenz	Tablets, 600mg
J05AR01	lamivudin+zidovudin	Tablets, 150mg+300mg
J05AR02	abakavir+lamivudin	Tablets, 600mg+300mg
J05AR03	emtricitabine+ tenofovir disoproksil	Tablets, 200mg+245mg
J05AE06	lopinavir+ritonavir	Tablets, 200mg+50mg

4. http://www.zdravstvo-srpske.org/files/liste_lijekova/cenovnikteretfonda.pdf

The Decision on the List of medicines with special method of procurement (covered by the Health Insurance Fund of the Brcko District), adopted on 18.10.2019, contains a list of 5 antiretroviral drugs. Public procurement plans may not include drugs that are not on this List.

Table 2.2.3 — Antiretroviral drugs with a special method of procurement covered by the Health Insurance Fund of the Brcko District[5]

ATC Code	INN	Pharmaceutical form and dosage
J05AF07	tenofovir disoproksil	Tablets, 245mg
J05AR03	emtricitabine+ tenofovir disoproksil	Tablets, 200mg+245mg
J05AF05	lamivudin	Tablets, 100mg
J05AG03	efavirenz	Tablets, 600mg
J05AR02	abakavir+lamivudin	Tablets, 600mg+300mg

The lists of essential medicines in 10 cantons of the Federation of Bosnia and Herzegovina do not include antiretroviral drugs, so their residents receive ARV therapy from the List of the Solidarity Fund of the Federation of Bosnia and Herzegovina.

HIV treatment protocol

Bosnia and Herzegovina has the Clinical Guidelines on HIV/AIDS Treatment[6] *(Клиничке водиље за третман HIV-a и AIDS-a у Босни и Херцеговини)*.

For guidance on HIV treatment, it is recommended to consider the WHO (World Health Organization) guidelines. The INN recommended as treatment regimens under the National Protocol is not a basis for establishing a list of ARVs to be purchased for the needs of HIV-positive patients in Bosnia and Herzegovina.

2.3. Expeditious procedures

According to the Medicinal Products Act, expeditious registration procedures for medicinal products are not provided for.

2.4. VAT

According to Article 23 of the Law on Value Added Tax[7], no discounted VAT rate has been approved for medicinal products (total VAT rate is 17%).

2.5. Legislative possibility of post-registration of medicinal products

In accordance with the tender documentation, the tenderer's application must include a certified copy of the decision regarding a marketing authorization granted by the Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina.

Post-registration for medicines is not legally available.

2.6. Conditions for non-residents

According to Article 32 of the Act of Medicinal Products and Medical Devices, an application for a marketing authorization may be submitted by:

- A manufacturer of medicinal products registered in Bosnia and Herzegovina;
- A representative of a foreign manufacturer registered in Bosnia and Herzegovina.

Non-residents cannot obtain a marketing authorization without a representative office in Bosnia and Herzegovina.

5. https://www.fzobrcko.ba/file/odluka-o-utvrdivanju-dodatne-liste-lijekova-2020-lat/985
6. http://zdravljezasve.ba/uimages/Klinicke%20vodilje%20za%20HiV%20i%20AIDS%20u%20BiH%20-%20Srpski%20jezik.pdf
7. http://www.uino.gov.ba/download/Dokumenti/Dokumenti/bos/Porezi/PDV/Zakon_o_PDV.pdf

3. PROCEDURE TO FORM A NOMENCLATURE OF MEDICINAL PRODUCTS

3.1. Registry of medicinal products

Table 3.1.1 — Registry of antiretroviral drugs [8]

ATC Code	INN	Name	Manufacturer	License holder	Form and dosage	Duration of permit
J05AE03	ritonavir	Norvir	ABBVIE INC., Sjedinjene Američke Države	AbbVie d.o.o.	Tablets, 100mg	20.03.2023
J05AF05	lamivudin	Zeffix	WELLCOME LIMITED, Velika Britanija	GlaxoSmithKline d.o.o.Sarajevo	Tablets, 100mg	05.06.2021
J05AF07	tenofovir disoproksil	Viread	GILEAD SCIENCES INTERNATIONAL Limited, Velika Britanija	MEDICOPHARMACIA d.o.o.	Tablets, 245mg	27.05.2020
J05AF07	tenofovir disoproksil	Tenofovir teva	TEVA PHARMA B.V, Nizozemska	PLIVA d.o.o.Sarajevo	Tablets, 245mg	26.10.2020
J05AF07	tenofovir disoproksil	Tenoviral	ABDI IBRAHIM ILAC SANAYI VE TICARET A.S., Turska	Abdi Ibrahim BH d.o.o. Sarajevo	Tablets, 245mg	29.04.2023
J05AF07	tenofovir disoproksil	Hiverac	ILKO ILAC SANAYI VE TICARET A.S., Turska	Tuzla-Farm d.o.o. Tuzla	Tablets, 245mg	15.10.2023
J05AG03	efavirenz	Stocrin	MERCK SHARP & DOHME BV, Nizozemska	Merck Sharp & Dohme BH d.o.o.	Tablets, 50mg	10.03.2020
J05AG03	efavirenz	Stocrin	MERCK SHARP & DOHME BV, Nizozemska	Merck Sharp & Dohme BH d.o.o.	Tablets, 600mg	10.03.2020
J05AG03	efavirenz	Stocrin	MERCK SHARP & DOHME BV, Nizozemska	Merck Sharp & Dohme BH d.o.o.	Tablets, 200mg	10.03.2020
J05AR01	lamivudin, zidovudin	Combivir	WELLCOME LIMITED, Velika Britanija	GlaxoSmithKline d.o.o.Sarajevo	Tablets, 150mg+300mg	21.09.2022
J05AR02	abakavir, lamivudin	Kivexa	WELLCOME LIMITED, Velika Britanija	GlaxoSmithKline d.o.o.Sarajevo	Tablets, 600mg+300mg	19.09.2022
J05AR03	emtricitabin, tenofovir disoproksil	Truvada	GILEAD SCIENCES INTERNATIONAL Limited, Velika Britanija	MEDICOPHARMACIA d.o.o.	Tablets, 245mg+200mg	In the process of obtaining a marketing authorization
J05AR08	emtricitabin, rilpivirin, tenofovir, disoproksil	Eviplera	GILEAD SCIENCES INTERNATIONAL Limited, Velika Britanija	MEDICOPHARMACIA d.o.o.	Tablets, 200mg+25mg+245mg	26.10.2020

8. http://lijekovi.almbih.gov.ba:8090/SpisakLijekova.aspx

J05AR10	lopinavir, ritonavir	Aluvia	ABBVIE INC., Sjedinjene Američke Države	AbbVie d.o.o.	Tablets, 200mg+50mg	19.12.2023
J05AR13	abakavir, dolutegravir, lamivudin	Triumeq	WELLCOME LIMITED, Velika Britanija	GlaxoSmithKline d.o.o.Sarajevo	Tablets, 50mg+600mg+300mg	22.05.2023
J05AX08	raltegravir	Isentress	MERCK SHARP & DOHME BV, Nizozemska	Merck Sharp & Dohme BH d.o.o.	Tablets, 400mg	08.04.2022
J05AX12	dolutegravir	Tivicay	WELLCOME LIMITED, Velika Britanija	GlaxoSmithKline d.o.o.Sarajevo	Tablets, 50mg	In the process of obtaining a marketing authorization

3.2. Nomenclature of medicinal products for procurement

The nomenclature of ARV drugs is formed by infectious disease clinics *(see section 4.2)* based on the needs of patients registered in these healthcare facilities and according to the centralized decisions of the Solidarity Fund of the Federation of Bosnia and Herzegovina, the Health Insurance Fund of the Republic of Serbia and the Health Insurance Fund of the Brcko District.

According to the tender documentation related to the procurement of antiretroviral drugs, only the antiretroviral drug available on the Lists of Medicines covered by the mandatory health insurance, may be subject to procurement *(see Section 2.2)*.

The nomenclature of ARVs is reviewed annually, prior to the start of tenders placed by the contracting authorities on the Public Procurement Portal.

The legislative capacity of NGOs in Bosnia and Herzegovina to participate in the formation of the ARV drug nomenclature has not been identified.

4. PUBLIC PROCUREMENT SYSTEM

4.1. Sources of procurement financing

There is no current strategy for HIV prevention and treatment in Bosnia and Herzegovina; the latest Strategy to Respond to HIV and AIDS in Bosnia and Herzegovina was developed for 2011-2016[9] *(Strategija za odgovor na HIV/AIDS u Bosni i Hercegovini 2011-2016).*

Since 2005, Bosnia and Herzegovina has implemented exclusively national funding for antiretroviral therapy provided at the expense of the Solidarity Fund of the Federation of Bosnia and Herzegovina (*Fond solidarnosti FBiH*), the Health Insurance Fund of the Republic of Serbia *(Fond zdravstvenog osiguranja Republike Srpske)* and the Health Insurance Fund of the Brcko District *(Fond zdravstvenog osiguranja Brčko distrikta).*

4.2. Entities purchasing anti-retroviral drugs

Medical procurement problems in Bosnia and Herzegovina are related to the fragmentation of the health care system (medicines and medical devices are purchased by 13 «customers»: 10 cantons, the Federation of Bosnia and Herzegovina, the Republic of Serbia and the Brcko District[10]). The country is unable to enter the free market through one national mechanism, which is why it faces higher prices when purchasing medicines and medical devices[11].

The procurement of ARV drugs is conducted both centralized, by the Solidarity Fund of the Federation of Bosnia and Herzegovina, the Health Insurance Fund of the Republic of Serbia and the Health Insurance Fund of the Brcko District, and decentralized, by infectious disease clinics that treat HIV patients. The expenses of ARVs to treat patients in specialized infectious disease clinics are reimbursed by the appropriate Funds.

The antiretroviral therapy required to treat HIV infection is free of charge for each patient (if covered by compulsory health insurance).

According to the Strategy to Respond to HIV and AIDS in Bosnia and Herzegovina for 2011–2016, direct treatment of patients with HIV is carried out in the following infectious disease clinics: the Clinical Center University of Sarajevo *(Klinički centar Univerziteta u Sarajevu)*, University Clinical Center Tuzla *(Univerzitetski klinički centar Tuzla)*, Clinical Hospital Mostar *(Klinička bolnica Mostar)* and University Clinical Center of the Republic of Srpska *(Univerzitetski klinički centar Republike Srpske).*

4.3. Ability to use international procurement mechanisms

The possibility of using international mechanisms for the procurement of ARVs is not provided by law.

4.4. E-Procurement

The Public Procurement Portal[12] *(Portal javnih nabavki/ nabava Bosne i Hercegovine)* works in Bosnia and Herzegovina.

Public procurement contracts for ARVs has a standard validity period of 1 year.

The subject of the tender is divided into separate positions (items). The tenderer may apply for any number of positions of the subject of the public procurement contract. A separate electronic auction is conducted for each separate position of the subject of the contract.

The criterion for the conclusion of the contract is the lowest price; there are no preferences for national producers when considering bids.

4.5. Procurement planning

Procurement planning is carried out by the Solidarity Fund of the Federation of Bosnia and Herzegovina, the Health Insurance Fund of the Republic of Serbia, the Health Insurance Fund of the Brcko District, and infectious disease clinics.

The customers prepare the procurement plan for 1 year. However, during the year, they may initiate additional procurement procedures in the event of shortages or unplanned increases in patients needs.

9. http://www.vladars.net/sr-SP-Cyrl/Vlada/Ministarstva/MZSZ/Documents/Strategija%20za%20odgovor%20na%20HIV%20i%20AIDS%20u%20BiH%202011-2016.pdf
10. http://www.euro.who.int/__data/assets/pdf_file/0019/75133/E78673r.pdf
11. http://www.aidspan.org/sites/default/files/publications/Bosnia%20Report%20.pdf
12. https://www.ejn.gov.ba/

5. PROCUREMENT OF ANTI-RETROVIRAL DRUGS

Public procurement procedures for antiretroviral drugs in 2017–2019 were conducted in the framework of centralized procurement procedures, at the expense of the Solidarity Fund of the Federation of Bosnia and Herzegovina, the Health Insurance Fund of the Republic of Srpska and the Health Insurance Fund of the Brcko District, and decentralized procedures at the expense of infectious disease clinics on Public Procurement Portal.

Announcements of contracts concluded with winners of electronic auctions contain information on prices and amounts of purchases by specific INNs and do not contain trade names of purchased ARVs and manufacturers names.

Information on possible manufacturers of drugs may be obtained from the Register of Medicinal Products, since only medicines registered in Bosnia and Herzegovina may be the subject of public procurement.

5.1. Purchases of antiretroviral drugs in 2019

A narrow list of ARVs is purchased in the framework of centralized procedures. For example, in 2017–2019, only 2 items of medicines were purchased for healthcare facilities by the Federal Solidarity Fund of Bosnia and Herzegovina.

Table 5.1.1 — Tenders for the purchase of ARVs by the Federal Solidarity Fund in 2017-2019

Year	2017	2018	2019
lamivudin, Tablets, 100mg			
Cost excluding VAT, KM	76 230	59 360	51 400
Cost excluding VAT, USD	41 926,5	35 616	29 298
Size, tablets	19 800	16 000	15 000
Contract date	22.08.2017	08.08.2018	23.07.2019
Winner	PHOENIX PHARMA D.O.O.	PHOENIX PHARMA D.O.O.	PHOENIX PHARMA D.O.O.
Name and manufacturer	Zeffix (WELLCOME LIMITED, Velika Britanija)	Zeffix (WELLCOME LIMITED, Velika Britanija)	Zeffix (WELLCOME LIMITED, Velika Britanija)
tenofovir disoproksil, Tablets, 245mg			
Cost excluding VAT, KM	161 611,20	103 000	72 900
Cost excluding VAT, USD	88 886,16	61 800	41 553
Size, tablets	61 920	79 000	88 000
Contract date	14.09.2017	27.08.2018	23.07.2019
Winner	HERCEGOVINALIJEK D.O.O. MOSTAR	«Tuzla-Farm» d.o.o. Tuzla	PHOENIX PHARMA D.O.O.
Name and manufacturer	**Viread** (GILEAD SCIENCES INTERNATIONAL Limited, Velika Britanija) **Tenofovir teva** (TEVA PHARMA B.V, Nizozemska) **Tenoviral** (ABDI IBRAHIM ILAC SANAYI VE TICARET A.S., Turska) **Hiverac** (ILKO ILAC SANAYI VE TICARET A.S., Turska)	**Viread** (GILEAD SCIENCES INTERNATIONAL Limited, Velika Britanija) **Tenofovir teva** (TEVA PHARMA B.V, Nizozemska) **Tenoviral** (ABDI IBRAHIM ILAC SANAYI VE TICARET A.S., Turska) **Hiverac** (ILKO ILAC SANAYI VE TICARET A.S., Turska)	**Viread** (GILEAD SCIENCES INTERNATIONAL Limited, Velika Britanija) **Tenofovir teva** (TEVA PHARMA B.V, Nizozemska) **Tenoviral** (ABDI IBRAHIM ILAC SANAYI VE TICARET A.S., Turska) **Hiverac** (ILKO ILAC SANAYI VE TICARET A.S., Turska)
Total, KM	**237 841**	**162 360**	**124 300**
Total, USD	**130 812,66**	**97 416,00**	**70 851,00**

The list of ARVs is broader because of purchases made by infectious disease clinics. For example, in 2017 procurement for the Infectious Diseases Clinic of the University of Sarajevo Center was conducted for 2 years.

Table 5.1.2 - Tenders for procurement of ARVs for the needs of the Infectious Diseases Clinic of the University of Sarajevo Center in 2017

INN, Form and dosage	Size, tablets	Cost excluding VAT		Supplier	Name and manufacturer
		KM	USD		
tenofovir +emtricitabin, Tablets, 245mg + 200mg	47 520	187 704	103 237,2	FARMIS DOO SARAJEVO	Truvada (GILEAD SCIENCES INTERNATIONAL Limited, Velika Britanija)
raltegravir, Tablets, 400mg	4 800	83 424	45 883,2	Evropa Lijek Pharma d.o.o.	Isentress (MERCK SHARP & DOHME BV, Nizozemska)
nevirapin, Tablets, 200mg	6 000	6 240	3 432	HERCEGOVINALIJEK D.O.O. MOSTAR	There is no information on the Register
Total in 2017		**277 368**	**152 552,4**		

NORTH MACEDONIA

2 077 132
Population, persons

45
Number of new HIV cases in 2018

383
Estimated number of people living with HIV, persons (The proportion of the population living with HIV — 0,02)

246
Number of HIV — infected people who know their status, persons

198
Number of HIV-infected people who know their status and covered by antiretroviral therapy, persons

* data as of 31.12.2018

http://www.stat.gov.mk/IndikatoriTS.aspx?id=2
http://www.cnlas.ro/images/doc/ecdc_continuumOfHIVCare.pdf
http://iph.mk/wp-content/uploads/2014/09/REPORT-ON-IMPLEMENTED-ACTIVITIES-AND-ACHIEVED-RESULTS-IN-ACCORDANCE-WITH-THE-PROGRAM-FOR-HIV-PROTECTION-IN-2018.pdf

1. SUMMARY *

Criteria	Comment
Characteristics of state registration procedures	
The law that regulates the registration of medicines	The Law on Medicinal Products and Medical Devices (Official Gazette of the Republic of North Macedonia, No. 53/16).
Registration authority	The Agency for Medicinal Products and Medical Devices of the Republic of North Macedonia *(MALMED — Агенцијата за лекови и медицински средства на Република Македонија)*.
Entities that have the right to sell medicinal products	• Medicines manufacturer registered in the Republic of North Macedonia. • Foreign manufacturer representative with a registered office in the Republic of North Macedonia. • A subsidiary of a foreign manufacturer with a registered office in the Republic of North Macedonia. • Trade representative office of a foreign manufacturer with a registered office in the Republic of North Macedonia.
Entities that have the right to participate in a tender	• Entities authorized to sell the medicinal product. • Entities authorized to import the medicinal product.
Packaging requirements	The availability of basic information about the medicinal product in Macedonian on the outer, inner packaging and in the instructions for the medicinal product. In certain circumstances, it is permissible to provide information on packages and instructions in a foreign language: if a label with basic information about the medicinal product in Macedonian is affixed to the package and Macedonian language instruction is included in the package. According to the Law, there are no restrictions on foreign languages.
The availability of restrictive lists (for example, a list of vital medicines)	Available List of Essential Medicines (Листа на есенцијални лекови). It determines the list of medicines, the pricing of which is subject to state regulation. According to the Medicinal Products Act, prices for medicines are set free, except for prescription drugs and medicines that are on the List of Essential Medicines. The List of Essential Medicines is approved by the Minister of Health. Public procurement plans may include medicines that are not on the List of Essential Medicines. Clinical Protocol — the HIV/AIDS Treatment Guideline. The INNs recommended as treatment regimens from the Guidelines do not form the basis for the list of ARVs to be purchased for the needs of HIV-infected patients in North Macedonia.
The availability of expeditious registration procedures	A general registration procedure - up to 210 days after receiving the full application for a marketing authorization. Compact procedures are available for medicinal products authorized in the EU (up to 15 days or up to 90 days, depending on reasons), as well as in the USA, Japan, Switzerland and Canada (up to 60 days).
VAT and tax benefits	For medicines, a preferential VAT rate of 5% is approved (the total VAT rate is 18%).
Availability of post-registration for medicines	The legislative ability to provide post-registration of medicines is available, but unregistered (not authorized for marketing) medicines require an import authorization to be issued by the Agency for Medicinal Products and Medical Devices.
Availability of special conditions for non-residents	Non-residents cannot obtain marketing authorization without establishing a foreign representative office in North Macedonia. In order to obtain an import authorization, a non-resident must either already have a marketing authorisation for the medicinal product, or schedule a parallel import or clinical trial of the medicinal product, or its medicinal product must comply with one of the following exceptions: • The medicinal product is included in the List of Essential Medicines of the Republic of North Macedonia (Листа на есенцијални лекови); • The medicinal product is not authorized for sale and is required for the treatment of one patient or group of patients in a hospital or other healthcare facility but in an amount that does not exceed 2,000 packages per year; • The medicinal has no marketing authorization and is required in exceptional cases (infections, poisoning, irradiation, etc.) and in cases of being of public interest, or others.

* Information as of the second half of 2019

Logistics	According to the tender documentation, the logistics partner is selected by the supplier.
Procedures of nomenclature formation	
Authorities responsible for the nomenclature lists formation	The nomenclature of ARVs for public procurement procedure is formed by the Clinic for Infectious Diseases and Febrile Conditions, based on the needs of patients registered at this healthcare facility.
The procurement nomenclature	The procurement item may be an antiretroviral drug from the WHO Model List of Essential Medicines, or the US Food and Drug Administration's List of approved and conditionally approved antiretroviral drugs, or among available for marketing in the EU. Despite the possibility that unregistered medications may be included in the nomenclature, the unofficial rule of giving priority to the registered drugs during the tender was in force in different years. The trend persists throughout 2018-2019.
Opportunity for NGOs and international organizations to participate in the nomenclature formation	In 2019, experts from NGOs were involved in the nomenclature formation.
Approval terms and frequency of the nomenclature revision	The period of the nomenclature revision is annual.
The functioning of the public procurement system	
Funding sources	Exclusively national funding from the Ministry of Health and designated government agencies starting from 2018.
Procuring entities	The Clinic for Infectious Diseases and Febrile Conditions is the only institution in the country to treat, diagnose, and monitor HIV patients.
Possibility to use international mechanisms/funding	The Ministry of Health's HIV/AIDS programs for 2018-2019 did not envisage funding from international organizations. North Macedonia lost the right to be supported by the Global Fund after it introduced a new funding model and eligibility criteria for grants in 2014, but in 2019 the Global Fund experts reclassified North Macedonia from a low-incidence-rate country to a high-incidence-rate one. This fact gives North Macedonia reason to expect further funding from the Global Fund. The possibility of procurement by international agencies/organizations is not provided by law.
Availability of transparent procedures	The electronic system for public procurement.
Availability of supply disruptions	In 2018, no applications from suppliers were received for a number of ART products.
Procurement planning	Procurement planning is carried out for 1 year.
Statistics on the volume of procurement of ART drugs	
Purchasing prices	Indicated in the tender documentation for each item.
Number of medicines purchased	Specified in the tender documentation for each item.
The total amount of procurement	2018 — MKD 31,424,700 (USD 607,000).
Reference to «originator/generic»	There is no information in the tender documentation. Among the registered drugs, there are generics manufactured by EMCURE Pharmaceuticals Lim-ited, Mylan Hungary Kft., TAD Pharma GmbH, PLIVA Hrvatska d.o.o.
Attitudes towards generics in the NGO/medical community	Prejudiced attitudes towards generics through stereotypes and myths about the quality and effectiveness of both groups.
Patient-centered procurement	According to the 2019 HIV Population Protection Program of the Republic of North Macedonia, the number of patients covered by ART is 260; budget for one patient is MKD 140,000 (USD 2,700).

2. STATE PROCEDURE OF MEDICINAL PRODUCTS REGISTRATION

2.1. General information

Registration of medicinal products in North Macedonia is carried out in accordance with the Law on Medicinal Products and Medical Devices (Official Gazette of the Republic of North Macedonia, No. 53/16, hereinafter referred to as the Medicinal Products Act)[1].

According to Article 5 of the Medicinal Products Act, the Agency for Medicinal Products and Medical Devices of the Republic of North Macedonia *(MALMED — Агенцијата за лекови и медицински средства на Република Македонија)*[2] is responsible for granting the marketing authorization of medicinal products and keeping a registry of medicinal products.

The Committee for Medicinal Products for Human Use *(Комисија за лекови за хумана употреба)*, which is a permanent expert advisory body, considers grounds for inclusion or deletion of a medicinal product from the register.

According to Article 8 of the Medicines Products Act, the director of the Agency for Medicinal Products and Medical Devices appoints members of the standing committees from among known medical, dental, pharmaceutical and other experts and scientists who have at least ten years of experience in the relevant field.

According to Article 11 of the Medicinal Products Act, a medicinal product may be marketed in the territory of North Macedonia, if an economic entity has a marketing or import authorization.

Marketing authorization

According to Article 17 of the Medicinal Products Act, a medicinal product may be placed on the market if it has obtained the relevant authorization from the Agency for Medicinal Products and Medical Devices. To be authorized, one shall submit an application, which, in accordance with Article 20 of the Medicinal Products Act, must contain the information given in the following table.

Information block	Content
Administrative part	• information about the medicinal product and the marketing authorizations issued; • information about a producer; • information about the manufacturing site; • conformity of production to GMP requirements and GMP certificate issued no earlier than 3 years prior to submission of this application; • information about the future holder of the marketing authorization; • a draft summary of product characteristics; • instruction for the patient; • packaging proposal (inner and / or outer); • certificate for a pharmaceutical product; • a list of countries that granted marketing authorization for the medicinal product; • a list of countries in which a similar application has been submitted, rejected or withdrawn; • expert opinions on documentation regarding the quality, safety and efficacy of the medicinal product.
Analytical part	• data on the quality of the medicinal product, the qualitative and quantitative composition of the medicinal product; • description of production methods; • quality control of input raw materials; • quality control of the manufacturing process; • quality control of the finished product; • a study on the quality of the medicinal product relating to health and the environment.
Pharmaco-toxicological part	• pharmacodynamic and pharmacokinetic characteristics of the medicinal product; • toxicity and effects on reproductive function; • data on embryonic-fetal toxicity; • mutagenic and carcinogenic potential; • data on tolerance.
Clinical part	• information on clinical trials, methods of their conduct; • compliance with ethical requirements; • clinical and pharmacological data; • bioavailability and bioequivalence data (if available); • data on clinical safety and efficacy, information about exceptional testing circumstances (if any); • data on using the medicinal product after marketing authorizations in other countries.

1. http://zdravstvo.gov.mk/wp-content/uploads/2018/01/ZAKON-ZA-LEKOVITE-I-MEDITSINSKITE-SREDSTVA-zakluchno-so-br.-53-od-2016.pdf
2. https://malmed.gov.mk/%d0%b7%d0%b0-%d0%bd%d0%b0%d1%81

According to Article 22 of the Medicinal Products Act, an applicant is not required to submit his own pharmacological or clinical trial results under the following conditions:

- Bibliographic data on pharmacological, toxicological and clinical trials used from the public literature, provided that the active substance in the medicinal product is established, the characteristics of the drug are well known, its efficacy has been demonstrated and the active substance in the preparation has been used as a medicinal product for at least 10 years in the Republic of North Macedonia or the EU, and the published scientific data are consistent and sufficient to permit the extrapolation from substance to the medicinal product for which marketing authorization is requested;
- The medicinal product is a generic of a reference medicinal product that has already been marketed in the Republic of North Macedonia or the EU for at least 8 years; a generic marketing authorization is issued after 10 years after the marketing authorization for the reference medicinal product has been granted. This period may be extended from 10 to 11 years if, during the first 8 years, the trade license holder has been authorized to have one or more new therapeutic units that, at the time of the pre-approval evaluation, have demonstrated significant clinical benefit over existing treatments.

According to Article 29 of the Medicinal Products Act, an application is submitted separately for each dosage form, dosage and packing size of the medicinal product.

The Agency decides (no later than 210 days after receipt of the full application for a marketing permit) to grant or refuse the marketing authorization, having received a conclusion on the reliability of the documentation and the evaluation of the quality, safety and efficacy of the medicinal product by the Committee for Medicinal Products.

According to Article 30 of the Medicinal Products Act, a marketing permit is issued for 5 years. The marketing permit holder must inform the Agency for Medicinal Products and Medical Devices of the date the medicinal product starts selling.

Import authorization

According to Article 79 of the Medicinal Products Act, an import authorization is granted for:

- medicinal products authorized for sale;
- medicinal products authorized for parallel import;
- medicinal products authorized for clinical trials.

At the same time, the Agency for Medicinal Products and Medical Devices may issue import authorizations for medicinal products belonging to one of the exceptions set out in Article 79 of the Medicinal Products Act *(see Article 2.6)*.

To obtain import authorizations for medicinal product that is not authorized for sale in the Republic of North Macedonia, the importer/wholesaler must submit an application to the Agency for Medicinal Products and Medical Devices and appropriate documentation, a certificate of quality and justification of the application (documentary confirmation of intention to conduct parallel import or clinical trials of the medicinal product, or of the fact that the medicinal product falls under the exceptions referred to in Article 79 of the Medicinal Products Act). No justification examples have been found.

The Agency for Medicinal Products and Medical Devices shall approve or reject the application within 30 days after receipt.

The Director of the Agency for Medicinal Products and Medical Devices shall set out the contents of the application and the procedure for obtaining the import authorization, as well as the duty payable.

Marking and instruction

According to Articles 83-85 of the Medicinal Products Act, the requirements are as follows:

- The availability of basic information about the medicinal product in Macedonian on the outer and inner packaging;
- The availability of the following basic information on the outer packaging about the medicinal product: name, qualitative and quantitative composition of the active substance, dosage form, dosage, packing size, producer/holder of the marketing authorization, a use method, a storage method, expiration date, method of use, a batch number, a number of the license for sale, European Article Number (EAN code) and Anatomical Therapeutic Chemical Classification (ATC code), application features, and the price of a medicine;
- The availability of the following basic information on the inner packaging: name and INN, the qualitative and quantitative composition of the active substance, dosage form, dosage, a producer, expiration date, and a batch number;
- The availability of an instruction in Macedonian with the following basic information about the medicinal product: name, qualitative and quantitative composition, dosage form, dosage and size of the package, a producer and marketing authorization holder, method of administration, indications, contraindications, application features, a method of administration, side effects, expiration date, and a storage method.

The name of the medicinal product must also be written in Braille on the outer package.

The provision of information on packages and instructions in a foreign language may be permitted under the following conditions:

- a label with basic information about the medicinal product in Macedonian is attached to the packaging;
- an instruction in Macedonian is put in the packaging.

There are no restrictions regarding foreign languages.

2.2. Restrictive lists

According to Article 107, paragraph 3, of the Medicinal Products Act, in 2015 the Minister of Health approved the List of Essential Medicines (Official Gazette of the Republic of North Macedonia, No. 19/2015).

The List of Essential Medicines (*Листа на есенцијални лекови*) in North Macedonia determines the list of medicines price formation of which is a subject to state regulation. This list does not establish a list of medicinal products subject to mandatory public procurement plans within separate public health programs.

Accordingly, public procurement plans may include medicines that are not on the List of Essential Medicines.

According to Article 107, paragraphs 1 and 3, of the Medicinal Products Act, prices for medicinal products are set free, except for prescription medicines and medicines included in the List of Essential Medicines. The List of Essential Medicines is approved by the Minister of Health.

According to Articles 108-109 of the Medicinal Products Act, pricing of medicines is carried out in such a way as to avoid dumping and discriminatory prices.

Table 2.2.1 — Antiretroviral drugs from the List of Essential Medicines [3]

ATC Code	INN	Pharmaceutical form and dosage
Nucleoside and nucleotide reverse transcriptase inhibitors		
J05AF06	Abacavir	Oral solution: (100mg/5ml) Tablets: 300mg
J05AF09	Emtricitabine	Oral solution: 10mg/ml Capsules: 200mg
J05AF05	Lamivudine	Oral solution: 50mg/5ml Tablets: 100mg
J05AF01	Zidovudine	Capsules: 100mg, 250mg Oral solution: 50mg/5ml Injectable solution: 10mg/ml Tablets: 300mg
J05AF07	Tenofovir disoproxil fumarate	Tablets: 300mg
J05AF02	Didanosine	Tablets: 25mg, 50mg, 100mg, 150mg, 200mg Capsules: 125mg, 200mg, 250mg, 400mg Oral solution: 100mg, 167mg, 250mg
J05AF04	Stavudine	Capsules: 15mg, 20mg, 30mg Oral solution: 5mg/5ml
Non-nucleoside reverse transcriptase inhibitors		
J05AG03	Efavirenz	Capsules: 50mg, 100mg, 200mg Oral solution: 150mg/5ml Tablets: 600mg
J05AG01	Nevirapine	Oral solution: 50mg/5ml Tablets: 200mg
Protease inhibitors		
J05AE02	Indinavir	Capsules: 400mg
J05AE06	Lopinavir+Ritonavir	Tablets: 250mg/50mg
J05AE04	Nelfinavir	Powder: 50mg Tablets: 250mg
J05AE03	Ritonavir	Capsules: 100mg

HIV treatment protocol

According to Article 27, paragraph 1 of the Law on Health Protection[4] (Official Gazette of the Republic of North Macedonia, No. 37/16), in 2015, the Minister of Health approved the HIV/AIDS Treatment Guidelines *(Упатство за медицинското згрижување при ХИВ инфекција)*[5] .

The HIV/AIDS Treatment Guidelines identifies ways to provide assistance to HIV-infected patients by medical workers at healthcare facilities in North Macedonia.

In relation to HIV treatment, this Guidelines refer to the guidelines of the CDC (US Centers for Disease Control and Prevention) and EACS 2008 (European AIDS Clinical Society). The INNs recommended as treatment regimens in the Guidelines are not the basis for formation of the list of ARV drugs to be purchased for the needs of HIV-infected patients in North Macedonia.

3. https://malmed.gov.mk/wp-content/uploads/11-Lista_na_esencijalni_lekovi-Sl.Vesnik-br.19-2015.pdf
4. http://zdravstvo.gov.mk/wp-content/uploads/2018/01/ZAKON-ZA-ZDRAVSTVENATA-ZASHTITA-zakluchno-so-br.-37-od-2016.pdf
5. http://zdravstvo.gov.mk/wp-content/uploads/2015/08/HIV-infekcija.pdf

2.3. Expeditious procedures

According to Article 29 of the Medicinal Products Act, an expeditious procedure for the registration of the medicinal product is possible under the following conditions:

1. If an application is submitted for the sale of a medicinal product with a marketing authorization in at least three Member States of the European Union, the Agency for Medicinal Products and Medical Devices shall approve the application no later than 15 days from the date of receipt of the complete package of documents.
2. If an application is submitted for the sale of a medicinal product with a marketing authorization in less than three Member States of the European Union, the Agency for Medicinal Products and Medical Devices shall approve or reject the application no later than 90 days after receipt of the complete package of documents.
3. If an application is submitted for the sale of a medicinal product with a marketing authorization in the United States, Japan, Switzerland and Canada, the Agency for Medicinal Products and Medical Devices shall approve or reject the application no later than 60 days from the date of receipt of the complete package of documents required as part of the licensing process in the United States, Japan, Switzerland and Canada and on the proposal of the Committee for Medicinal Products.

2.4. VAT

According to Articles 28-30 of the Law on Value Added Tax, the general rate is 18% and an approved preferential rate for medicines is 5% [6].

2.5. Legislative possibility of post-registration of medicinal products

According to the tender documentation on the procurement of antiretroviral drugs in 2018-2019, in order to be qualified as capable of fulfilling a relevant procurement contract in terms of technical or professional capacity, an economic operator must meet the following minimum requirements.

The economic operator offering a registered medicinal product must provide a marketing authorization decision of the finished medicinal product on the market or to grant a temporary/permanent authorization for parallel import.

The economic operator offering an unregistered medicinal product must provide a decision on the issue of an import authorization.

That is, the legal possibility of post-registration of medicinal products is available, but there is requirements for unregistered (not authorized) medicinal products that the import license to be issued by the Agency for Medicinal Products and Medical Devices of the Republic of North Macedonia *(Агенцијата за лекови и медицински средства на Република Македонија)*.

2.6. Conditions for non-residents

In order to import a medicinal product into the territory of North Macedonia, a non-resident must have marketing or import authorization. According to Article 18 of the Medicinal Products Act, an application for marketing authorization for a medicinal product may be submitted by the following entities:

- a manufacturer of medicinal products registered in the Republic of North Macedonia;
- a legal representative of a foreign manufacturer with a registered office in the Republic of North Macedonia, if he/she has concluded an agency agreement which includes insurance in the territory of the Republic of North Macedonia;
- a subsidiary of a foreign manufacturer with a registered office in the Republic of North Macedonia provided that the insurance is extended to the territory of the Republic of North Macedonia;
- a trade office of a foreign manufacturer with a registered office in the Republic of North Macedonia provided that the insurance is extended to the territory of the Republic of North Macedonia.

The applicant holds a trade license (marketing authorization). It is the responsibility of the marketing authorization holder to place the medicinal product on the market. The marketing authorization holder must establish and maintain a pharmacovigilance system and appoint on a regular basis a person responsible for pharmacovigilance. That person must have received a degree in pharmacy or medicine and hold a certificate in pharmacovigilance training or pharmacovigilance specialization.

In order to obtain an import authorization, a non-resident must either already have a marketing authorization for the medicinal product, or schedule a parallel import or clinical trial of the medicinal product, or its medicinal product must meet one of the conditions described in Article 79 of the Medicinal Products Act.

According to Article 79 of the Medicinal Products Act, the Agency for Medicinal Products and Medical Devices may issue an import authorization for the medicinal product under the following conditions:

- the medicinal product is included in the List of Essential Medicines of the Republic of North Macedonia (на есенцијални лекови);
- the medicinal product has a marketing authorization and is an immunological medicinal product, a radiopharmaceutical medicinal product or a medicinal product obtained from the treatment of human blood or plasma;
- the medicinal product is a copy of a medicinal product which is indicated when applying for a parallel import authorization;
- the medicinal product is not authorized for sale and is required for the treatment of one patient or group of patients in a hospital or other healthcare facility but in an amount not exceeding 2,000 packages per year; in this case, the Director of the Agency shall set up a Committee for the issue of a license for import of medicinal products, consisting of 5 members with a term of office - 3 years;
- the medicinal product is not authorized for sale and is required to continue treatment initiated abroad;
- the medicinal product is not authorized for sale and is required in exceptional cases (infections, poisoning, irradiation, etc.) or other cases of public health interest;
- the medicinal product is intended for preclinical trials, research and development;
- the medicinal product is intended for further production;
- the medicine is intended for promotional activities.

6. https://finance.gov.mk/files/u8/zakon-za_ddv_2017%20-1.pdf

3. PROCEDURE TO FORM A NOMENCLATURE OF MEDICINAL PRODUCTS

3.1. Registry of medicinal products

Table 3.1.1 — Registry of antiretroviral drugs [7]

Name	INN	Form, quantity in packing and dosage	Producer	License holder	Registration date
Abakavir/ Lamivudin PLIVA	Abacavir, Lamivudine	Tablets 30x (600mg/300mg)	PLIVA Hrvatska d.o.o, Загреб, Хрватска, TEVA Pharma B.V., Харлем, Холандија, Merckle GmbH, Улм, Германија	ПЛИВА дооел	12.12.2018
Darunavir KRKA	Darunavir	Tablets 60x400mg	TAD Pharma GmbH, Куксхавен, Германија, KRKA d.d. (Лочна), Ново Место, Словенија	КРКА - ФАРМА дооел	01.04.2019
Darunavir KRKA	Darunavir	Tablets 60x600mg	TAD Pharma GmbH, Куксхавен, Германија, KRKA d.d. (Лочна), Ново Место, Словенија	КРКА - ФАРМА дооел	01.04.2019
Darunavir KRKA	Darunavir	Tablets 30x800mg	TAD Pharma GmbH, Куксхавен, Германија, KRKA d.d. (Лочна), Ново Место, Словенија	КРКА - ФАРМА дооел	01.04.2019
Efavirenz/ Emtricitabine/ Tenofovir disoproxil KRKA	Emtricita-bine, Tenofovir, Efavirenz	Tablets 30x(600mg/ 200mg/245mg)	TAD Pharma GmbH, Куксхавен, Германија, KRKA d.d. (Лочна), Ново Место, Словенија	КРКА - ФАРМА дооел	01.04.2019
Emtricitabine/ Tenofovir disoproxil KRKA	Emtricita-bine, Tenofovir	Tablets 30x(200mg/ 245mg)	TAD Pharma GmbH, Куксхавен, Германија, KRKA, d.d., Novo mesto (Шмајрешка цеста 6), Ново Место, Словенија	КРКА - ФАРМА дооел	05.06.2018
Emtricitabine/ Tenofovir disoproxil KRKA	Emtricita-bine, Tenofovir	Tablets 90x(200mg/ 245mg)	TAD Pharma GmbH, Куксхавен, Германија, KRKA, d.d., Novo mesto (Шмајрешка цеста 6), Ново Место, Словенија	КРКА - ФАРМА дооел	05.06.2018
Emtricitabin tenofovir dizoproksil PLIVA	Emtricita-bine, Tenofovir	Tablets 30x(200mg/ 245mg)	PLIVA Hrvatska d.o.o, Загреб, Хрватска, TEVA Operations Poland Sp. Z.o.o., Краков, Полска, MERCKLE GmbH, Блаубојрен, Германија, TEVA Pharma B.V., Харлем, Холандија	ПЛИВА дооел	14.12.2018
Eviplera	Emtricita-bine, Rilpi-virine, Tenofovir	Tablets 30x(200mg/ 25mg/245mg)	GILEAD Sciences Ireland UC, Ко. Корк, Ирска	МЕДИКО ФАРМАЦИЈА дооел	22.06.2018

7. https://lekovi.zdravstvo.gov.mk/drugsregister/overview

Tavin	Tenofovir	Tablets 30x300mg	EMCURE Pharmaceuticals Limited, Бари Брахмана, Јаму, Индија	АД Д-р ПАНОВСКИ	16.07.2019
Tenofovir disoproxil Mylan	Tenofovir Disoproxil	Tablets 30x245mg	Mylan Hungary Kft., Комаром, Унгарија, McDermott Laboratories Limited T/A Gerard Laboratories T/A Mylan Dublin, Даблин, Ирска	МАКЕДОНИЈАЛЕК доо	22.07.2019
Tivicay	Dolutegravir	Tablets 30x50mg	GLAXOSMITHKLINE Pharmaceuticals S.A, Познан, Полска, Glaxo Wellcome S.A., Бургос, Шпанија	ГлаксоСмитКлајн Експорт Лтд, Претставништво	20.06.2018
Triumeq	Dolutegravir, Abacavir, Lamivudine	Tablets 30x(50mg/ 600mg/300mg)	GLAXOSMITHKLINE Pharmaceuticals S.A, Познан, Полска, Glaxo Wellcome S.A., Бургос, Шпанија	ГлаксоСмитКлајн Експорт Лтд, Претставништво	20.06.2018
Valganci-klovir PLIVA	Valganciclo-vir	Tablets 60x450mg	PLIVA Hrvatska d.o.o, Загреб, Хрватска	ПЛИВА дооел	25.04.2016
Viread	Tenofovir	Tablets 30x245mg	GILEAD Sciences Ireland UC, Ко. Корк, Ирска, TAKEDA GmbH, Ораниенбург, Германија	МЕДИКО ФАРМАЦИЈА дооел	11.01.2019
Zeffix	Lamivudine	Tablets 28x100mg	GLAXOSMITHKLINE Pharmaceuticals S.A, Познан, Полска	ГлаксоСмитКлајн Експорт Лтд, Претставништво	16.02.2015

3.2. Nomenclature of medicinal products for procurement

The nomenclature of ARVs for public procurement is formed by the Clinic for Infectious Diseases and Febrile Conditions *(Клиника за инфективни болести и фебрилни состојби),* based on the needs of patients registered at this healthcare facility (*see Section 4.2).*

The nomenclature of ARVs (specific list of INNs, forms and dosage) is reviewed annually, prior to the start of a tender that is announced by the Clinic for Infectious Diseases and Febrile Conditions on the e-procurement site. For example, in 2018, procurements included a broader list of medicines than in 2019 *(see Section 5).*

According to the tender documentation, the procurement item may be an antiretroviral drug from the WHO Model List of Essential Medicines or the US Food and Drug Administration's List of approved and conditionally approved antiretroviral drugs or among available for marketing in the EU, that is, the drug offered by the potential supplier may be both original and generic.

Despite the possibility that unregistered preparations may be included in the nomenclature, the unofficial rule of giving priority to the registered preparations during the tender was in force in different years. According to the information available to us, this trend has been maintained for the last two years.

The legislative capacity of the North Macedonian NGOs to participate in the formation of the ARV drugs nomenclature for the procurement procedure has not been identified.

At the same time, an NGO expert was involved in the formation of the nomenclature in 2019.

However, in North Macedonia, NGOs may be involved in public procurement of other services for HIV-infected people. According to the Public competition for the selection of associations and the allocation of funds for associations, which will implement the measures envisaged by the 2019 HIV Population Protection Program in the Republic of North Macedonia[8], the state funding of NGO activities was envisaged in the following areas:

- HIV prevention among key population groups (programs for men who have sex with men, programs against injecting drugs, programs for sex workers);
- Psychosocial support for people with HIV and their partners, drug users;
- HIV educational activities and counseling on HIV, sexual and reproductive health in key groups.

The most influential in North Macedonia is the HERA Public Association *(Собранието на Здружението «ХЕРА» — Асоцијација за здравствена едукација и истражување),* which in 2014 initiated the creation of a specialized Platform for sustainability of services for key populations, that resulted in provision of full national funding of HIV treatment services offered by civil society organizations starting from 2018[9].

8. http://zdravstvo.gov.mk/javen-povik-programa-za-zashtita-na-naselenieto-od-hiv-infekcija-vo-republika-makedonija-za-2019-godina/
9. https://hera.org.mk/shto-rabotime/hiv/

4. PUBLIC PROCUREMENT SYSTEM

4.1. Sources of procurement financing

Strategic measures for the HIV prevention and treatment in North Macedonia are set out in the annual *HIV Population Protection Program* of the Ministry of Health *(Министерство за здравство)*. The Republic of North Macedonia has fully transitioned to national funding for the HIV Population Protection Program in 2018. According to the 2019 Program, the following budget was planned[10]:

MKD 36.4 million (USD 0.7 million)	Budget for the procurement of antiretroviral thera-py drugs and HIV screening tests
MKD 90 million (USD 1.7 million)	The total budget of the Republic of North Macedonia's 2019 HIV Population Protection Program
Structure of Procurement Financing	72,2% of funding from the Ministry of Health 27,8% of funding from state specialized institutions

4.2. Entities purchasing anti-retroviral drugs

According to the *HIV Population Protection Program* of the Republic of North Macedonia for 2018 and 2019, the single customer - the Clinic for Infectious Diseases and Febrile Conditions (Клиника за инфективни болести и фебрилни состојби) in Skopje — provides the procurement of antiretroviral therapy and screening tests for HIV infection. It is the only healthcare facility providing tertiary (highly specialized) health care for infectious diseases in the Republic of North Macedonia. Due to the small number of HIV-infected patients in the country, they receive ARVs monthly only at this clinic[11]. The Clinic has the HIV/AIDS Division that deals with the treatment, diagnosis and care of HIV patients.

The procuring entity conducts public procurement in accordance with the Law on Public Procurement (Official Gazette of the Republic of North Macedonia No. 24/2019).

The antiretroviral therapy required for the treatment of HIV infection is free of charge for each patient (if he or she has health insurance under the Health Insurance Fund of North Macedonia) at the Clinic for Infectious Diseases and Febrile Conditions *(Клиника за инфективни болести и фебрилни состојби)*[12].

4.3. Ability to use international procurement mechanisms

North Macedonia lost the right to be supported by the Global Fund after the organization has introduced a new funding model and eligibility criteria for grants in 2014. North Macedonia has been identified as a country with an above-average income and low burden of HIV infection[13].

In order to ensure a more responsible transition to national funding for the HIV Population Protection Program, provision of the Global Fund grant for North Macedonia in the 2014-2016 funding round has been extended to 2017 [14].

Until 2017, the program was funded by public funds (the national budget and other resources of the Ministry of Health) and by grants from the Global Fund to Fight AIDS, Tuberculosis and Malaria. The recipient of the Global Fund grants in North Macedonia was the Ministry of Health *(Министерство за здравство)* [15].

In 2019, the Global Fund experts reclassified North Macedonia from a low-incidence country to a high-incidence country. This fact gives North Macedonia reason to expect further funding from the Global Fund.

As of 2019, other international organizations have not implemented projects to purchase antiretroviral drugs for North Macedonia. And the Ministry of Health's *HIV Population Protection Program* for 2018-2019 did not envisage funding from international organizations [16]. The legislative opportunities of purchasing ARVs by international agencies/organizations for budgetary funds are not provided.

4.4. E-Procurement

The Republic of North Macedonia has the Electronic System for Public Procurement (ЕСЈН — Електронски систем за јавни набавки), which was established in 2009 by the Public Procurement Bureau of the Ministry of Finance (Министерство за финансии) [17].

According to the tender documentation on the procurement of antiretroviral drugs, a public procurement contract is concluded through a public procurement procedure, which ends with an electronic auction as the last stage of the procedure.

10. http://zdravstvo.gov.mk/wp-content/uploads/2019/02/2019-Programa-za-zashtita-na-naselenieto-od-HIV-infektsija.pdf
11. http://www.deso.mk/GetFile.ashx?f=3&pd=1444&pdf=3
12. http://zdravstvo.gov.mk/makedonija-zemja-primer-za-uspeshno-partnerstvo-megju-vladata-instituciite-i-gragjanskiot-sektor-vo-spravuvanjeto-so-hiv-infekcijata/
http://i-base.info/wp-content/uploads/2007/05/VOVED-VO-ART-Macedonian-Intro-to-ART.pdf
13. https://eecaplatform.org/wp-content/uploads/2018/05/SEE-Sustainability-Case-Studies-Nov-2017-1.pdf
14. https://eecaplatform.org/obzor-perehod-veca/
15. https://eecaplatform.org/wp-content/uploads/2017/12/Macedonia_RU-global-fund-case-study-2016.pdf
16. https://www.crownagents.com/where-we-work/eastern-europe-central-asia/
17. https://www.e-nabavki.gov.mk

The subject of the contract is divided into separate positions. The tenderer may apply for one, several or all of the items of the subject of the public procurement contract. A separate electronic auction is conducted for each individual item of the contract subject through the Electronic System for Public Procurement (Електронски систем за јавни набавки).

The criterion for the conclusion of the public procurement contract is the lowest price, which includes all costs, discounts and import duties, excluding VAT, and there are no preferences for national producers when considering bids.

Electronic procurements are conducted once a year. The winner of the electronic auction enters into a short-term contract under which he/she is obliged to deliver the medicinal products once upon a written request of the customer within 30 days from the date of signing the contract. The place of delivery is the premises of the Clinic for Infectious Diseases and Febrile Conditions (Клиника за инфективни болести и фебрилни состојби). Delivery costs, as well as preliminary costs, are borne by the contractor.

4.5. Procurement planning

Procurement planning is carried out by the Clinic for Infectious Diseases and Febrile Conditions (Клиника за инфективни болести и фебрилни состојби) on the basis of allocated funding in accordance with the HIV Population Protection Program of the Republic of North Macedonia, developed by the Ministry of Health (Министерство за здравство).

The periods of the HIV Population Protection Program and the procurement plan for antiretroviral drugs is 1 year. The procurement plan for antiretroviral drugs of the Clinic for Infectious Diseases and Febrile Conditions (Клиника за инфективни болести и фебрилни состојби) is available in the Electronic System for Public Procurement (Електронски систем за јавни набавки) for 2019 only.

5. PROCUREMENT OF ANTI-RETROVIRAL DRUGS

Public procurement procedures for antiretroviral drugs № 5/2018 and № 5-1/2018 in 2018 were conducted by the customer, Clinic for Infectious Diseases and Febrile Conditions (Клиника за инфективни болести и фебрилни состојби), through the Electronic System for Public Procurement (Електронски систем за јавни набавки).

The contracts concluded with the winners of the electronic auctions contain information on prices and amounts of purchases by specific INNs and do not contain the trade names of the purchased ARVs and producers names. The contracts are placed on the pages of the completed procedures in the Electronic System for Public Procurement.

5.1. Purchases of antiretroviral drugs in 2019

Table 5.1.1 — Public procurement procedure No. 5/2018 [18]

ATC Code	INN	Form	Form, quantity in packing and dosage	Packs	Price, inc VAT		Price, inc VATT		Successful tenderer
					MKD, ths.	USD, ths.	MKD, ths.	USD, ths.	
J05AG03	Efavirenz	Tablets	30x600 mg	96	848,93	16,40	81497,28	1574,40	Зегин ДОО Скопје
J05AG01	Nevirapine	Tablets	60x200 mg	648	411,61	7,95	266723,28	5151,60	ДППХКП Елбијор ДООЕЛ увоз извоз Скопје
J05AX12	Dolutegravir	Tablets	30x50 mg	120	27183,33	525,08	3261999,60	63009,60	Македонијалек ДООЕЛ Скопје

18. https://e-nabavki.gov.mk/PublicAccess/home.aspx#/dossie/6725b06c-6359-4583-8255-d73942d1da99/1

J05AE03	Ritonavir	Capsules/ Tablets	30x100 mg	204	2850,00	55,05	581400,00	11230,20	Галинос Фарм ДОО Скопје
J05AE10	Darunavir	Tablets	60x600 mg	36	13284,00	256,60	478224,00	9237,60	Септима ДООЕЛ Скопје
J05AE10	Darunavir	Tablets	30x800 mg	132	6079,85	117,44	802540,20	15502,08	Еуро-Фарм ДООЕЛ Битола
J05AX08	Raltegravir	Tablets	60x400 mg	216	18000,00	347,69	3888000,00	75101,04	Галинос Фарм ДОО Скопје
J05AF07	Tenofovir disoproxil fumarate	Tablets	30x300 mg	36	13973,00	269,91	503028,00	9716,76	Зегин ДОО Скопје
J05AR03	Tenofovir disoproxil + Emtricitabine	Tablets	30x(245 mg + 200 mg)	1068	3450,00	66,64	3684600,00	71171,52	Еуро-Фарм ДООЕЛ Битола
J05AR06	Tenofovir disoproxil+ Emtricita-bine+ Efavirenz	Tablets	30x(245 mg + 200 mg + 600 mg)	1260	1521,45	29,39	1917027,00	37031,40	Македонијалек ДООЕЛ Скопје
J05AR08	Tenofovir disoproxil+ Emtricita-bine+ Rilpivirine	Tablets	30x(245 mg + 200 mg + 25 mg)	72	35141,54	678,80	2530190,88	48873,60	Зегин ДОО Скопје
J05AR13	Abacavir+ Dolutegravir+ Lamivudine	Tablets	30x(600 mg+ 50 mg+ 300 mg)	120	31665,26	611,65	3799831,20	73398,00	Македонијалек ДООЕЛ Скопје
J05AR02	Abacavir+ Lamivudine	Tablets	30x(600 mg + 300 mg)	348	1908,00	36,86	663984,00	12827,28	Зегин ДОО Скопје
J05AR10	Lopinavir+ Ritonavir	Tablets	120x(200 mg+ 50 mg)	324	4882,00	94,30	1581768,00	30553,20	Медика Интернационал ДОО Илинден
J05AR01	Lamivudine+ Zidovudine	Tablets	60x(150 mg + 300 mg)	36	3300,00	63,74	118800,00	2294,64	Галинос Фарм ДОО Скопје
J05AR17	Tenofovir alafenamide + Emtricitabine	Tablets	30x(25 mg + 200 mg)	60	31950,00	617,15	1917000,00	37029,00	Зегин ДОО Скопје
J05AF05	Lamivudine	Oral Solution	10 mg/ml	24 (240 ml)	1759,30	33,98	42223,20	815,52	Македонијалек ДООЕЛ Скопје
J05AF01	Zidovudine	Oral Solution	10 mg/ml	60 (200 ml)	1194,88	23,08	71692,80	1384,80	Македонијалек ДООЕЛ Скопје
J05AG01	Nevirapine	Oral Solution	10 mg/ml	120	No application was submitted				
J05AG03	Efavirenz	Capsules	50 mg	73	No application was submitted				
J05AF07	Tenofovir disoproxil fumarate	Granules	33 mg/г	36 (60г)	No application was submitted				
J05AF07	Tenofovir disoproxil	Tablets	123 mg	12	11780,00	227,54	141360,00	2730,48	Септима ДООЕЛ Скопје
J05AR10	Lopinavir+ Ritonavir	Tablets	60x(100 mg/ 25 mg)	12	No application was submitted				
J05AR10	Lopinavir+ Ritonavir	Oral Solution	80 mg+ 20 mg/ml	24	No application was submitted				
Total							**26 331 889,44**	**508 632,72**	

Table 5.1.2 — Public procurement procedure No. 5-1/2018 [19]

ATC Code	INN	Form	Form, quantity in packing and dosage	Packs	Price, inc VAT		Price, inc VATT		Successful tenderer
					MKD, ths.	USD, ths.	MKD, ths.	USD, ths.	
J05AE08	Atazanavir	Capsules	30x300mg	24	No application was submitted				
J05AB14	Valgancik-lovir	Tablets	60x450mg	48	38997,69	753,29	1871889,12	36157,92	Македонијалек ДООЕЛ Скопје
J05AB01	Aciklovir	Ampules	250mg	7000	128,58	2,48	900060,00	17360,00	Алкалоид Конс ДООЕЛ Скопје
J02AX04	Caspofungin	Ampules	50mg	56	18022,97	348,14	1009286,32	19495,84	Алкалоид Конс ДООЕЛ Скопје
Total							**3781235,44**	**73013,76**	

5.2. Procurement plan for antiretroviral drugs in 2019

Announcement of the public procurement procedure for antiretroviral drugs No. 07422/2019 in 2019 was published on September 5, 2019, by the Clinic for Infectious Diseases and Febrile Conditions (Клиника за инфективни болести и фебрилни состојби) in the Electronic System for Public Procurement (Електронски систем за јавни набавки).

Table 5.2.1 - Public procurement procedure No. 077422/2019 [20]

ATC Code	INN	Form	Dosage	Tablets, pcs/ml
J05AG03	Efavirenz	Tablets	600mg	1200
J05AF07	Tenofovir disoproxil fumarate	Tablets	300mg	450
J05AG01	Nevirapine	Tablets	200mg	15900
J05AX12	Dolutegravir	Tablets	50mg	3150
J05AE03	Ritonavir	Capsules/Tablets	100mg	5730
J05AE10	Darunavir	Tablets	800mg	5400
J05AX08	Raltegravir	Tablets	400mg	3960
J05AF07	Atazanavir	Tablets	300mg	240
J05AR03	Tenofovir disoproxil + Emtricitabine	Tablets	(245mg + 200mg)	18690
J05AR06	Tenofovir disoproxil +Emtricitabine+ Efavirenz	Tablets	(245mg + 200mg + 600mg)	26040
J05AR08	Tenofovir disoproxil+ Emtricita-bine+Rilpivirine	Tablets	(245mg + 200mg + 25mg)	840
J05AR13	Abacavir+ Dolutegravir+Lamivudine	Tablets	(600mg+50mg+ 300mg)	6450
J05AR02	Abacavir+Lamivudine	Tablets	(600mg + 300mg)	5670
J05AR18	Elvitegravir+Cobicistat+ Emtricita-bine+Tenofovir alafenamide fumarate	Tablets	(150mg+150mg+200mg+10mg)	510
J05AR17	Tenofovir alafenamide + Emtricitabine	Tablets	(25mg + 200mg)	750
J05AF05	Lamivudine	Oral Solution	10mg/ml	3120
J05AF01	Zidovudine	Oral Solution	10mg/ml	7000

19. https://e-nabavki.gov.mk/PublicAccess/home.aspx#/dossie/1f0fd619-c844-4b4e-b21c-6f4d0ee21e20/1
20. https://e-nabavki.gov.mk/PublicAccess/home.aspx#/dossie/c8b7eb7f-e76f-46d1-8eb4-96b5e7f61c71/1

MONTENEGRO

622 182
Population, persons

26
Number of new HIV cases in 2017

437
Estimated number of people living with HIV, persons (The proportion of the population living with HIV — 0,07)

201
Number of HIV — infected people who know their status, persons

140
Number of HIV-infected people who know their status and covered by antiretroviral therapy, persons

* data as of 31.12.2018

https://www.ecdc.europa.eu/sites/default/files/documents/HIV-continuum-of-care-monitoring-dublin-declaration-progress-report-2018.pdf
http://www.monstat.org/cg/page.php?id=273&pageid=48
https://www.euprava.me/ResourceManager/FileDownload.aspx?rId=962&rType=2

1. SUMMARY *

Criteria	Comment
Characteristics of state registration procedures	
The law that regulates the registration of medicines	The Law on Medicines (Official Gazette of Montenegro, No. 56/2011, 6/2013)
Registration authority	The Agency for Medicines and Medical Devices of Montenegro (CALIMS —Agencija za ljekove i medicinska sredstva)
Entities that have the right to sell medicinal products	• A medicines manufacturer registered in Montenegro. • A representative of a medicines foreign manufacturer registered in Montenegro. • A representative of a foreign legal entity, registered in Montenegro, that is not the manufacturer but the holder of the marketing authorization (the trade license) in an EU Member State. • A legal entity, registered in Montenegro, to which a local manufacturer has granted the right to obtain a marketing authorization for its medicines.
Entities that have the right to participate in a tender	• An economic entity authorized to sell the medicinal product.
Packaging requirements	The availability of basic information on the medicinal product in Montenegrin on the outer, inner packaging and in the instructions of the medicinal product. The instructions must be provided in the Montenegrin language and other languages officially used in Montenegro (Serbian, Bosnian, Croatian, and Albanian). Legislative possibility of providing information on packaging and instructions in a language other than officially used in Montenegro has not been identified.
The availability of restrictive lists (for example, a list of vital medicines)	In Montenegro, there is the Medicines List, which includes the Main List of Medicines and the List of Medicines to be provided upon co-payment from the insured person. ARVs are included in the Main Medicines List; in other words, the insured person does not make any additional payments for them. Insured persons in Montenegro have the right to medicines from the List of Medicines covered by the mandatory health insurance upon the written medical prescription. Public procurement plans for ARVs may not include drugs that are not on this List.
The availability of expeditious registration procedures	The general registration procedure lasts up to 210 days after receiving the complete application for a marketing authorization. Expeditious procedures for medicines are available under one of the following conditions: • The drug is of great interest for the protection of public health; it is a therapeutic innovation. • The medicinal product has already obtained a marketing authorization under a centralized procedure (the marketing authorization procedure provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council), a mutual recognition procedure or a decentralized procedure. The expeditious registration procedure lasts up to 150 days after receiving the complete application for a marketing authorization.
VAT and tax benefits	Medicinal products have a discounted VAT rate of 7% (total VAT rate is 21%). A VAT rate of 0% is approved for medicines from the Medicines List to be covered by the Montenegro Health Insurance Fund.
Availability of post-registration for medicines	According to the tender documentation, the medicinal product already authorized for sale is allowed to participate in public procurement. Post-registration for medicines is not legally available.
Availability of special conditions for non-residents	Non-residents cannot obtain a marketing authorization without a representative office in Montenegro.
Logistics	According to the tender documentation, the supplier selects a logistics partner.

* Information as of the second half of 2019

Procedures of nomenclature formation	
Authorities responsible for the nomenclature lists formation	The ARV drug nomenclature is formed by the Montenegro Pharmaceutical Agency «Montefarm» based on an assessment of needs received from the healthcare institution responsible for providing antiretroviral therapy to the citizens - the Clinic for Infectious Diseases at the Clinical Center of Montenegro.
The procurement nomenclature	The subject-matterof procurement may only be antiretroviral drugs available in the List of Medicines to be prescribed and issued on the account of the mandatory health insurance.
Opportunity for NGOs and international organizations to participate in the nomenclature formation	No relevant information has been found.
Approval terms and frequency of the nomenclature revision	The nomenclature is revised on annual basis.
The functioning of the public procurement system	
Funding sources	Only national funding from the Health Insurance Fund of Montenegro.
Procuring entities	The Pharmaceutical Agency of Montenegro «Montefarm» is a health care institution to purchase medicines.
Possibility to use international mechanisms/funding	The National HIV/AIDS Strategy for Montenegro in 2015-2020 did not envisage funding from international organizations. The procurement by international agencies/ organizations is not provided by law.
Availability of transparent procedures	The Public Procurement Portal.
Availability of supply disruptions	No relevant information was found.
Procurement planning	Procurement planning is carried out for 1 year.
Statistics on the volume of procurement of ART drugs	
Purchasing prices	Specified in the tender documentation for each item.
Number of medicines purchased	Specified in the tender documentation for each item.
The total amount of procurement	In 2019 - EUR 84,900 (USD 95,100).
Reference to «originator/generic»	There is no information in the tender documentation.
Attitudes towards generics in the NGO/medical community	Prejudiced attitudes of both groups toward generics through stereotypes and myths about their quality and effectiveness.
Patient-centered procurement	The National HIV / AIDS Strategy for Montenegro in 2015-2020 does not specify the number of patients to be covered by ART.

2. STATE PROCEDURE OF MEDICINAL PRODUCTS REGISTRATION

2.1. General information

The registration of medicinal products in Montenegro is carried out in accordance with the Law on Medicines[1] (Official Gazette of Montenegro, No. 56/2011, 6/2013).

According to Articles 7-8 of the Law on Medicines, the Agency for Medicines and Medical Devices of Montenegro (CALIMS — Agencija za ljekove i medicinska sredstva)[2] is responsible for granting a marketing authorization and keeping a registry of medicines.

According to Articles 12 to 13 of the Law on Medicines, the Agency, with the prior approval of the Minister of Health, establishes an advisory body (Commission) which draws a conclusion on the quality, safety and efficacy of the medicinal product while issuing the marketing authorization. Members of the Commission may be permanent or temporary to evaluate certain types of medicinal products. The members of the Commission are selected from among the foremost experts in the field of medicines and medical devices, appointed for four years and may be reappointed.

According to the Law on Medicines, a medicinal product may be sold in the territory of Montenegro, provided that the economic entity has a marketing authorization or import authorization.

Authorization for sale

According to Article 2 of the Law on Medicines, the medicinal product may be marketed in the territory of Montenegro provided that the economic entity has the marketing or import authorization.

To obtain a marketing authorization, one submits an application which, in accordance with Article 31 of the Law on Medicines, must contain the documentation provided in the following table.

Information block	Content
Administrative part	• The name of the medicinal product and the INN; • Information on the active substance, pharmaceutical form and dosage; • Proposed summary characteristic of the medicinal product; • Instructions for patients; • Names and addresses of the applicant, the manufacturer and the manufacturing site; • Manufacturing license issued by the national competent authority in the country of production; • Packaging proposal; • Available marketing authorization or proof that the medicinal product is in the process of being granted a marketing authorization in the country of origin or that it is marketed, or reasons for its withdrawal from the market in that country; • A list of countries in which the medicinal product has marketing authorization; • The certificate of the Good Manufacturing Practice.
Pharmaceutical and chemical part	• Data on the qualitative and quantitative composition of the medicinal product; • A description of the manufacturing process; • Quality control of input raw materials; • Quality control of the manufacturing process; • Quality control of the finished product; • Data on the environmental safety assessment of the medicinal product.
Pharmaco-toxicological part	• Pharmacodynamic and pharmacokinetic characteristics of the medicinal product; • Data on toxicity and reproductive function effects; • Data on embryonic and perinatal toxicity; • Data on mutagenic and carcinogenic potential.
Clinical part	• Information on clinical trials and their results; • Clinical and pharmacological data; • Bioavailability and bioequivalence data (if applicable); • Clinical safety and efficacy data; • Information about exceptional testing circumstances; • Data on using the medicinal product after marketing authorization in other countries.

1. http://www.mzd.gov.me/ResourceManager/FileDownload.aspx?rid=217730&rType=2&file=Zakon%20o%20ljekovima.pdf
2. https://www.calims.me/

According to Article 32 of the Law on Medicines, instead of his/her own research on the pharmacotoxicological and clinical parts, the applicant may submit data published in professional publications based on the biological equivalence of the medicinal product and the reference medicinal product. The reference medicinal product refers to the medicinal product used for at least ten years in Montenegro, in one of the EU countries or a country with identical marketing authorization requirements, and for which there is a peer-reviewed publication containing all the necessary pharmacology -toxicological and clinical information confirming the safety and efficacy of the medicinal product.

According to Article 35 of the Law on Medicines, the marketing authorization for an equivalent medicinal product is granted after a period of 10 years since the authorization permit for the reference medicinal product has been granted.

According to Article 38 of the Law on Medicines, the Agency decides (no later than 210 days after receipt of a complete application for a marketing authorization) to grant a marketing authorization or to reject the application, having received a conclusion on the reliability of the documentation and the evaluation of the quality, safety and efficacy of the medicinal product by the Commission.

According to section 40 of the Law on Medicines, a marketing authorization is granted for a period of 5 years.

Import authorization

There are no exceptions in the legislation under which ARVs could be admitted to the public procurement tender without a marketing authorization in Montenegro *(see section 2.5)*.

However, there are a number of cases in which the medicinal product may be imported into Montenegro without its participation in a tender.

In accordance with Article 45 of the Law on Medicines, the Agency for Medicines and Medical Devices of Montenegro may, as an exception, provide import authorization for a medicinal product with no marketing authorization in Montenegro in the following cases:

- The medicinal product is intended for scientific and medical research: it is issued upon the application of the person engaged in research activity; the volume of medicinal products, for which authorization is granted, is limited;
- The medicinal product is intended for further processing: the authorization is granted upon the application of the manufacturer;
- The medicinal product is intended for the treatment of a particular patient or group of patients who have a special need for it: issued on the request of a healthcare facility; the volume of medicinal products, for which authorization is granted, is limited (does not exceed six months of one person's need or annual need of a healthcare facility);
- The medicinal product identified by the Ministry of Health of Montenegro based on a proposal from the Agency for Medicines and Medical Devices.

Marking and instruction

According to Articles 118-121 of the Law on Medicines, the requirements are as follows:

- The Agency for Medicines and Medical Devices of Montenegro approves the marking of the outer, inner packaging of the medicinal product and the instructions for the patient enclosed into a package;
- Information on the packaging about the main characteristics must be provided in the Montenegrin language;
- The instruction must contain the main product characteristics and be provided in the Montenegrin language and other languages officially used in Montenegro (Serbian, Bosnian, Croatian, Albanian).

The name of the medicinal product must also be written in Braille on the outer package.

The legal possibility to provide information on packaging and instructions in a foreign language other than officially used in Montenegro has not been identified.

2.2. Restrictive lists

The decision on approval the Medicines List[3] (Official Gazette of Montenegro, Nos. 002/18, 023/18, 077/18, 006/19) defines the Main List of Medicines and the List of Medicines to be provided upon co-payment from the insured person.

ARVs are included in the Main List of Medicines, that is, the insured person does not make any additional payments for them.

Public procurement plans for ARVs may not include drugs that are not on this List.

3. https://fzocg.me/documents/3_POO/Odluka_lista_ljekova.pdf

Table 2.2.1 — Antiretroviral drugs from the List of Medicines to be covered by the mandatory health insurance (void for 2020)[4]

ATC Code	INN	Name	Pharmaceutical form, quantity in packing and dosage	Manufacturer's name
J05AE03	ritonavir	Norvir	Tablets, 30x100mg	AbbVie Deutschland GmbH
J05AF01	zidovudin	Not specified	Capsules, 100mg	Not specified
J05AF01	zidovudin	Не вказана	Capsules, 250mg	Not specified
J05AF05	lamivudin	Zeffix	Tablets, 28x100mg	Glaxo Smith Kline
J05AF05	lamivudin	Epivir	Tablets, 60x150mg	Glaxo Smith Kline
J05AF06	abakavir	Ziagen	Tablets, 60x300mg	Glaxo Smith Kline
J05AF07	tenofovir	Not specified	Tablets, 245mg	Not specified
J05AG03	efavirenz	Stocrin	Tablets, 30x600mg	Merck Sharp & Dohme BV
J05AR01	lamivudin, zidovudin	Combivir	Tablets, 60x(150mg + 300mg)	Glaxo Smith Kline
J05AR02	abakavir, lamivudin	Kivexa	Tablets, 30x(600mg + 300 mg)	Glaxo Smith Kline
J05AR03	tenofovir, emtricitabin	Truvada	Tablets, 245mg+200mg	Not specified
J05AR10	lopinavir, ritonavir	Aluvia	Tablets, 120x(200mg + 50mg)	AbbVie Deutschland GmbH
J05AX08	raltegravir	Isentress	Tablets, 60x400mg	Merck Sharp & Dohme BV
J05AX12	dolutegravir	Tivicay	Tablets, 30x50mg	Glaxo Smith Kline

HIV treatment protocol

Montenegro has a national protocol for HIV treatment[5].

As part of recommendations regarding HIV treatment, the Protocol refers to the guidelines of the European AIDS Clinical Society (EACS)[6]. The INNs, which are recommended as treatment regimens under the National Protocol, are not the basis for establishing a list of ARVs to be purchased for the needs of HIV-infected patients in Montenegro.

2.3. Expeditious procedures

According to Article 41 of the Law on Medicines, the expeditious procedure of obtaining marketing authorization for a medical product is possible under the following conditions:

1. The drug is of great interest for the protection of public health, it is a therapeutic innovation;
2. The medicinal product has already obtained a marketing authorization under the centralized procedure (the marketing authorization procedure provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council), a mutual recognition procedure or a decentralized procedure.

The Agency for Medicines and Medical Devices of Montenegro shall decide, no later than 150 days after receipt of the complete application, to issue a marketing authorization or reject the application.

2.4. VAT

According to Article 24 of the Law on Value Added Tax[7], a discounted VAT rate of 7% (total VAT rate is 21%) was approved for medicinal products.

According to Article 25 of this Law, a VAT rate of 0% is approved for medicinal products specified in the List of Medicines to be covered by the Health Insurance Fund.

2.5. Legislative possibility of post-registration of medicinal products

According to the tender documentation, the medicinal product with marketing authorization is allowed to participate in public procurement.

There is no legal possibility for post-registration of medicines.

2.6. Conditions for non-residents

According to Article 30 of the Law on Medicines, an application for a marketing authorization may be submitted by:

- A manufacturer of medicines registered in Montenegro.
- A representative of a foreign manufacturer registered in Montenegro.
- A representative of a foreign legal entity registered in Montenegro that is not the manufacturer but the holder of the marketing authorization (trade license) in an EU Member State.
- A legal entity registered in Montenegro to which a local manufacturer has granted the right to obtain a marketing authorization for medicinal products of own manufacture.

Non-residents cannot obtain the marketing authorization without a representative office in Montenegro.

4. https://fzocg.me/documents/3_POO/Lista_ljekova_2020.pdf
5. http://www.rtcg.me/vijesti/drustvo/260889/hiv-90-inficiranih-su-muskarci.html
6. https://www.ijzcg.me/me/hiv-aids
7. http://www.poreskauprava.gov.me

3. PROCEDURE TO FORM A NOMENCLATURE OF MEDICINAL PRODUCTS

3.1. Registry of medicinal products

Table 3.1.1 — Registry of antiretroviral drugs [8]

ATC Code	Name	INN	Form, quantity in packing and dosage	Manufacturer
J05AE03	Norvir	ritonavir	Tablets, 30x100mg	AbbVie Deutschland GmbH & Co. KG
J05AE07	Telzir	fosamprenavir	Tablets, 60x700mg	Glaxo Wellcome Operations
J05AF05	Epivir	lamivudin	Tablets, 60x150mg	Glaxo Wellcome Operations, GlaxoSmithKline Pharmaceuticals S.A.
J05AF05	Zeffix	lamivudin	Tablets, 28x100mg	GlaxoSmithKline Pharmaceuticals S.A.
J05AF06	Ziagen	abakavir	Tablets, 60x300mg	GlaxoSmithKline Pharmaceuticals S.A., Glaxo Wellcome Operations
J05AG03	Stocrin	efavirenz	Tablets, 30x600mg	Merck Sharp & Dohme BV
J05AR01	Combivir	zidovudin, lamivudin	Tablets, 60x(300mg+150mg)	Glaxo Wellcome Operations, GlaxoSmithKline Pharmaceuticals S.A.
J05AR02	Kivexa	abakavir, lamivudin	Tablets, 30x(600mg+300mg)	Glaxo Wellcome Operations, Glaxo Wellcome S.A.
J05AR10	Aluvia	lopinavir, ritonavir	Tablets, 120x(200mg+50mg)	AbbVie Deutschland GmbH & Co. KG
J05AX08	Isentress	raltegravir	Tablets, 60x400mg	Merck Sharp & Dohme BV
J05AX12	Tivicay	dolutegravir	Tablets, 30x50mg	Glaxo Wellcome S.A.

3.2. Nomenclature of medicinal products for procurement

The ARV drug nomenclature is formed by the Montenegro Pharmaceutical Agency «Montefarm» based on an assessment of needs received from the healthcare institution responsible for providing antiretroviral therapy to the citizens - the Clinic for Infectious Diseases at the Clinical Center of Montenegro.

The Montenegro Pharmaceutical Agency «Montefarm» is a health care institution established by the decision of the Assembly of the Republic of Montenegro No. 1771 of May 15, 1991 (Official Gazette of Montenegro No. 21/91). «Montefarm» purchases and issues medicines to all health care institutions and citizens through its pharmacies.

The Notes on the List of Medicines covered by the Health Insurance Fund contain information explaining that medicines for HIV treatment are being introduced into therapy at the proposal of the Board of the Clinic for Infectious Diseases at the Clinical Center of Montenegro after approval by the Medical Products Commission of the Health Insurance Fund.

According to the tender documentation for the procurement of antiretroviral drugs, only the antiretroviral drug available in the List of Medicines covered by the Health Insurance Fund may be subject to procurement *(see Section 2.2)*.

The nomenclature of ARVs is reviewed annually prior to the start of the tender on the Public Procurement Portal by the Montenegro Pharmaceutical Agency «Montefarm». In 2018–2019, the list of medicines for procurement has dropped significantly, as compared to 2017, to one position.

The legislative capacity of the Montenegrin NGOs for legal participation in the formation of the ARVs nomenclature has not been identified.

8. https://www.alims.gov.rs/ciril/lekovi/pretrazivanje-humanih-lekova/

4. PUBLIC PROCUREMENT SYSTEM

4.1. Sources of procurement financing

Strategic measures for the HIV prevention and treatment in Montenegro are set out in the National Strategy on HIV/AIDS in Montenegro for 2015-2020[9]. In Montenegro, the Health Insurance Fund of Montenegro[10] *(Fond za zdravstveno osiguranje Crne Gore)* exclusively provides the national funding for antiretroviral therapy.

The National Strategy on HIV/AIDS in Montenegro for 2015-2020 and the financial documentation of the Health Insurance Fund of Montenegro do not specify the amount of funding for the purchase of ARVs.

The Health Insurance Fund pays the invoices for ARV drugs delivered to the Clinic for Infectious Diseases at the Clinical Center of Montenegro from the only purchasing organization — the Montenegro Pharmaceutical Agency «Montefarm».

4.2. Entities purchasing anti-retroviral drugs

The antiretroviral therapy required to treat HIV infection is free of charge for each patient if he or she carries insurance within the Health Insurance Fund of Montenegro[11].

According to the National Strategy on HIV/AIDS in Montenegro for 2015-2020, HIV treatment is carried out at the Clinic for Infectious Diseases at the Clinical Center of Montenegro (Klinika za infektivne bolesti Kliničkog centra Crne Gore — KCCG). Only two medical experts of the Clinic have the right to provide ARV prescriptions whci are being submitted to the Montenegro Pharmaceutical Agency «Montefarm».

The contracting authority conducts public procurement in accordance with the Public Procurement Law[12] (Official Gazette of Montenegro, No 42/11, 57/14, 28/15 and 42/17).

Medicines from the List of Medicines covered by the Health Insurance Fund of Montenegro are available upon prescription at «Montefarm's» pharmacies. The drugs available on prescription are paid by the Health Insurance Fund of Montenegro[13].

«Montefarm» purchases ARVs from the above List at the request of the Clinic for Infectious Diseases and these drugs are not offered for free sale to the public.

4.3. Ability to use international procurement mechanisms

The National Strategy on HIV/AIDS in Montenegro for 2015-2020 did not envisage funding from international organizations. The possibility of procurement by international agencies/organizations is not provided by law.

4.4. E-Procurement

The Public Procurement Portal [14] *(Portal javnih nabavki)* works in Montenegro.

The Montenegro Pharmaceutical Agency «Montefarm», as the contracting authority (buyer), carries out the public procurement procedure according to the nomenclature approved by the Council for Infectious Diseases of the Clinical Center of Montenegro[15].

Public procurement contracts for ARVs have a standard validity period of 1 year.

The supplier is obliged to provide monthly to the customer invoices, signed by the authorized person, including VAT (0%), for delivered medicinal products, which are the subject-matter of the contract.

The subject-matter of the tender is divided into separate positions (items). The tenderer may apply for any number of items of the subject-matter of the public procurement contract.

The criterion for the conclusion of the contract is the lowest price; there are no preferences for national manufacturers when considering bids[16].

4.5. Procurement planning

The Montenegro Pharmaceutical Agency «Montefarm» conducts procurement planning. The customer makes the procurement plan for 1 year.

Prior to the beginning of the year, the contracting authority publishes the procurement plan for this year on the Public Procurement Portal; this plan contains indicative amounts of expenditures for general procurement areas.

9. http://www.mzdravlja.gov.me/ResourceManager/FileDownload.aspx?rid=218618&rType=2&file=Nacionalna%20strategija%20za%20borbu%20protiv%20HIV-AIDS%202015-2020.pdf
10. https://fzocg.me/
11. https://www.vijesti.me/vijesti/drustvo/u-crnoj-gori-se-nerado-testiraju-na-hiv-koriscenje-kondoma-ispod-africkog-prosjeka
12. https://www.paragraf.me/propisi-crnegore/zakon-o-javnim-nabavkama.html
13. http://www.montefarm.co.me/
14. http://portal.ujn.gov.me/delta2015/search/noticeSearch.html
15. https://fzocg.me/documents/Finansije/Izvjestaji_o_radu/9._izvjestaj_o_radu_i_poslovanju_fonda_za_2015.pdf
16. http://portal.ujn.gov.me/delta2015/search/displayNotice.html?id=124775&type=InvitationPublicProcure

5. PROCUREMENT OF ANTI-RETROVIRAL DRUGS

Public procurement procedures for antiretroviral drugs in 2017–2019 were conducted on the Public Procurement Portal in the framework of a centralized procurement procedure of the customer, the Montenegro Pharmaceutical Agency «Montefarm».

The contracts concluded with the winners contain information on the purchase prices by specific INNs and do not contain information on the manufacturers of medicines.

Information on manufacturers of medicines can be obtained from the List of Medicines covered by the Health Insurance Fund, since the purchasing nomenclature is formed on its basis.

However, some items in the List do not include trade names and/or manufacturers.

5.1. Purchases of antiretroviral drugs in 2019

In 2017, the largest number of ARVs procurement tenders were conducted; in 2018-2019 the list of medicines for purchase was reduced to one position.

Table 5.1.1 — Public procurement procedures No. 0719, 0718, 1617, 1517, 1317, 1217, 0117

INN	Name	Manufacturer	Form, quantity in packing and dosage	Packes, pcs.	Price, inc VAT		Value, inc VAT		Supplier
					EUR	USD	EUR ths	USD ths	
Procedure № 0719 of 22.08.2019									
tenofovir, emtricitabin	Truvada	Not specified	Tablets, 30x(245mg+ 200mg)	1500	56,6	63,4	84,9	95,1	Farmegra d.o.o. Podgorica
Total in 2019							**84,9**	**95,1**	
Procedure № 0718 of 20.06.2018									
tenofovir, emtricitabin	Truvada	Not specified	Tablets, 30x(245mg+ 200mg)	1000	52,3	62,8	52,3	62,8	Farmegra d.o.o. Podgorica
Total in 2018							**52,3**	**62,8**	
Procedure № 1617 of 13.12.2017									
tenofovir, emtricitabin	Truvada	Not specified	Tablets, 30x(245mg+ 200mg)	300	60,0	68,4	18,0	20,5	Farmegra d.o.o. Podgorica
raltegravir	Isentress	Merck Sharp & Dohme BV	Tablets, 60x400mg	100	537,0	612,2	53,7	61,2	Glosarij CD d.o.o. Podgorica
Procedure № 1617 of 13.12.2017									
raltegravir	Isentress	Merck Sharp & Dohme BV	Tablets, 60x400mg	100	537,0	612,2	53,7	61,2	Glosarij CD d.o.o. Podgorica
Procedure № 1317 of 17.08.2017									
sakvinavir	Not specified	Not specified	Tablets, 120x500mg	6	216,7	247,0	1,3	1,5	Glosarij d.o.o. Podgorica
ritonavir	Norvir	AbbVie Deutschland GmbH	Tablets, 30x100mg	35	20,0	22,8	0,7	0,8	Glosarij d.o.o. Podgorica

lopinavir, ritonavir	Aluvia	AbbVie Deutschland GmbH	Tablets, 120x(200mg+ 50mg)	30	60,0	68,4	1,8	2,1	Glosarij d.o.o. Podgorica
darunavir	Not specified	Not specified	Tablets, 60x600mg	8	587,5	669,8	4,7	5,4	Glosarij d.o.o. Podgorica
lamivudin	Zeffix	Glaxo Smith Kline	Tablets, 28x100mg	120	50,8	57,9	6,1	7,0	Glosarij d.o.o. Podgorica
lamivudin	Epivir	Glaxo Smith Kline	Tablets, 60x150mg	18	94,4	107,6	1,7	1,9	Glosarij d.o.o. Podgorica
abakavir	Ziagen	Glaxo Smith Kline	Tablets, 60x300mg	8	212,5	242,3	1,7	1,9	Glosarij d.o.o. Podgorica
tenofovir dizoproksil fumarat	Viread	Gilead Sciences, Inc	Tablets, 30x245mg	160	41,9	47,8	6,7	7,6	Farmegra d.o.o. Podgorica
abakavir, lamivudin	Kivexa	Glaxo Smith Kline	Tablets, 30x(600mg+ 300mg)	160	315,0	359,1	50,4	57,5	Glosarij d.o.o. Podgorica
efavirenz	Stocrin	Merck Sharp & Dohme BV	Tablets, 30x600mg	320	208,4	237,6	66,7	76,0	Glosarij CD d.o.o. Podgorica
lamivudin, zidovudin	Combivir	Glaxo Smith Kline	Tablets, 60x(150mg+ 300mg)	53	190,6	217,3	10,1	11,5	Glosarij d.o.o. Podgorica
Procedure № 1217 of 14.06.2017									
emtricitabin, tenofovir dizoproksil	Truvada	Not specified	Tablets, 30x(200mg+ 245mg)	420	60,0	68,4	25,2	28,7	Farmegra d.o.o. Podgorica
raltegravir	Isentress	Merck Sharp & Dohme BV	Tablets, 60x400mg	310	537,1	612,3	166,5	189,8	Glosarij CD d.o.o. Podgorica
Procedure № 0117 of 17.02.2017									
sakvinavir	Not specified	Not specified	Tablets, 120x500mg	4	225,0	256,5	0,9	1,0	Glosarij d.o.o. Podgorica
ritonavir	Norvir	AbbVie Deutschland GmbH	Tablets, 30x100mg	35	20,0	22,8	0,7	0,8	Glosarij d.o.o. Podgorica
lopinavir, ritonavir	Aluvia	AbbVie Deutschland GmbH	Tablets, 120x(200mg+ 50mg)	73	120,5	137,4	8,8	10,0	Glosarij d.o.o. Podgorica
zidovudin	Not specified	Not specified	Capsules, 100x100mg	4	75,0	85,5	0,3	0,3	Glosarij d.o.o. Podgorica
lamivudin	Zeffix	Glaxo Smith Kline	Tablets, 28x100mg	100	50,0	57,0	5	5,7	Glosarij d.o.o. Podgorica
lamivudin	Epivir	Glaxo Smith Kline	Tablets, 60x150mg	18	94,4	107,6	1,7	1,9	Glosarij d.o.o. Podgorica
abakavir	Ziagen	Glaxo Smith Kline	Tablets, 60x300mg	4	225,0	256,5	0,9	1,0	Glosarij d.o.o. Podgorica

tenofovir dizoproksil fumarat	Viread	Gilead Sciences, Inc	Tablets, 30x245mg	160	41,9	47,8	6,7	7,6	Farmegra d.o.o. Podgorica
abakavir, lamivudin	Kivexa	Glaxo Smith Kline	Tablets, 30x(600mg+ 300mg)	156	315,4	359,6	49,2	56,1	Glosarij d.o.o. Podgorica
efavirenz	Stocrin	Merck Sharp & Dohme BV	Tablets, 30x600mg	310	208,4	237,6	64,6	73,6	Glosarij CD d.o.o. Podgorica
lamivudin, zidovudin	Combivir	Glaxo Smith Kline	Tablets, 60x(150mg+ 300mg)	53	192,5	219,5	10,2	11,6	Glosarij d.o.o. Podgorica
emtricitabin, tenofovir dizoproksil	Truvada	Not specified	Tablets, 30x(200mg+ 245mg)	294	59,9	68,3	17,6	20,1	Farmegra d.o.o. Podgorica
raltegravir	Isentress	Merck Sharp & Dohme BV	Tablets, 60x400mg	155	536,8	612,0	83,2	94,8	Glosarij CD d.o.o. Podgorica
Total in 2017							**718,8**	**819,4**	

ROMANIA

22 171 000
Population, persons

387
Number of new HIV cases in 2018

17 000
Estimated number of people living with HIV, persons (The proportion of the population living with HIV — 0,08)

15 009
Number of HIV — infected people who know their status, persons

11 557
Number of HIV-infected people who know their status and covered by antiretroviral therapy, persons

* data as of 31.12.2018

http://www.insse.ro/cms/sites/default/files/com_presa/com_pdf/popdom1ian2019r.pdf
http://www.cnlas.ro/images/doc/ecdc_continuumOfHIVCare.pdf
http://www.cnlas.ro/images/doc/31122018_rom.pdf

1. SUMMARY *

Criteria	Comment
Characteristics of state registration procedures	
The law that regulates the registration of medicines	The Law No. 95/2006 on Healthcare Reform.
Registration authority	The National Agency for Medicines and Medical Devices of Romania (ANMDMR — Agentia Nationala a Medicamentului si a Dispozitivelor Medicale din Romania).
Entities that have the right to sell medicinal products	• An economic entity registered in Romania. • An economic entity registered in an EU country.
Entities that have the right to participate in a tender	• The resident economic entity in case it provides corporate registration documents, confirmation of the tax residence status, as well as the wholesale permit issued under Romanian law. • The non-resident economic entity in case it provides corporate registration documents, confirmation of the tax residence status, as well as the wholesale permit issued under the current legislation in the country of its registration.
Packaging requirements	The availability of basic information about the medicinal product in Romanian on the packaging and in the package leaflet. Information shall be provided both in other languages and Romanian simultaneously if the data is identical. According to the Law, there are no restrictions on foreign languages. If the medicinal product does not reach patients in the package (for example, when dispensing medicines by the piece of pills or injections for inpatient care, etc.), or if there are significant problems with the availability of the medicinal product, ANMDMR may exempt the obligation to indicate some information on the packaging and in package leaflet and also not to use the Romanian language. Specifications regarding specific types of medicines (including ARVs) are not provided in this context.
The availability of restrictive lists (for example, a list of vital medicines)	The list of medicinal products used in the health insurance system and national health programs is available. Within the Romanian health insurance system, the cost of the medicines available on this List is reimbursed. Reimbursable medicinal products are divided into five positive drug lists. ARVs are placed on the list C2 — these are the drugs delivered through hospital pharmacies within national treatment programs. Medicines from the list C2 are the subject to 100% reimbursement. Public procurement plans may not include drugs that are not on this Medicines List. Clinical Protocol. In 2013—2014, the National Guideline for Antiretroviral Therapy were in force. It has not been updated since 2014, as the National Committee for Infectious Diseases and local experts (upon agreement of the Ministry of Health) decided to use the EACS Guidelines. The EACS Guidelines provide only INN ARVs that can be used in different treatment regimens and do not establish a list of ARVs that must be purchased for HIV-infected patients in Romania.
The availability of expeditious registration procedures	A general registration procedure takes up to 210 days after receiving a complete application for a marketing authorization, and the expeditious procedure is only applicable for medicinal products already registered in the EU. Expeditious procedures for medicinal products are available in the framework of a centralized procedure, mutual recognition or a decentralized market placement procedure in the EU. If the medicinal product has already obtained marketing authorisation in an EU country at the time of application in Romania, then ANMDMR recognizes the marketing authorization granted by that EU country. The expedtious registration procedure lasts up to 90 days after receipt of the documents (an evaluation report) from the EU country in which the marketing authorization for the medicinal product is already valid.
VAT and tax benefits	Medicines have a discounted VAT rate of 9% (total VAT rate of 19%).
Availability of post-registration for medicines	The legislation provides for the possibility of post-registration of medicinal products in Romania.

* Information as of the second half of 2019

Availability of special conditions for non-residents	To participate in tenders for the procurement of antiretroviral drugs, a non-resident may submit documents prepared in accordance with the current legislation in the country of its registration. There are no other special conditions for non-residents.
Logistics	The logistics partner is selected by the supplier.
Procedures of nomenclature formation	
Authorities responsible for the nomenclature lists formation	The nomenclature of ARVs for the public procurement procedure is formed separately by each local healthcare facility involved in the National HIV/AIDS Program for Treatment.
The procurement nomenclature	Procurement nomenclature should include ARVs from the list C2 of medicines used in the health insurance system and national health programs, but a specific list of INNs is established by healthcare facilities involved in the National HIV/AIDS Program for Treatment based on HIV treatment regimens selected for patients.
Opportunity for NGOs and international organizations to participate in the nomenclature formation	No relevant information has been found.
Approval terms and frequency of the nomenclature revision	The periodicity of the nomenclature revision is not regulated. The initiation of tendering procedures and the determination of the ARVs nomenclature may be conducted several times a year, based on the needs of patients and available supplies.
The functioning of the public procurement system	
Funding sources	Funding is provided through the state budget, the budget of the Unified National Health Insurance Fund, local budgets, international sources (the Global Fund to Fight AIDS, Tuberculosis and Malaria, the European Social Fund, Norwegian funds and others). The volume of funding with a structural breakdown of funding sources in the 2019-2021 National Strategic Plan for Surveillance, Control and Prevention of HIV/AIDS is not specified.
Procuring entities	Local healthcare facilities (ambulance hospitals, infectious disease clinics); the procurement is conducted in a decentralized manner.
Possibility to use international mechanisms/funding	According to the 2019-2021 National Strategic Plan for Surveillance, Control and Prevention of HIV/AIDS, the possibility of funding procurement by international agencies/organizations was envisaged. The implementation of the most recent grant for HIV of the Global Fund for AIDS, Tuberculosis and Malaria was completed in 2010. In August 2019, EUR 161.9 million is expected to be reimbursed under the European Social Fund (ESF) within the project SMIS Code 126692 titled «Medical Services for Treatment People with HIV/AIDS».
Availability of transparent procedures	The system for electronic public procurement. The criterion for the conclusion of the agreement is the lowest price; there are no preferences for national producers when considering a tender proposal. Long-term contracts are available; a contract of up to 3 years is concluded with the successful tenderer.
Availability of supply disruptions	The National Union of Organizations of PLHIV in Romania (Uniunea Naţională a Organizaţiilor Persoanelor Afectate de HIV/SIDA — UNOPA) documents supply disruptions. The latest news about a shortage of antiretroviral drugs was posted in its press release on 29 Aug. 2019 [1].
Procurement planning	Procurement planning is carried out throughout the year, based on records of patients receiving ARV therapy and assessment of their current annual needs.
Statistics on the volume of procurement of ART drugs	
Purchasing prices	There is no information in the tender documentation.
Number of medicines purchased	Specified in the tender documentation for each item.
The total amount of procurement	Specified in the tender documentation for each item.
Reference to «originator/generic»	There is no information in the tender documentation.
Attitudes towards generics in the NGO/medical community	Prejudiced attitudes towards generics through stereotypes and myths about the quality and effectiveness of both groups.
Patient-centered procurement	According to the 2019-2021 National Strategic Plan for Surveillance, Control and Prevention of HIV/AIDS, the number of patients covered by ART is planned to 12,000 people in 2019, 13,000 people in 2020, and 14,000 people in 2021.

1. https://unopa.ro/pacientii-cu-hiv-din-romania-raman-fara-tratament/

2. STATE PROCEDURE OF MEDICINAL PRODUCTS REGISTRATION

2.1. General information

The registration of medicinal products in Romania is carried out in accordance with the Law No. 95/2006 on Health Reform [2] (hereinafter - the Health Reform Law).

According to Article 704 of the Health Reform Law, a medicinal product may be placed on the Romanian market if the National Agency for Medicines and Medical Devices of Romania *(ANMDMR — Agentia Nationala a Medicamentului si a Dispozitivelor Medicale din Romania)* [3] has granted a marketing authorization or if the authorization was granted by the European Medicines Agency in accordance with a centralized procedure (the procedure for obtaining a marketing authorization provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council). According to Article 705 of this Law, only the applicant registered in Romania or in an EU country can be granted a marketing authorization.

According to Article 25 of the Decision No. 1522 [4] of 9 October 2019, On approval of the Regulation on the organization and operation of the National Agency for Medicines and Medical Devices of Romania, the Commission includes the Directorate-General for Evaluation and Authorization (Direcţia generală evaluare-autorizare). The Directorate-General reports to one of the vice-presidents of ANMDMR, who is responsible for scientific activities in the field of medicines and medical devices for human use. The organizational structure is as follows:

- National Procedure Department;
- European Procedure Department;
- Pharmacovigilance and Risk Management Department;
- Authorization Issue Desk;
- Testing Unit;
- Nomenclature Unit;
- Unit for Evaluation of Biological Products.

The application for marketing authorization shall be accompanied by data and documents prepared in accordance with the analytical, pharmacotoxicological and clinical standards and protocols regarding the testing of medicinal products approved by the orders of the Minister of Health of Romania:

- The name and permanent/legal address of the applicant and, if appropriate, the producer;
- The name of the medicinal product;
- Qualitative and quantitative characteristics of all compounds of the medicinal product, including its international non-proprietary name (INN), recommended by WHO (if any);
- Assessment of potential environmental risks associated with the medicinal product; the impact in each case should be assessed, and specific measures should be taken to minimize it;
- A description of the manufacturing method;
- Therapeutic indications, contraindications and side reactions;
- Dosage, pharmaceutical form, method of administration and expiration date;
- The reasons for any precautionary measures and measures to be taken for the storage of the medicinal product, delivery it to patients and the waste disposal, together with an indication of the potential risks posed by the medicinal product to the environment;
- A written confirmation with a date of the audit and a statement of its results regarding the conformity of production with the Good Manufacturing Practice (GMP);
- Results of the pharmaceutical (physico-chemical, biological or microbiological) analysis, preclinical (toxicological and pharmacological) studies, and clinical trials;
- A brief description of the applicant's pharmacovigilance system, which must include the following elements: proof that the applicant has a qualified person responsible for pharmacovigilance, an EU country in which the qualified person resides and performs his/her duties, contact details of the qualified person, a statement signed by the applicant stating that he/she has the necessary funds to fulfill the tasks and responsibilities listed in section X «Pharmacovigilance» of this Law, a reference to the storage location of the main file of the pharmacovigilance system for medicinal products;
- A description of risks and a risk management plan;
- A statement that clinical trials conducted outside Romania and the EU meet the ethical criteria of the Good Clinical Practice Standards for Clinical Trials on Medicinal Products for Human Use approved by order of the Minister of Health of Romania;
- A summary of the product characteristics, the layout of the outer packaging and the inner packaging of the medicinal product, together with instructions for the patient;
- A document certifying the producer's right to manufacture medicines in his/her country;
- Copies of the following documents: marketing authorization obtained in another EU country or in a third country, a summary of the data on safety, including data available in the Periodic Safety Update Reports (if any), adverse reaction reports,

2. https://www.anm.ro/en/_/LEGI%20ORDONANTE/Titlul%20XVIII_Med_2016_EN%20.pdf
3. https://www.anm.ro/
4.https://www.anm.ro/_/ORGANIZAREA%20SI%20FUNCTIONAREA%20INSTITUTIEI/OMS%201522-2019%20ROF%20Monitorul%20oficial.pdf

and a list of those EU countries in which an application for a marketing authorization has been submitted in accordance with Directive 2001/83 / EC on the Community Code relating to Medicinal Products for Human Use and is under consideration;

- A summary of the product characteristics proposed by the applicant under Article 712 or approved by the ANMDMR under Article 781;
- Details of any decision to refuse authorization in an EU country or a third country, and reasons for such a decision.
- A copy of the approval of medicine as a medicinal product for the treatment of rare diseases in accordance with Regulation (EU) No 141/2000 of the European Parliament and of the Council on orphan medicinal products, published in OJEC No L018 of 22 January 2000, accompanied by a copy of the relevant opinion of the European Medicines Agency.

Article 708 of the Health Reform Law specifies Article 706 of this Law regarding the permission for an applicant not to provide pre-clinical and clinical trial results if he demonstrates that the medicinal product is a generic of a reference medicinal product which has marketing authorization or had one during at least eight years in Romania, in an EU country or under a centralized EU procedure. The generic authorized under this provision shall not be marketed earlier than 10 years after the initial marketing authorization for the reference medicinal product has been obtained.

The legislation regulates the submission of an application for a marketing authorization for a generic of a reference medicinal product not authorized in Romania. The applicant shall indicate the EU Member State in which the reference medicinal product is authorized or was authorized. The ANMDMR sends a request for confirmation of this fact to the competent authority of the EU Member State, together with an indication of the reference product composition and other relevant documentation, if necessary.

According to Article 709 of the Health Reform Law, instead of the results of an own pharmacotoxicological and clinical trial of the medicinal product, previously published information from the public literature, containing all the necessary documentation, may be submitted, provided that the components of the preparation, their safety and efficacy is well known, and the active substance has been used for at least 10 years as a medicine in EU countries.

According to Article 726 of the Health Reform Law, the duration of the marketing authorization procedure is up to 210 days from the date of application.

According to Article 738 of the Health Reform Law, a marketing authorization for a medicinal product is valid for 5 years.

Marking and instruction

According to Article 774 of the Health Reform Law, the outer and inner packaging of medicinal products must contain the following information:

- The name of the medicinal product, its use, dosage, pharmaceutical form, wether it is designed for children, adolescents or adults (if necessary);
- International non-proprietary name (INN) or generic name if the product contains up to three active substances;
- Qualitative and quantitative composition of the active substance;
- A list of excipients that have a specific action and are included in the detailed guidance of the National Agency for Medicines and Medical Devices of Romania (if the medicinal product is used as injection or a topical drug - all excipients are indicated);
- Special warning about the storage of the medicinal product out of children's reach;
- Expiration date with indication of a month and year;
- Special precautions for storage, if any;
- Disposal measures for unused medicines or waste derived from medicines;
- Name and address of the holder of the registration certificate, if necessary, the name of his/her representative;
- A marketing authorization number of the medicinal product;
- Producer's lot number;
- Instructions for use (for medicines without a prescription);
- Holographic security elements that allow distributors and suppliers to verify the authenticity of the product, identify individual packages and verify the fact of forgery.

According to Article 785 of the Health Reform Law, the information on the packaging and in the instructions for the patient must be given in Romanian. It is also permitted to indicate this information in foreign languages, provided that the same information is used in all the languages. There are no restrictions on foreign languages.

If the medicinal product doesn't reach patients in the package (for example, when dispensing medicines in form of pills or injections in a single-piece manner in course of inpatient care, etc.), or if there are significant problems with the availability of the medicinal product, ANMDMR may grant an exemption to indicate some information on the packaging and in instructions and also not to use the Romanian language. Specifications regarding specific types of medicines (including ARVs) are not provided in this context.

2.2. Restrictive lists

The framework of the health insurance system provides for reimbursement of the cost of inpatient and outpatient medicines is made in Romania.

The Government by its Decree No. 720/2008[5] has approved a List containing international common names corresponding to medicinal products from which insured persons receive medicinal products on the basis of full or partial reimbursement, according to medical prescription, in the health insurance system, as well as international common names, corresponding to medicines provided in national health programs and medicines subject to reimbursement. All medicines are divided into five positive lists.

5. https://www.anm.ro/_/LEGI%20ORDONANTE/HG%20720_2008%20actualizata%2023%20martie%202018.pdf

The lists of essential medicines are available on the website of the National Medical Insurance House of Romania[6] (Casa Naţională de Asigurări de Sănătate).

List A includes vital drugs (mostly generics) that are reimbursed at 90%.

List B drugs are considered less vital and reimbursed at 50%. Drugs from lists C1, C2 and C3 are 100% reimbursed. The list C1 includes drugs for the treatment of chronic diseases available at drug retailers upon special prescription; the list C2 includes drugs supplied through hospital pharmacies within national treatment programs (for example, for the treatment of certain cardiovascular diseases, cirrhosis, leukemia, epilepsy, schizophrenia, dementia, Parkinson's disease, HIV/AIDS, some types of tumors, tuberculosis, multiple sclerosis, diabetes, kidney failure, osteoporosis, organ transplants, etc.); the list C3 consists of drugs from lists A and B for children, students and pregnant women.

According to the Decision No. 861/2014 of Ministry of Health[7], pharmaceutical companies are required to apply for evaluation of their products and their inclusion into the lists. From 2015, the lists should be updated at least once a year and approved by government regulations.

Public procurement plans may not include drugs that are not on the list.

Table 2.2.1 — Antiretroviral drugs from the list C2 (the list is as of 01 Jan. 2019)

ATC Code	INN	Name	Pharmaceutical form, quantity in packing and dosage	Producer
J05AE03	Ritonavirum	Norvir 100 mg	Tablets, 30x100mg	ABBVIE LTD.
J05AE03	Ritonavirum	Ritonavir Mylan 100 mg	Tablets, 30x100mg	MYLAN S.A.S.
J05AE03	Ritonavirum	Ritonavir Accord 100 mg	Tablets, 30x100mg	ACCORD HEALTHCARE LIMITED
J05AE07	Fosamprenavirum	Telzir 700mg	Tablets, 60x700mg	VIIV HEALTHCARE UK LIMITED
J05AE07	Fosamprenavirum	Telzir 50mg/ml	Oral Solution, 50mg/ml	VIIV HEALTHCARE UK LIMITED
J05AE08	Atazanavirum	Reyataz 150 mg	Capsules, 60x150mg	BRISTOL-MYERS SQUIBB PHARMA EEIG
J05AE08	Atazanavirum	Reyataz 200 mg	Capsules, 60x200mg	BRISTOL-MYERS SQUIBB
J05AE08	Atazanavirum	Reyataz 300 mg	Capsules, 30x300mg	BRISTOL-MYERS SQUIBB PHARMA EEIG
J05AE10	Darunavirum	Prezista 150 mg	Tablets, 240x150mg	JANSSEN-CILAG INTERNATIONAL NV
J05AE10	Darunavirum	Prezista 400mg	Tablets, 60x400mg	JANSSEN-CILAG INTERNATIONAL NV
J05AE10	Darunavirum	Darunavir Alvogen 400 mg	Tablets, 60x400mg	ALVOGEN MALTA OPERATIONS (ROW) LTD
J05AE10	Darunavirum	Darunavir Krka 400 mg	Tablets, 60x400mg	KRKA, D.D., NOVO MESTO
J05AE10	Darunavirum	Darunavir Sandoz 400 mg	Tablets, 60x400mg	SANDOZ S.R.L.
J05AE10	Darunavirum	Darunavir Zentiva 400 mg	Tablets, 60x400mg	ZENTIVA, K.S.
J05AE10	Darunavirum	Darunavir Mylan 600 mg	Tablets, 60x600mg	MYLAN S.A.S.
J05AE10	Darunavirum	Prezista 600mg	Tablets, 60x600mg	JANSSEN-CILAG INTERNATIONAL NV
J05AE10	Darunavirum	Darunavir Alvogen 600 mg	Tablets, 60x600mg	ALVOGEN MALTA OPERATIONS (ROW) LTD.
J05AE10	Darunavirum	Darunavir Teva 600 mg	Tablets, 60x600mg	TEVA PHARMACEUTICALS S.R.L.
J05AE10	Darunavirum	Darunavir Sandoz 600 mg	Tablets, 60x600mg	SANDOZ S.R.L.
J05AE10	Darunavirum	Darunavir Zentiva 600 mg	Tablets, 60x600mg	ZENTIVA, K.S.
J05AE10	Darunavirum	Darunavir Krka 600 mg	Tablets, 60x600mg	KRKA, D.D., NOVO MESTO

6. http://www.cnas.ro/page/lista-medicamentelor-2019.html#
7. https://www.anm.ro/en/_/ORDINE/Order%20861_23.07.2014%20and%20Annexes.pdf

J05AE10	Darunavirum	Prezista 75 mg	Tablets, 480x75mg	JANSSEN-CILAG INTERNATIONAL NV
J05AE10	Darunavirum	Darunavir Teva 800 mg	Tablets, 30x800mg	TEVA B.V.
J05AE10	Darunavirum	Darunavir Teva 800 mg	Tablets, 30x800mg	TEVA B.V.
J05AE10	Darunavirum	Darunavir Mylan 800 mg	Tablets, 30x800mg	MYLAN S.A.S.
J05AE10	Darunavirum	Darunavir Alvogen 800 mg	Tablets, 30x800mg	ALVOGEN MALTA OPERATIONS (ROW) LTD.
J05AE10	Darunavirum	Darunavir Sandoz 800 mg	Tablets, 30x800mg	SANDOZ S.R.L.
J05AE10	Darunavirum	Darunavir Zentiva 800 mg	Tablets, 30x800mg	ZENTIVA, K.S.
J05AE10	Darunavirum	Prezista 800 mg	Tablets, 30x800mg	JANSSEN-CILAG INTERNATIONAL NV
J05AE10	Darunavirum	Darunavir Krka 800 mg	Tablets, 30x800mg	KRKA, D.D., NOVO MESTO
J05AE10	Darunavirum	Prezista 100 mg/ml	Oral Solution, 100mg/ml	JANSSEN-CILAG INTERNATIONAL NV
J05AF01	Zidovudinum	Retrovir (R)	Capsules, 100x100mg	VIIV HEALTHCARE UK LIMITED
J05AF01	Zidovudinum	Retrovir 10 mg/ml	Oral Solution, 10mg/ml	VIIV HEALTHCARE UK LIMITED
J05AF04	Stavudinum	Zerit 30 mg	Capsules, 56x30mg	BRISTOL-MYERS SQUIBB PHARMA EEIG
J05AF04	Stavudinum	Zerit 40 mg	Capsules, 56x40mg	BRISTOL-MYERS SQUIBB PHARMA EEIG
J05AF05	Lamivudinum	Lamivudina Aurobindo 150 mg	Tablets, 60x150mg	AUROBINDO PHARMA (MALTA) LIMITED
J05AF05	Lamivudinum	Epivir 150mg	Tablets, 60x150mg	VIIV HEALTHCARE UK LIMITED
J05AF05	Lamivudinum	Lamivudina teva pharma B.V. 300 mg	Tablets, 30x300mg	TEVA B.V.
J05AF05	Lamivudinum	Epivir 300mg	Tablets, 30x300mg	VIIV HEALTHCARE UK LIMITED
J05AF05	Lamivudinum	Epivir 10mg/ml	Oral Solution, 10mg/ml	VIIV HEALTHCARE UK LIMITED
J05AF06	Abacavirum	Ziagen 300 mg	Tablets, 60x300mg	VIIV HEALTHCARE UK LIMITED
J05AF06	Abacavirum	Ziagen 20 mg/ml	Oral Solution, 20mg/ml	VIIV HEALTHCARE UK LIMITED
J05AF07	Tenofovirum disoproxil	Tenofovir disoproxil Zentiva 245 mg	Tablets, 30x245mg	ZENTIVA, K.S.
J05AF07	Tenofovirum disoproxil	Tenofovir disoproxil Accord 245 mg	Tablets, 30x245mg	ACCORD HEALTHCARE LIMITED
J05AF07	Tenofovirum disoproxil	Tenofovir disoproxil Teva 245 mg	Tablets, 30x245mg	TEVA PHARMACEUTICALS S.R.L
J05AF07	Tenofovirum disoproxil	Tenofovir disoproxil Aurobindo 245 mg	Tablets, 30x245mg	AUROBINDO PHARMA ROMANIA S.R.L.
J05AF07	Tenofovirum disoproxil	Tenofovir disoproxil Teva 245 mg	Tablets, 30x245mg	TEVA PHARMACEUTICALS S.R.L
J05AF07	Tenofovirum disoproxil	Tenofovir disoproxil Sandoz 245 mg	Tablets, 30x245mg	SANDOZ S.R.L.
J05AF07	Tenofovirum disoproxil	Virofob 245 mg	Tablets, 30x245mg	ALVOGEN IPCO S.AR.L.
J05AF07	Tenofovirum disoproxil	Tenofovir disoproxil Mylan	Tablets, 30x245mg	MYLAN S.A.S

J05AF09	Emtricitabinum	Emtriva 200mg	Capsules, 30x200mg	GILEAD SCIENCE INTERNATIONAL LIMITED
J05AF09	Emtricitabinum	Emtriva 200mg	Capsules, 30x200mg	GILEAD SCIENCES IRELAND UC
J05AG01	Nevirapinum	Nevirapina Sandoz 200 mg	Tablets, 60x200mg	SANDOZ S.R.L.
J05AG01	Nevirapinum	Nevirapina Teva 200mg	Tablets, 60x200mg	TEVA B.V.
J05AG01	Nevirapinum	Viramune 400mg	Tablets, 30x400mg	BOEHRINGER INGELHEIM INTERNATIONAL GMBH
J05AG01	Nevirapinum	Nevirapina Accord 400 mg	Tablets, 30x400mg	ACCORD HEALTHCARE LIMITED
J05AG01	Nevirapinum	Viramune 50mg/5ml	Oral Solution, 50mg/5ml	BOEHRINGER INGELHEIM INTERNATIONAL GMBH
J05AG03	Efavirenzum	Stocrin 600 mg	Tablets, 30x600mg	MERCK SHARP & DOHME (OLANDA)
J05AG03	Efavirenzum	Stocrin 600 mg	Tablets, 30x600mg	MERCK SHARP & DOHME (MAREA BRITANIE)
J05AG04	Etravirinum	Intelence	Tablets, 120x100mg	JANSSEN-CILAG INTERNATIONAL NV
J05AG04	Etravirinum	Intelence 200 mg	Tablets, 60x200mg	JANSSEN-CILAG INTERNATIONAL NV
J05AG04	Etravirinum	Intelence 25 mg	Tablets, 120x25mg	JANSSEN-CILAG INTERNATIONAL NV
J05AG05	Rilpivirinum	Edurant	Tablets, 30x25mg	JANSSEN-CILAG INTERNATIONAL NV
J05AR01	Combinatii (Lamivudinum+ Zidovudinum)	Lamivudina/Zidovudina Accord 150 mg/300 mg	Tablets, 60x150mg/300mg	ACCORD HEALTHCARE LIMITED
J05AR01	Combinatii (Lamivudinum+ Zidovudinum)	Lamivudina/Zidovudina Aurobindo 150 mg/300 mg	Tablets, 60x150mg/300mg	AUROBINDO PHARMA (MALTA) LIMITED
J05AR01	Combinatii (Lamivudinum+ Zidovudinum)	Lamivudina/Zidovudina Teva	Tablets, 60x150mg /300mg	TEVA B.V.
J05AR01	Combinatii (Lamivudinum+ Zidovudinum)	Combivir 150mg/300mg	Tablets,60x(150mg/300mg)	VIIV HEALTHCARE UK LIMITED
J05AR02	Abacavirum+ Lamivudinum	Kivexa 600mg/300mg	Tablets, 30x(600mg/ 300mg)	VIIV HEALTHCARE UK LIMITED
J05AR03	Combinatii (Emtricitabinum+ Tenofovirum)	Emtricitabina/Tenofovir disoproxil Mylan 200 mg/245 mg	Tablets, 30x(200mg/ 245mg)	MYLAN S.A.S
J05AR03	Combinatii (Emtricitabinum+ Tenofovirum)	Emtricitabina/Tenofovir disoproxil Accord 200 mg/245 mg	Tablets, 30x(200mg/ 245mg)	ACCORD HEALTHCARE LIMITED
J05AR03	Combinatii (Emtricitabinum+ Tenofovirum)	Emtricitabina/Tenofovir disoproxil Teva 200 mg/245 mg	Tablets, 30x(200mg/ 245mg)	TEVA PHARMACEUTICALS S.R.L.
J05AR03	Combinatii (Emtricitabinum+ Tenofovirum)	Dunotrisin 200 mg/245 mg	Tablets, 30x(200mg/ 245mg)	ALVOGEN IPCO S.AR.L.
J05AR04	Abacavirum+ Lamivudinum+ Zidovudinum	Trizivir 300mg/150mg/300mg	Tablets, 60x(300mg/ 150mg/300mg)	VIIV HEALTHCARE UK LIMITED

J05AR10	Lopinavirum+ Ritonavirum	Kaletra 200mg/50mg	Tablets,120x(200mg/50mg)	ABBVIE LTD.
J05AR10	Lopinavirum+ Ritonavirum	Lopinavir/Ritonavir Mylan 200 mg/50 mg	Tablets,120x(200mg/50mg)	MYLAN S.A.S.
J05AR10	Lopinavirum+ Ritonavirum	Lopinavir/Ritonavir Accord 200 mg/50 mg	Tablets, 120x(200mg/50mg)	ACCORD HEALTHCARE LIMITED
J05AR10	Lopinavirum+ Ritonavirum	Kaletra 80mg/ml+20mg/ml	Oral Solution, 5x (80mg/ ml+ 20mg/ml)	ABBVIE LTD.
J05AR13	Combinatii (Dolutegravirum+ Abacavirum+ Lamivudinum)	Triumeq 50 mg/600 mg/300mg	Tablets, 30x(50mg/ 600mg/300mg)	VIIV HEALTHCARE UK LIMITED
J05AR14	Combinatii (Darunavirum+ Cobicistatum)	Rezolsta 800 mg/150 mg	Tablets, 30x(800mg/ 150mg)	JANSSEN-CILAG INTERNATIONAL NV
J05AR17	Combinatii (Emtricitabinum+ Tenofovirum alafenamida)	Descovy 200 mg/10 mg	Tablets, 30x(200mg/ 10mg)	GILEAD SCIENCES IRELAND UC
J05AR17	Combinatii (Emtricitabinum+ Tenofovirum alafenamida)	Descovy 200 mg/10 mg	Tablets, 30x(200mg/ 10mg)	GILEAD SCIENCES INTERNATIONAL LTD.
J05AR17	Combinatii (Emtricitabinum+ Tenofovirum alafenamida)	Descovy 200 mg/25 mg	Tablets, 30x(200mg/ 25mg)	GILEAD SCIENCES IRELAND UC
J05AR17	Combinatii (Emtricitabinum+ Tenofovirum alafenamida)	Descovy 200 mg/25 mg	Tablets, 30x(200mg/ 25mg)	GILEAD SCIENCES INTERNATIONAL LTD.
J05AR18	Elvitegravir+ Cobicistat+ Emtricitabine+ Tenofovir	Genvoya 150 mg/150 mg/200 mg/10 mg	Tablets, 30x(150mg/ 150mg/200mg/10mg)	GILEAD SCIENCES IRELAND UC
J05AR18	Elvitegravir+ Cobicistat+ Emtricitabine+ Tenofovir	Genvoya 150 mg/150 mg/200 mg/10 mg	Tablets, 30x(150mg/ 150mg/200mg/10mg)	GILEAD SCIENCES INTERNATIONAL LTD.
J05AX08	Raltegravirum	Isentress 400mg	Tablets, 60x400mg	MERCK SHARP & DOHME (MAREA BRITANIE)
J05AX08	Raltegravirum	Isentress 400mg	Tablets, 60x400mg	MERCK SHARP & DOHME (OLANDA)
J05AX08	Raltegravirum	Isentress 600 mg	Tablets, 60x600mg	MERCK SHARP & DOHME (OLANDA)
J05AX08	Raltegravirum	Isentress 600 mg	Tablets, 60x600mg	MERCK SHARP & DOHME (MAREA BRITANIE)
J05AX09	Maravirocum	Celsentri 150mg	Tablets, 60x150mg	VIIV HEALTHCARE UK LIMITED
J05AX09	Maravirocum	Celsentri 300mg	Tablets, 60x300mg	VIIV HEALTHCARE UK LIMITED
J05AX12	Dolutegravirum	Tivicay 50 mg	Tablets, 30x50mg	VIIV HEALTHCARE BV
J05AX12	Dolutegravirum	Tivicay 50 mg	Tablets, 30x50mg	VIIV HEALTHCARE UK LIMITED

HIV treatment protocol

In Romania, the ART Guidelines [9] were in force; the document was developed by the Ministry of Health (Ministerului Sanatatii) and «Prof. Dr. Matei Bals» National Institute of Infectious Diseases (Institutul Național de Boli Infecțioase «Prof. Dr. Matei Balș») for the period of 2013-2014. It has not been updated since 2014, as the National Committee for Infectious Diseases and local experts (with the agreement of the Ministry of Health) have decided to use the EACS (European AIDS Clinical Society) guidelines. The latest EACS Guidelines, Version 8.1 of 2016 [10] , have been translated into Romanian and used locally, but no official document related to this has been issued. The EACS Guidelines are only provided for INN ARVs that can be used in different treatment regimens and do not establish a list of ARVs that must be purchased for the needs of HIV-infected patients in Romania.

2.3. Expeditious procedures

According to Article 741 of the Health Reform Law, there is the expeditious procedure for obtaining a marketing authorization for medicinal products that have already received such authorization under a centralized procedure or in other EU countries.

In the presence of such authorization the applicant sends a requests for provision of the evaluation report for the medicinal product in the EU country where its marketing is already permitted. The duration of the expeditious procedure for obtaining a marketing authorization is up to 90 days.

2.4. VAT

According to Article 291 of the Romanian Tax Code [11], the total VAT rate is 19% and a discounted rate of 9% is approved for medicines.

2.5. Legislative possibility of post-registration of medicinal products

According to the tender documentation for the procurement of antiretroviral drugs, the requirements for tenderers are as follows:

- Availability of documents on the registration of a legal entity, as well as on the confirmation of the status of a tax resident;
- Availability of a wholesale permit (issued by the Ministry of Health of Romania under Article 800 of the Health Reform Law and subject to a marketing authorization).

Foreign legal entities may submit corporate registration documents of the legal entity, confirmation of the status of a tax resident, as well as a wholesale permit, issued according to the current legislation in the country of their registration.

Non-residents have legal opportunities of post-registration of medicinal products in Romania.

2.6. Conditions for non-residents

To participate in tenders for the procurement of antiretroviral drugs, a non-resident may submit documents prepared in accordance with the current law in the country of registration *(see section 2.5)*. There are no other special conditions for non-residents.

9. http://www.cnlas.ro/images/doc/GhidTARV_2014.pdf
10. https://www.eacsociety.org/files/guidelines-8.1-russian.pdf
11. https://static.anaf.ro/static/10/Anaf/legislatie/Cod_fiscal_norme_12062019.htm

3. PROCEDURE TO FORM A NOMENCLATURE OF MEDICINAL PRODUCTS

3.1. Registry of medicinal products

At the time of the preparation of this report, 491 items of antiretroviral drugs (listed in Annex 1) are available in the registry.

The electronic registry of registered medicinal products is available on the website of the National Agency for Medicines and Medical Devices of Romania [12].

3.2. Nomenclature of medicinal products for procurement

The nomenclature of ARVs for public procurement is formed individually by each local healthcare facility involved in the National HIV/AIDS Program for Treatment, based on the needs of the patients on record *(see section 4.2)*.

The procurement nomenclature should include ARV drugs from the list C2 of medicines used in the health insurance system and national health programs, but a specific list of INNs is established by healthcare facilities based on the HIV treatment regimens selected for patients.

The initiation of tender procedures and the determination of the nomenclature of ARVs may be based on an assessment of patients' needs and available inventory and carried out several times a year by each of the procurement entities on the E-Procurement website.

The legislative capacity of the Romanian NGOs to participate in the formation of the ARV drug nomenclature for the procurement has not been identified.

4. PUBLIC PROCUREMENT SYSTEM

4.1. Sources of procurement financing

The 2019-2021 National Strategic Plan for the Surveillance, Control and Prevention of HIV/AIDS in Romania [13] (Planul Național Strategic pentru supravegherea, controlul și prevenirea cazurilor de infecție cu HIV/SIDA în perioada 2019 – 2021) provides for funding from the state budget, the budget of the Unified National Fund of Social and Health Insurance (Fondul Naţional Unic de Asigurări Sociale), local budgets, international sources (the Global Fund to Fight AIDS, Tuberculosis and Malaria, the European Social Fund, Norwegian funds, etc.). The funds are distributed by the National HIV/AIDS Strategic Plan Implementation and Coordination Unit (UIC-PNS).

The 2019-2021 National Strategic Plan for the Surveillance, Control and Prevention of HIV/AIDS does not specify the volume of funding with a structural breakdown according to funding sources.

The 2019-2021 National Strategic Plan for the Surveillance, Control and Prevention of HIV/AIDS in Romania provides information on the estimated costs of ARV therapy, based on the following facts.

From 2008 to 2016, the number of patients receiving ARV therapy increased by 47.2% (from 7,444 in 2008 to 10,942 in 2016).

From 2007 to 2010, the annual budget for ARV therapy was approximately EUR 32 million. In 2016, costs were increased to EUR 60 million because of an increase in the number of patients by 47.2%.

Due to the increasing number of patients (at average 714 new cases per year), the need for the budget increase in for ARV therapy is estimated at EUR 4.6 million annually. The National Strategic Plan does not identify more specific annual budget amounts [14].

4.2. Entities purchasing anti-retroviral drugs

According to the 2019-2021 National Strategic Plan for the Surveillance, Control and Prevention of HIV/AIDS in Romania, 9 regional centers provide ARV therapy.

«Prof. Dr. Matei Bals» National Institute of Infectious Diseases (Institutul Național de Boli Infecțioase «Prof. Dr. Matei Balș») coordinates the diagnosis and treatment of HIV in collaboration with regional HIV/AIDS centers.

In 2018, the following medical institutions (ambulance hospitals, infectious diseases) purchased antiretroviral drugs:

- Spitalul Judetean de Urgenta Sf. Ioan cel Nou Suceava
- Spitalul Județean de Urgență Satu Mare
- Spitalul de Boli infectioase si Psihiatrie Baia Mare
- Institutul Național de Boli Infecțioase «Prof.Dr. Matei Balș»
- Spitalul Judetan de Urgenta «Mavromati» Botosani
- Spitalul Clinic de Boli Infectioase si Pneumoftiziologie «Dr.Victor Babes»
- Spitalul Clinic de Boli Infectioase Constanta, and others.

12. https://www.anm.ro/nomenclator/medicamente
13. http://www.ms.ro/wp-content/uploads/2018/11/Anexa-la-HG-Plan-National-HIV-2019-2021.pdf
14. http://www.ms.ro/wp-content/uploads/2018/11/Anexa-la-HG-Plan-National-HIV-2019-2021.pdf (ст.11-12)

Data on the need for antiretroviral drugs is submitted to the above-mentioned institutions for analysis and approval by the Commission on Medicinal Products within the National HIV/AIDS Program for Treatment, and then the information is submitted to the procurement department of the Program.

4.3. Ability to use international procurement mechanisms

The implementation of the last grant, within the HIV component, from the Global Fund to Fight AIDS, Tuberculosis and Malaria was finished in 2010, while there was no plan for the transition from the Global Fund funding to national one[15].

On the eve of the thirty-ninth meeting of the Global Fund Board, which discussed the Global Fund Eligibility Policy regarding countries criteria for grants, the Position document of civil society organizations requested not to restrict access to HIV programs for countries not included on the list of recipients of official support for the development from the Development Assistance Committee at the Organization for Economic Co-operation and Development (OECD).

The requirement that only those upper middle income countries, which are included to the aforementioned list, can receive the Global Fund funding for HIV Programs exsists since 2007. At the time of the distribution of funding, from 2017 to 2019, this requirement restricted access to HIV programs for only two countries - Romania and Bulgaria. Both countries have high rates of HIV incidence. In Romania, where at the time of the completion of the last Global Fund HIV grant implementation, there was a low incidence of HIV among vulnerable groups, but the situation has changed dramatically after a few years when, because of lack of political will of the state and without any support, most of HIV prevention services for these groups were closed[16].

On August 6, 2019, the Ministry of Health of Romania announced the completion of the SMIS Code 126692 project «Medical Services for Treatment People with HIV/AIDS» which was funded by the European Social Fund (ESF) under the Operational Program «Human Capital» for 2014-2020.

The main activity of the project was to provide early treatment for HIV-infected and AIDS patients involved in the 2019-2021 National Strategic Plan for the Surveillance, Control and Prevention of HIV/AIDS. Due to the project, the expenses for the treatment, which were assigned between January 1, 2015, and December 31, 2018, were claimed for reimbursement. Between January 1, 2015, and July 31, 2019, nearly 10,800 Romanian HIV/AIDS patients from vulnerable groups received special free early treatment. That is, the procurement of antiretroviral drugs was envisaged in the framework of this program.

The total amount claimed for reimbursement is RON 907 million (approximately EUR 191.7 million) (also costs to be included in the final application for reimbursement), of which the ESF grant is approximately RON 765.9 million (approximately EUR 161,9 million), co-financing by the beneficiary (Romania) is RON 141.1 million (around EUR 29.8 million)[17].

Grants from the European Economic Area (EEA) and Norway are contributions from Iceland, the Principality of Liechtenstein and the Kingdom of Norway to reduce economic and social inequality in the European Economic Area and to strengthen bilateral relations with the 15 beneficiary countries of the Eastern and Northern European and Baltic states. Grants from the European Economic Area are co-financed by all three donors, and Norwegian grants are funded exclusively by Norway and available in 13 countries that joined the EU after 2003 (including Romania) [18].

Romania received financial assistance within Norwegian grants in 2009-2014; their aim was to help to reduce economic and social disparities in the European Economic Area and to strengthen co-operation between the donor state (Norway) and beneficiary countries through the RO19 priority sector «Public Health Initiatives». The project should result in the reduction of HIV infection. One of the results was also seen as an intensification of HIV-related efforts to train, diagnose, care and monitor. This program did not envisage the purchase of antiretroviral drugs [19].

On 13 October 2016, the Memorandum of Understanding between the governments of Romania and the EEA (Norway, Iceland, and Liechtenstein) was signed on the implementation of the European Economic Area's Financial Mechanism for 2014-2021. Within this Financial Mechanism, the Ministry of Health implements the program titled «Issues of Public Health at European Level». The budget is EUR 47 058 824 (85% is a grant and 15% is co-financing from Romania). None of the 8 projects under this program is aimed at purchasing antiretroviral drugs. Only the «Small Grant Scheme 2» with EUR 1 million was available for non-governmental organizations to provide advocacy services to vulnerable populations in order to increase prevention and reduce the impact of diseases, especially infectious diseases, affecting the population[20].

As of 2019, other international organizations have not implemented projects to purchase antiretroviral drugs for Romania[21].

There is a legal possibility to provide funding for procurement from international agencies/organizations; according to the 2019-2021 National Strategic Plan for the Surveillance, Control and Prevention of HIV/AIDS, funding from international sources was envisaged. Procurement directly by international agencies/organizations was not carried out.

15. https://eecaplatform.org/wp-content/uploads/2018/09/ehrn_report_on_responsible_transition_in_eeca_rus_0.pdf
16. http://harmreductioneurasia.org/wp-content/uploads/2018/05/Eligibility-Position-Statement-2018-updated-RUS.pdf
17. http://www.ms.ro/2019/08/06/finalizare-proiect-pocu-475-4-9-126692/
18. https://www.eeagrants.ro/programe/sanatate/conferinta-de-lansare-a-programului-provocari-in-sanatatea-publica-la-nivel-european
19. https://www.eeagrants.ro/files/upload-dir/195-final-strategic-report-2009-2014.pdf

4.4. E-Procurement

The Electronic System for Public Procurement [22] (SEAP — Sistemul electronic de achizitii publice) operates in Romania. This is a platform that offers Romanian public institutions to purchase goods and services through electronic auctions. Publication of auctions in SEAP began in 2006 in order to save public money and increase the transparency of the public procurement process. In April 2018, a new version of the SEAP platform called SICAP, Collaborative Informative System for Public Procurement (Sistem informatic colaborativ pentru mediu performant de desfasurare al achizitiilor publice) [23] was released.

The procurement of antiretroviral drugs on the SICAP site is monitored by the activity «SANATATE, ASISTENTA SOCIALA» and by CPV code «33651400-2 Antivirale pentru uz sistemic (Rev.2)» (antiretroviral drugs belong to antiviral agents for systemic use).

A contract for up to 3 years is concluded with the winner of the tender. The cost of the contract and the number of medicinal products are indicated in the tender documents and in the range from the minimum to the maximum value, as they may be corrected over a period. Multiple vendor agreements are considered acceptable.

The subject of the tender is divided into separate positions. The tenderer may apply for one, several or all of the items of the subject of the public procurement contract. A separate electronic auction is conducted for each individual item of the subject of the contract.

The criterion for the conclusion of the agreement is the lowest price; there are no preferences for national producers when considering bids.

4.5. Supply disruptions

The National Union of Organizations of HIV/AIDS (Uniunea Naţională a Organizaţiilor Persoanelor Afectate de HIV/SIDA — UNOPA) is a non-governmental organization aimed at promoting continuous and free antiretroviral treatment for all HIV-infected people in Romania.

UNOPA protects the rights of HIV-positive people by documenting cases of antiretroviral drug shortages, communicating directly with the Ministry of Health, publishing these cases in the press, and developing researches on the National HIV/AIDS Program for Treatment [24].

The latest report about antiretroviral drugs shortage was published in the UNOPA press release «Pacienții cu HIV din România rămân fără tratament!» of 29 Aug. 2019. The situation was caused by an insufficient allocation of funding at the beginning of the year for the National HIV/AIDS Program for Treatment implemented by the Ministry of Health. The funds were allocated for the purchase of drugs until August 2018, which led to a shortfall in hospitals' budgets for the replenishment of ARVs [25].

4.6. Procurement planning

Procurement planning is carried out locally by entities purchasing antiretroviral drugs *(see section 4.2)* based on their records of patients receiving ARV therapy and on patients' current annual needs in drugs. If necessary, additional procedures for the procurement of antiretroviral drugs are announced during the year.

5. PROCUREMENT OF ANTI-RETROVIRAL DRUGS

For the period from 01 Jan. 2018 to 31 Dec. 2018, 38 announcements about the procurement procedures with the current status of «Atribuita» (award of the contract) were placed in the system for electronic public procurement. Details of the procurement announcements and contract award numbers are in the menu section «Initieri de procedure de achizitie», sub-section «Anunturi de participare».

The contract award pages of the Collaborative Informative System for Public Procurement (SICAP) does not contain the trade names of the purchased ARVs and producers' names; they only have the names of the suppliers and the estimated procurement amounts (since the contract value may be changed during the period for which it is concluded).

5.1. Purchases of antiretroviral drugs in 2018

In 2018, 19 procurement procedures for antiretroviral drugs were initiated *(listed in «ANNEXE 2. PURCHASE OF ANTI-RETROVIRAL DRUGS IN 2018»).*

20. http://www.ms.ro/wp-content/uploads/2019/09/Prezentare-Program-SEE-2014-2021_site_ro.pdf
21. https://www.crownagents.com/where-we-work/eastern-europe-central-asia/
https://www.iplussolutions.org/sites/default/files/file/isolutions_jaarverslag_2018_v7_1.pdf
22. https://sicap-prod.e-licitatie.ro/pub
23. http://licitatiiseap.ro/seap-sistemul-electronic-de-achizitii-publice/
24. https://unopa.ro/intrerupere-de-tratament-arv-in-spitalul-in-care-te-tratezi-anunta-ne/
25. https://unopa.ro/pacientii-cu-hiv-din-romania-raman-fara-tratament/

SERBIA

6 982 604
Population, persons

178
Number of new HIV cases in 2017

2 700
Estimated number of people living with HIV, persons (The proportion of the population living with HIV — 0,04)

2 441
Number of HIV — infected people who know their status, persons

1 723
Number of HIV-infected people who know their status and covered by antiretroviral therapy, persons

* data as of 31.12.2018

https://publikacije.stat.gov.rs/G2019/PdfE/G20191180.pdf
https://www.ecdc.europa.eu/sites/default/files/documents/HIV-continuum-of-care-monitoring-dublin-declaration-progress-report-2018.pdf
http://www.batut.org.rs/download/izvestaji/Godisnji%20izvestaj%20zarazne%20bolesti%202017.pdf

1. SUMMARY *

Criteria	Comment
Characteristics of state registration procedures	
The law that regulates the registration of medicines	The Law on Medicinal Products and Medical Devices (Official Gazette of the Republic of Serbia, No. 30/10, 107/12)
Registration authority	The Medicines and Medical Devices Agency of Serbia (Агенција за лекове и медицинска средства Србије)
Entities that have the right to sell medicinal products	• Medicines manufacturer who has a license to manufacture medicines in Serbia. • A representative of a foreign manufacturer registered in Serbia. • A representative of a foreign legal entity that is not the manufacturer but the holder of the marketing authorization (trade license) in an EU Member State or in a country with identical marketing authorization requirements. • A legal entity registered in the Republic of Serbia, to which the manufacturer has granted the right to obtain a marketing authorization for medicinal products made by the manufacturer.
Entities that have the right to participate in a tender	• An economic entity authorized to sell the medicinal product. • An economic entity that does not have a marketing authorization but offers a medicine that is on the list D of medicines prescribed and issued at the expense of compulsory health insurance.
Packaging requirements	The availability of basic information on the medicinal product on the outer and inner packaging in Serbian, as well as in the instructions for the medicinal product. The provision of information on packaging and instructions in a foreign language may be permitted for a medicinal product authorized in Serbia, if the lack of these medicines may endanger the health of the population, or a medicinal product that is not authorized in Serbia but has import permission. But in both cases, the instruction in Serbian must be included in the package of the medicinal product. There are no restrictions on foreign languages.
The availability of restrictive lists (for example, a list of vital medicines)	According to the Rules on the list of medicines prescribed and issued at the expense of compulsory health insurance in Serbia, there are 5 lists: • List A (14 groups) — medicines prescribed and issued upon prescription. • List A1 (12 groups) — medicines prescribed and issued upon prescription, and are therapeutically alternative to the List A medicines. • List B (12 groups) — medicines used in outpatient or inpatient treatment. • List C (5 groups) — special regime medicines. • List D (14 groups) — unregistered medicinal products that have the same INNs as the registered medicines, the shortage of which is observed in the Serbian market. Lists of medicines prescribed and issued at the expense of compulsory health insurance lay down a list of the items of medicines subject to mandatory public procurement plans. ARVs are included in Lists A (capsules, tablets) and D (oral solutions).
The availability of expeditious registration procedures	The general registration procedure lasts up to 210 days after receiving the complete application for a marketing authorization. Expeditious procedures for medicines are available under one of the following conditions: • The medicine is of great interest for the protection of public health; it is a therapeutic innovation. • The medicinal product has already obtained a marketing authorization under a centralized procedure (the marketing p authorization procedure provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council). The expeditious registration procedure lasts up to 150 days after receiving the complete application for a marketing authorization.

* Information as of the second half of 2019

VAT and tax benefits	Medicines have a discounted VAT rate of 10% (total VAT rate is 20%).
Availability of post-registration for medicines	In accordance with the tender documentation for the procurement of antiretroviral drugs, the medicinal product offered by the tenderer must have a valid marketing authorization in the Republic of Serbia on the day of the opening of the auction. The exception to this condition is the tender offers for List D medicines — they do not require a marketing authorization in Serbia. The legislative possibility of post-registration of medicinal products is possible only for ARVs from List D in the form of oral solutions.
Availability of special conditions for non-residents	In order to participate in the public procurement of ARVs, the participant must have a marketing authorization for the medicinal product (with the exception of proposals for items of medicinal products on List D). Non-residents cannot obtain a permit for sale without establishing a foreign representative office in Serbia.
Logistics	According to the tender documentation, the supplier selects the logistics partner.
Procedures of nomenclature formation	
Authorities responsible for the nomenclature lists formation	The nomenclature of ARV drugs is formed by the National Health Insurance Fund of the Republic of Serbia, based on an assessment of the needs received from healthcare facilities which are responsible for providing antiretroviral therapy to the public.
The procurement nomenclature	The subject of procurement may be only the antiretroviral drug available in the Lists of medicines prescribed and issued at the expense of compulsory health insurance.
Opportunity for NGOs and international organizations to participate in the nomenclature formation	No relevant information has been found.
Approval terms and frequency of the nomenclature revision	The period of revision of the nomenclature is annual.
The functioning of the public procurement system	
Funding sources	Since 1997, national funding has exclusively been provided at the expense of the National Health Insurance Fund of Serbia.
Procuring entities	The National Health Insurance Fund of Serbia purchases medicinal product.
Possibility to use international mechanisms/funding	The Action Plan for the implementation of the HIV/AIDS Prevention and Control Strategy in the Republic of Serbia for 2018-2025 did not envisage receiving funding from international organizations. The possibility of procurement by international agencies/ organizations is not provided by law.
Availability of transparent procedures	The Public Procurement Portal.
Availability of supply disruptions	No relevant information was found.
Procurement planning	Procurement planning is carried out for 1 year.
Statistics on the volume of procurement of ART drugs	
Purchasing prices	Specified in the tender documentation for each item.
Number of medicines purchased	Specified in the tender documentation for each item.
The total amount of procurement	In 2019, the amount was RSD 274,206,900 (USD 2,605,000).
Reference to «originator/generic»	There is no information in the tender documentation.
Attitudes towards generics in the NGO/medical community	Prejudiced attitudes towards generics through stereotypes and myths about the quality and effectiveness of both groups.
Patient-centered procurement	The Action Plan for the implementation of the HIV/AIDS Prevention and Control Strategy in the Republic of Serbia for the period 2018-2025 does not specify the number of patients to be covered by ART.

2. STATE PROCEDURE OF MEDICINAL PRODUCTS REGISTRATION

2.1. General information

Registration of medicinal products in Serbia is carried out in accordance with the Law on Medicines and Medical Devices [1] (Official Gazette of the Republic of Serbia, No. 30/10, 107/12, hereinafter referred to as the Medicines Law).

According to Article 3 of the Medicines Law, The Medicines and Medical Devices Agency of Serbia *(Агенција за лекове и медицинска средства Србије)*[2] is responsible for granting authorization for the sale of medicinal products and keeping a registry of medicines.

According to Article 9 of the Medicines Law, after approval of the Minister of Health of Serbia, the Agency establishes an advisory body (Commission) which draws a conclusion on the quality, safety and efficacy of the medicinal product while issuing the marketing authorization. Members of the Commission may be permanent or temporary to evaluate certain types of medicinal products.

The members of the Commission are selected from among the foremost experts in the field of medicines and medical devices, appointed for four years and may be reappointed.

The medicinal product may be marketed in the territory of Serbia provided that the economic entity has the authorization for sale or import.

Authorization for sale

According to Article 33 of the Medicines Law, a medicinal product may be placed on the market if it has obtained a marketing authorization (trade license) from the Medicines and Medical Devices Agency.

To obtain a marketing authorization, one submits an application which, in accordance with Article 29 of the Medicines Law, must contain the documentation provided in the following table.

Information block	Content
Administrative part	• the names of the medicinal product and the INN; • information on the active substance, pharmaceutical form and dosage; • a draft summary of product characteristics; • instructions for patients; • names and addresses of the applicant, the manufacturer and the manufacturing site; • production license issued by the competent authority; • packaging proposal; • available marketing authorization or proof that the medicinal product is in the process of being granted a marketing authorization in the country of origin or that it is being marketed, or reasons for its withdrawal from the market in that country; • a list of countries in which the medicinal product has marketing authorization; • the certificate of the Good Manufacturing Practice issued by a competent ministry in accordance with this Law or a certificate from an EU Member State or other countries with similar requirements.
Pharmaceutical and chemical part	• data on the qualitative and quantitative composition of the medicinal product; • a description of the manufacturing process; • quality control of input raw materials; • quality control of the manufacturing process; • quality control of the finished product; • data on the environmental safety assessment of the medicinal product.
Pharmaco-toxicological part	• pharmacodynamic and pharmacokinetic characteristics of the medicinal product; • data on toxicity and reproductive function effects; • data on embryonic and perinatal toxicity; • data on mutagenic and carcinogenic potential; • data on tolerance.
Clinical part	• information on clinical trials and their results; • clinical and pharmacological data; • bioavailability and bioequivalence data (if applicable); • clinical safety and efficacy data; • information about exceptional testing circumstances; • data on using the medicinal product after marketing authorization in other countries.

1. http://rfzo.rs/download/zakoni/zakon_lekovi22112012.pdf
2. https://www.alims.gov.rs/ciril/

According to Article 28 of the Medicines Law, complete or abbreviated documentation may be submitted for marketing authorization.

According to Article 30 of this Law, an application with abbreviated documentation may be submitted for a generic medicinal product. In this case, instead of own research on the pharmaco-toxicological and clinical parts, the applicant submits data based on the biological equivalence of the generic and the original (reference) medicinal product.

According to Article 31 of the Medicines Law, a generic marketing authorization is issued after a period of 10 years since the marketing authorization for the reference medicinal product has been granted.
According to Article 33 of this Law, the application shall be submitted separately for each pharmaceutical form, dosage and package size of the medicinal product.
The Agency decides (no later than 210 days after receipt of the complete application for a marketing authorization) to grant a marketing authorization or to reject the application, having received a conclusion on the reliability of the documentation and the evaluation of the quality, safety and efficacy of the medicinal product by the Commission.

A marketing authorization is issued for a period of 5 years.

Import authorization

According to Article 141 of the Medicines Law, the Medicines and Medical Devices Agency of Serbia may, as an exception, authorize the importation of a non-Serbian medicinal product through pharmacies or medical organizations for the treatment of a specific patient or group of patients. The amount and other conditions required are evaluated by the Agency based on the number of such patients. This volume should not exceed the annual requirement.

The Agency may also authorize the importation of a medicinal product which is not authorized for sale but which is intended for medical or scientific testing.

An application for import license can only be submitted by a holder of the license for the wholesale of medicines through pharmacies and medical organizations in Serbia.

Marking and instruction

According to Articles 152-156 of the Medicines Law, the requirements are as follows:

- The availability of basic information about the medicinal product in Serbian on the outer and inner packaging;
- The availability of the following basic information about the medicinal product on the outer packaging: name and INN, active substance in quantitative or qualitative expression per unit dose, pharmaceutical form, dosage, size of pack, list of excipients with proven effect, method of administration, all necessary warnings, expiration date, storage conditions, safety precautions for the disposal of the medicinal product, name and address of the trade license holder (marketing authorization), trade license number, batch number, European Article Number (EAN code), Anatomical Therapeutic Chemical Classification (ATX code);
- The availability of the following basic information on the inner packaging: name and INN, pharmaceutical form, dosage, expiration date, batch number;
- The availability of basic product characteristics in instruction in the Serbian language.
- The name of the medicinal product must also be written in Braille on the outer package.
- The provision of information on packages and instructions in a foreign language may be permitted for:
- A medicinal product that is authorized for sale in Serbia and the lack of this medicine may endanger the public health;
- A medicinal product that is not authorized in Serbia has import authorisation.
- But in both cases, the instruction in Serbian must be included in the package of the medicinal product. There are no restrictions on foreign languages.

2.2. Restrictive lists

Rules on the list of medicines prescribed and issued at the expense of compulsory health insurance [3] *(Правилник о листи лекова који се прописују и издају на терет средстава обавезног здравственог осигурања)* envisage 5 lists of medicines:

- List A (14 groups) — medicines prescribed and issued upon prescription.
- List A1 (12 groups) — medicines prescribed and issued upon prescription and are therapeutically alternative to the List A medicines.
- List B (12 groups) — medicines used in outpatient or inpatient treatment.
- List C (5 groups) — special regime medicines.
- List D (14 groups) — unregistered medicinal products that have the same INNs as the registered medicines, the shortage of which is observed in the Serbian market.

When receiving medicines from List A, the insured person pays a fixed amount of 50 dinars ($ 0.5) per pack.
When receiving medicines from List A1, the insured person pays from 10% to 90% of the retail price of one package.
Insured persons do not pay for medicines from List A and List A1 used during inpatient treatment.
The National Health Insurance Fund reimburses the full cost of medicines on List B, List C, and List D.
The insured person pays a fixed amount of 50 dinars ($ 0.5) per order for the medicines from List B used in primary care facilities.
The lists of medicines that are prescribed and issued at the expense of compulsory health insurance include a list of medicines subject to mandatory incorporation in public procurement plans. Public procurement plans may not include medicines that are not on these Lists.

3. http://www.rfzo.rs

Table 2.2.1 — Antiretroviral Drugs from the Lists of medicines prescribed and issued at the expense of compulsory health insurance [4] (effective on 19 Feb.2020)

ATC Code	INN	Name	Pharmaceutical form, quantity in packing and dosage	Manufacturer's name
			List A	
J05AR10	lopinavir, ritonavir	Aluvia	Tablets, 120x (200 mg +50 mg)	Abbvie Deutschland GMBH & Co. KG
J05AR10	lopinavir, ritonavir	Aluvia	Tablets, 60 x (100 mg + 25 mg)	Abbvie Deutschland GMBH & Co. KG
J05AE03	ritonavir	Norvir	Tablets, 30 x 100 mg	Abbvie Deutschland GMBH & Co. KG
J05AE07	fosamprenavir	Telzir	Tablets, 60 x 700 mg	Glaxo Wellcome Operations; Glaxo Wellcome S.A.
J05AE10	darunavir	Prezista	Tablets, 60 x 600 mg	Janssen-Cilag S.P.A.
J05AF01	zidovudin	Zidosan	Capsules, 100 x 100 mg	Slaviamed d.o.o.
J05AF05	lamivudin	Zeffix	Tablets, 28 x 100 mg	GlaxoSmithKline Pharmaceuticals S.A; Glaxo Wellcome Operations
J05AF05	lamivudin	Epivir	Tablets, 60 x 150 mg	GlaxoSmithKline Pharmaceuticals S.A; Glaxo Wellcome Operations
J05AF06	abakavir	Ziagen	Tablets, 60 x 300 mg	GlaxoSmithKline Pharmaceuticals S.A.; Glaxo Wellcome Operations
J05AF07	tenofovir	Viread	Tablets, 30 x 245 mg	Gilead Sciences Ltd.
J05AF07	tenofovir	Gilestra	Tablets, 30 x 245 mg	Remedica LTD
J05AF07	tenofovir	Tenofovir disoproxil Mylan	Tablets, 30 x 245 mg	Mylan Hungary KFT.;
J05AG01	nevirapin	Viramune	Tablets, 60 x 200 mg	Boehringer Ingelheim Pharma GmbH
J05AG03	efavirenz	Stocrin	Tablets, 30 x 600 mg	Merck Sharp & Dohme
J05AR01	zidovudin, lamivudin	Combivir	Tablets, 60 x (300 mg + 150mg)	Glaxo Operations UK Limited; GlaxoSmithKline Pharmaceuticals S.A
J05AR02	abakavir, lamivudin	Kivexa	Tablets, 30 x (600 mg + 300 mg)	Glaxo Wellcome Operations; Glaxo Wellcome S.A.
J05AR02	lamivudin, abakavir	Amalibra	Tablets, 30 x (300 mg + 600 mg)	Pliva Hrvatska d.o.o.
J05AR03	tenofovir, emtricitabin	Truvada	Tablets, 30 x (245 mg+200 mg)	Gilead Sciences Ltd.
J05AR03	tenofovir, emtricitabin	Gilestra duo	Tablets, 30 x (245 mg+200 mg)	Remedica LTD
J05AR03	tenofovir, emtricitabin	Tenofovir dizoproksil/ Emtricitabin krka	Tablets, 30 x (245 mg + 200 mg)	Krka d.d., Novo Mesto; Tad pharma GmbH
J05AR08	emtricitabin, tenofovir, rilpivirin	Eviplera	Tablets, 30 x (200 mg + 245 mg + 25 mg)	Gilead Sciences Ireland UC
J05AR13	lamivudin, abakavir, dolutegravir	Triumeq	Tablets, 30 x (300 mg + 600 mg + 50 mg)	Glaxo Wellcome S.A
J05AR14	darunavir, kobicistat	Rezolsta	Tablets, 30 x (800 mg+150 mg)	Janssen-Cilag S.P.A
J05AX08	raltegravir	Isentress	Tablets, 60 x 400 mg	Merck Sharp & Dohme B.V.
J05AX08	raltegravir	Isentress	Tablets, 60 x 600 mg	Merck Sharp & Dohme B.V.
J05AX09	maravirok	Celsentri	Tablets, 60 x 150 mg	Pfizer Manufacturing Deutschland GmbH
J05AX09	maravirok	Celsentri	Tablets, 60 x 300 mg	Pfizer Manufacturing Deutschland GmbH

4. http://www.rfzo.rs/index.php/osiguranalica/lekovi-info/lekovi-actual

J05AX12	dolutegravir	Tivicay	Tablets, 30 x 50 mg	Glaxo Wellcome S.A.
		List D		
J05AE03	ritonavir	-	Oral Solution, 80 mg/ml	-
J05AE07	fosamprenavir	-	Oral Solution, 50 mg/ml	-
J05AE09	tipranavir	-	Oral Solution, 100 mg/ml	-
J05AR10	lopinavir, ritonavir	-	Oral Solution, 80 mg/ml + 20 mg/ml	-
J05AF01	zidovudin	-	Oral Solution, 50 mg/5 ml	-
J05AF04	stavudin	-	Oral Solution, 1 mg/ml	-
J05AF05	lamivudin	-	Oral Solution, 10 mg/ml	-
J05AF06	abakavir	-	Oral Solution, 20 mg/ml	-

HIV treatment protocol

There is no national protocol for HIV treatment.

As part of recommendations regarding HIV treatment, the HIV/AIDS Prevention and Control Strategy in the Republic of Serbia for 2018-2025 [5] recommends taking into account the guidelines of the WHO (World Health Organization) and EACS (European AIDS Clinical Society).

2.3. Expeditious procedures

According to Article 34 of the Medicines Law, the expeditious procedure of medicinal product registration is possible under the following conditions:

1. The drug is of great interest for the protection of public health, and it is a therapeutic innovation.
2. The medicinal product has already obtained a marketing authorization under the centralized procedure (the marketing authorization procedure provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council).

The application for a marketing authorization using the expeditious procedure must mention all the reasons related to the protection of public health and the necessary documentation must be provided in accordance with this Law.

Having obtained the conclusion on the reliability of the documentation and the evaluation of the quality, safety and efficacy of the medicinal product, the Medicines and Medical Devices Agency shall decide (no later than 150 days after receipt of the complete application) to issue a marketing authorization or reject the application.

2.4. VAT

A discounted VAT rate of 10% is approved for medicinal products (total VAT rate is 20%) according to Article 23 of the Law on Value-Added Tax [6].

2.5. Legislative possibility of post-registration of medicinal products

According to the tender documentation for the procurement of antiretroviral drugs, the medicinal product offered by the tenderer must have a valid marketing authorization in the Republic of Serbia on the day of the opening of the auction [7].

The exceptions to this condition are the tender offers for the medicines from List D *(see Section 2.2)* — they do not require a marketing authorization in Serbia. List D includes some items of ARVs in the form of oral solutions.

The vast majority of ARVs (tablets and capsules) are on List A.

The legislative possibility of post-registration of medicinal products is possible only for ARVs from List D in the form of oral solutions.

2.6. Conditions for non-residents

In order to participate in the public procurement of ARVs, the participant must have a marketing authorization for the medicinal product (with the exception of proposals for items of medicinal products on List D).

According to Article 27 of the Medicines Law, an application for a marketing authorization may be submitted by:

- A medicines manufacturer licensed to manufacture medicines in Serbia.
- A representative of a foreign manufacturer registered in Serbia.
- A representative of a foreign legal entity that is not the manufacturer but the holder of the marketing authorization (trade license) in an EU Member State or in a country having identical marketing authorization requirements.
- A legal entity registered in the Republic of Serbia to which the manufacturer has granted the right to obtain a marketing authorization for the medicinal products of own manufacture.

Non-residents cannot obtain a marketing authorization without establishing a foreign representative office in Serbia.

5. http://www.pravno-informacioni-sistem.rs/SlGlasnikPortal/eli/rep/sgrs/vlada/strategija/2018/61/2/reg
6. https://www.paragraf.rs/propisi/zakon-o-porezu-na-dodatu-vrednost.html#
7. http://portal.ujn.gov.rs/Dokumenti/IzmenaKonkursneDokumentacije.aspx?idd=2022702&idp=1998749

3. PROCEDURE TO FORM A NOMENCLATURE OF MEDICINAL PRODUCTS

3.1. Registry of medicinal products

Table 3.1.1 — Registry of antiretroviral drugs [8]

ATC Code	Name	INN	Form, quantity in packing and dosage	Manufacturer
J05AE03	Norvir	ritonavir	Tablets, 1x30x100mg	ABBVIE DEUTSCHLAND GMBH & CO. KG
J05AE07	Telzir	fosamprenavir	Tablets, 1x60x700mg	GLAXO WELLCOME OPERATIONS
J05AE07	Telzir	fosamprenavir	Tablets, 1x60x700mg	GLAXO WELLCOME S.A.
J05AE10	Darunavir Krka	darunavir	Tablets, 1x30x400mg	KRKA D.D., NOVO MESTO
J05AE10	Darunavir Krka	darunavir	Tablets, 2x30x400mg	KRKA D.D., NOVO MESTO
J05AE10	Darunavir Krka	darunavir	Tablets, 1x30x600mg	KRKA D.D., NOVO MESTO
J05AE10	Darunavir Krka	darunavir	Tablets, 2x30x600mg	KRKA D.D., NOVO MESTO
J05AE10	Darunavir Krka	darunavir	Tablets, 1x30x800mg	KRKA D.D., NOVO MESTO
J05AE10	Darunavir Krka	darunavir	Tablets, 2x30x800mg	KRKA D.D., NOVO MESTO
J05AE10	Prezista	darunavir	Tablets, 1x60x400mg	JANSSEN-CILAG S.P.A.
J05AE10	Prezista	darunavir	Tablets, 1x60x600mg	JANSSEN-CILAG S.P.A.
J05AE10	Prezista	darunavir	Tablets, 1x30x800mg	JANSSEN-CILAG S.P.A.
J05AF01	Zidosan	zidovudin	Capsules, 1x100x100mg	SLAVIAMED DOO BEOGRAD
J05AF05	Epivir	lamivudin	Tablets, 1x60x150mg	GLAXO WELLCOME OPERATIONS
J05AF05	Epivir	lamivudin	Tablets, 1x60x150mg	GLAXOSMITHKLINE PHARMACEUTICALS S.A.
J05AF05	Zeffix	lamivudin	Tablets, 2x14x100mg	GLAXO WELLCOME OPERATIONS
J05AF05	Zeffix	lamivudin	Tablets, 2x14x100mg	GLAXOSMITHKLINE PHARMACEUTICALS S.A.
J05AF06	Ziagen	abakavir	Tablets, 6x10x300mg	GLAXO WELLCOME OPERATIONS
J05AF06	Ziagen	abakavir	Tablets, 6x10x300mg	GLAXOSMITHKLINE PHARMACEUTICALS S.A.
J05AF07	Gilestra	tenofovir	Tablets, 1x30x245mg	REMEDICA LTD
J05AF07	Tenofovir Teva	tenofovir	Tablets, 1x30x245mg	TEVA GYOGYSZERGYAR ZRT.
J05AF07	Tenofovir Teva	tenofovir	Tablets, 1x30x245mg	TEVA PHARMACEUTICAL INDUSTRIES LTD.
J05AF07	Tenofovir disoproxil Mylan	tenofovir	Tablets, 1x30x245mg	MCDERMOTT LABORATORIES LTD T/A GERARD LABORATORIES T/A MYLAN DUBLIN
J05AF07	Tenofovir disoproxil Mylan	tenofovir	Tablets, 1x30x245mg	MYLAN HUNGARY KFT.
J05AF07	Viread	tenofovir	Tablets, 1x30x245mg	GILEAD SCIENCES IRELAND UC

8. https://www.alims.gov.rs/ciril/lekovi/pretrazivanje-humanih-lekova/

J05AF13	Vemlidy	tenofovir alafenamid	Tablets, 1x30x25mg	GILEAD SCIENCES IRELAND UC
J05AG01	Viramune	nevirapin	Tablets, 6x10x200mg	BOEHRINGER INGELHEIM ELLAS A.E.
J05AG01	Viramune	nevirapin	Tablets, 6x10x200mg	BOEHRINGER INGELHEIM PHARMA GMBH & CO.KG
J05AG03	Efavirenz SK	efavirenz	Tablets, 3x10x600mg	PHARMADOX HEALTHCARE LTD.
J05AG03	Stocrin	efavirenz	Tablets, 1x30x600mg	MERCK SHARP & DOHME B.V.
J05AR01	Combivir	lamivudin, zidovudin	Tablets, 6x10x(150mg+300mg)	GLAXO WELLCOME OPERATIONS
J05AR01	Combivir	lamivudin, zidovudin	Tablets, 6x10x(150mg+300mg)	GLAXOSMITHKLINE PHARMACEUTICALS S.A.
J05AR01	Zidovudin Lamivudin SK	lamivudin, zidovudin	Tablets, 6x10x(150mg+300mg)	PHARMADOX HEALTHCARE LTD.
J05AR02	Amalibra	lamivudin, abakavir	Tablets, 3x10x(300mg+600mg)	PLIVA HRVATSKA D.O.O.
J05AR02	Kivexa	lamivudin, abakavir	Tablets, 3x10x(300mg+600mg)	GLAXO WELLCOME S.A.
J05AR02	Lamivudin Abakavir SK	lamivudin, abakavir	Tablets, 3x10x(300mg+600mg)	PHARMADOX HEALTHCARE LTD.
J05AR02	Lamivudin/ Abakavir Remedica	lamivudin, abakavir	Tablets, 3x10x(300mg+600mg)	REMEDICA LTD
J05AR03	Gilestra Duo	tenofovir, emtricitabin	Tablets, 1x30x(245mg+200mg)	REMEDICA LTD
J05AR03	Gilestra Duo T	tenofovir, emtricitabin	Tablets, 1x30x(245mg+200mg)	MERCKLE GMBH
J05AR03	Gilestra Duo T	tenofovir, emtricitabin	Tablets, 1x30x(245mg+200mg)	PLIVA HRVATSKA D.O.O.
J05AR03	Gilestra Duo T	tenofovir, emtricitabin	Tablets, 1x30x(245mg+200mg)	TEVA OPERATIONS POLAND SP.Z.O.O.
J05AR03	Gilestra Duo T	tenofovir, emtricitabin	Tablets, 1x30x(245mg+200mg)	TEVA PHARMA B.V.
J05AR03	Tenofovir dizoproksil/ emtricitabin Krka	tenofovir, emtricitabin	Tablets, 1x30x(245mg+200mg)	KRKA D.D., NOVO MESTO
J05AR03	Tenofovir dizoproksil/ emtricitabin Krka	tenofovir, emtricitabin	Tablets, 1x30x(245mg+200mg)	TAD PHARMA GMBH
J05AR03	Truvada	tenofovir, emtricitabin	Tablets, 1x30x(245mg+200mg)	GILEAD SCIENCES IRELAND UC
J05AR08	Eviplera	emtricitabin, tenofovir, rilpivirin	Tablets, 1x30x(200mg+245mg+ 25mg)	GILEAD SCIENCES IRELAND UC
J05AR10	Aluvia	lopinavir, ritonavir	Tablets, 1x60x(100mg+25mg)	ABBVIE DEUTSCHLAND GMBH & CO.KG
J05AR10	Aluvia	lopinavir, ritonavir	Tablets, 1x120x(200mg+50mg)	ABBVIE DEUTSCHLAND GMBH & CO.KG
J05AR13	Triumeq	lamivudin, abakavir, dolutegravir	Tablets, 1x30x(300mg+600mg+ 50mg)	GLAXO WELLCOME S.A.

J05AR13	Triumeq	lamivudin, abakavir, dolutegravir	Tablets, 1x30x(300mg+600mg+ 50mg)	GLAXOSMITHKLINE PHARMACEUTICALS S.A.
J05AR14	Rezolsta	darunavir, kobicistat	Tablets, 1x30x(800mg+150mg)	JANSSEN-CILAG S.P.A.
J05AR21	Juluca	dolutegravir, rilpivirin	Tablets, 1x30x(50mg+25mg)	GLAXO WELLCOME S.A.
J05AX08	Isentress	raltegravir	Tablets, 1x60x600mg	MERCK SHARP & DOHME B.V.
J05AX08	Isentress	raltegravir	Tablets, 1x60x400mg	MERCK SHARP & DOHME B.V.
J05AX09	Celsentri	maravirok	Tablets, 6x10x150mg	PFIZER MANUFACTURING DEUTSCHLAND GMBH — BETRIEBSSTATTE FREIBURG
J05AX09	Celsentri	maravirok	Tablets, 6x10x300mg	PFIZER MANUFACTURING DEUTSCHLAND GMBH — BETRIEBSSTATTE FREIBURG
J05AX12	Tivicay	dolutegravir	Tablets, 1x30x50mg	GLAXO WELLCOME S.A.

3.2. Nomenclature of medicinal products for procurement

The nomenclature of ARV drugs is formed by the National Health Insurance Fund of the Republic of Serbia, based on an assessment of needs received from healthcare facilities which are responsible for providing antiretroviral therapy to the public.

According to notes on the Lists of medicines that are prescribed and issued at the expense of compulsory health insurance, there are the following institutions:

- Clinic for Infectious and Tropical Diseases of the Clinical Center of Serbia (Klinike za infektivne i tropske bolesti Kliničkog centra Srbije);
- Clinic for Infectious Diseases of the Clinical Center Niš (Klinike za infektivne bolesti Kliničkog centra Niš);
- Clinic for Infectious Diseases of the Clinical Center of Vojvodina (Klinike za infektivne bolesti Kliničkog centra Vojvodine);
- Clinic for Infectious Diseases of the Clinical Center Kragujevac (Klinike za infektivne bolesti Kliničkog centra Kragujevac).

According to the tender documentation for the procurement of antiretroviral drugs in 2018, only the antiretroviral drugs, available on the Lists of medicines prescribed and issued at the expense of compulsory health insurance, may be subject to procurement *(see Section 2.2)*.

The nomenclature of ARVs is reviewed annually, prior to the start of the tender that announced by the National Health Insurance Fund on the Public procurement portal.

The possibility of the Serbian NGO to legallyparticipate in the formation of the ARV drugs nomenclature has not been identified.

4. PUBLIC PROCUREMENT SYSTEM

4.1. Sources of procurement financing

Strategic measures for the HIV prevention and treatment in Serbia are set out in the HIV/AIDS Prevention and Control Strategy in the Republic of Serbia for 2018-2025. Since 1997, the country has provided exclusively national funding at the expense of the National Health Insurance Fund of Serbia *(Републички фонд за здравствено осигурање)*[9].

According to the Action Plan for the implementation of the HIV/AIDS Prevention and Control Strategy in the Republic of Serbia for 2018-2025 [10], in 2017 the National Health Insurance Fund of Serbia spent RSD 1,401.4 million (USD 14 million) to provide access to ARV therapy to HIV-infected patients. In 2018-2021, annual funding was based on the previous year amount, providing additional funds as needs grew.

4.2. Entities purchasing anti-retroviral drugs

According to the HIV/AIDS Prevention and Control Strategy in the Republic of Serbia for 2018-2025, the procurement of antiretroviral therapy is carried out by the single customer — the National Health Insurance Fund of Serbia.

The customer conducts public procurement in accordance with the Public Procurement Law (Official Gazette of the Republic of Serbia, No. 124/2012, 14/2015 and 68/2015)[11].

The antiretroviral therapy required to treat HIV infection is free of charge for each patient (if he or she has health insurance within the National Health Insurance Fund of Serbia)[12].

Until 2008, treatment was available only at the Clinic for Infectious and Tropical Diseases of the Clinical Center of Serbia (Klinike za infektivne i tropske bolesti Kliničkog centra Srbije). In 2009, decentralization of medical services was carried out, which made the antiretroviral therapy available in 3 more clinics.

According to the Action Plan for the implementation of the HIV/AIDS Prevention and Control Strategy in the Republic of Serbia for 2018-2025, the access to antiretroviral therapy is provided at 4 independent HIV treatment centers (clinics for infectious diseases), and ARV drugs are used in the therapy of HIV-infected patients based on the opinion of the following institutions: Clinic for Infectious and Tropical Diseases of the Clinical Center of Serbia, Clinic for Infectious Diseases of the Clinical Center Niš, Clinic for Infectious Diseases of the Clinical Center of Vojvodina, and Clinic for Infectious Diseases of the Clinical Center Kragujevac *(see. Section 3.2).*

4.3. Ability to use international procurement mechanisms

The Action Plan for the implementation of the HIV/AIDS Prevention and Control Strategy in the Republic of Serbia for 2018-2025 did not envisage receiving funding from international organizations.

4.4. E-Procurement

Since 2009, the Public procurement portal has been functioning in Serbia *(Портал јавних набавки)*[13].

The National Health Insurance Fund, being a contracting authority (a customer), carries out the procedure of public procurement on behalf of healthcare institutions which treat patients with HIV.

For the public procurement of ARVs an agreement with a standard 4-month validity term is concluded.

Public procurement contracts are concluded by medical institutions which treat HIV patients.

The number of medicinal products specified in the technical specification is an indicative amount for the needs of healthcare institutions for a 4-month period.

The subject of the tender is divided into separate positions (items). The tenderer may apply for any number of items of the public procurement contract.

The criterion for the conclusion of the agreement is the lowest price; there are no preferences for national producers when considering bids.

4.5. Procurement planning

Procurement planning is carried out by the National Health Insurance Fund, based on the funding within the Fund allocated for the public procurement of ARV drugs.

According to Article 3 of the Public Procurement Law, the customer prepares a procurement plan for 1 year.

9. https://covekoljublje.org/en/uploaded/publikacije/Monitoring%20of%20Rights%20of%20People%20Living%20with%20HIVAIDS%20in%20Serbia.pdf
10. http://www.pravno-informacioni-sistem.rs/SlGlasnikPortal/prilozi/1.html&doctype=reg&abc=cba&eli=true&eliActId=426474&regactid=426474
11. https://www.paragraf.rs/propisi/zakon_o_javnim_nabavkama.html
12. http://www.rts.rs/page/magazine/ci/story/481/zdravlje/3635237/smanjen-broj-obolelih-od-sifilisa-vise-inficiranih-hiv-om.html
13. http://portal.ujn.gov.rs/Pretraga.aspx?tab=1

5. PROCUREMENT OF ANTI-RETROVIRAL DRUGS

Public procurement procedures for antiretroviral drugs in 2019 was conducted in the framework of the centralized procurement procedure of the customer — The National Health Insurance Fund of Serbia within the Public procurement portal.

5.1. Purchases of antiretroviral drugs in 2019

In 2019, public procurement contracts for ARVs were concluded with the following suppliers.

Table 5.1.1 — Public Procurement in 2019 [14]

INN	Name	Manufacturer	Form, quantity in packing and dosage	Packes, pcs.	Price, inc VAT		Value, inc VAT		Supplier
					RSD	USD	RSD ths	USD ths	
ritonavir	Norvir	Abbvie Deutschland GMBH & Co. KG	Tablets, 30x100mg	651	2423,1	23,0	1577,4	15,0	Medica Linea Pharm
fosampre-navir	Telzir	Glaxo Wellcome Operations; Glaxo Wellcome S.A.	Tablets, 60x700mg	150	34410,1	326,9	5161,5	49,0	Phoenix Pharma d.o.o.
darunavir	Prezista	Janssen-Cilag S.P.A.	Tablets, 60x600mg	197	52837,5	502,0	10409,0	98,9	Phoenix Pharma d.o.o.
zidovudin	Zidosan	Slaviamed d.o.o.	Capsules, 100x100mg	60	8259,3	78,5	495,6	4,7	Phoenix Pharma d.o.o.
lamivudin	Zeffix	GlaxoSmithKline Pharmaceuticals S.A; Glaxo Wellcome Operations	Tablets, 28x100mg	2600	5858,0	55,7	15230,9	144,7	Phoenix Pharma d.o.o.
lamivudin	Epivir	GlaxoSmithKline Pharmaceuticals S.A; Glaxo Wellcome Operations	Tablets, 60x150mg	212	8864,0	84,2	1879,2	17,9	Phoenix Pharma d.o.o.
abakavir	Ziagen	GlaxoSmithKline Pharmaceuticals S.A.; Glaxo Wellcome Operations	Tablets, 60x300mg	50	24984,0	237,3	1249,2	11,9	Phoenix Pharma d.o.o.
tenofovir	Viread	Gilead Sciences Ltd.	Tablets, 30x245mg	3372	19597,2	186,2	66081,8	627,8	Ino-pharm d.o.o.
tenofovir	Gilestra	Remedica LTD	Tablets, 30x245mg	51	18799,6	178,6	958,8	9,1	Vega d.o.o.
nevirapin	Viramune	Boehringer Ingelheim Pharma GmbH	Tablets, 60x200mg	109	3573,1	33,9	389,5	3,7	Farmalogist d.o.o.
efavirenz	Stocrin	Merck Sharp & Dohme	Tablets, 30x600mg	1062	22429,4	213,1	23820,0	226,3	Phoenix Pharma d.o.o.

14. http://portal.ujn.gov.rs/Dokumenti/JavnaNabavka.aspx?idd=2115458

zidovudin, lamivudin	Combivir	Glaxo Operations UK Limited; GlaxoSmithKline Pharmaceuticals S.A	Tablets, 60x(300mg+ 150mg)	62	18157,2	172,5	1125,7	10,7	Phoenix Pharma d.o.o.
abakavir, lamivudin	Kivexa	Glaxo Wellcome Operations; Glaxo Wellcome S.A	Tablets, 30x(600mg+ 300mg)	1847	23010,9	218,6	42501,2	403,8	Phoenix Pharma d.o.o.
lamivudin, abakavir	Amalibra	Pliva Hrvatska d.o.o.	Tablets, 30x(300mg+ 600mg)	140	22189,8	210,8	3106,6	29,5	Vega d.o.o.
tenofovir, emtricitabin	Truvada	Gilead Sciences Ltd.	Tablets, 30x(245mg+ 200mg)	377	25170,0	239,1	9489,1	90,1	Ino-pharm d.o.o.
tenofovir, emtricitabin	Gilestra duo	Remedica LTD	Tablets, 30x(245mg+ 200mg)	68	24145,6	229,4	1641,9	15,6	Vega d.o.o.
emtricitabin, tenofovir, rilpivirin	Eviplera	Gilead Sciences Ireland UC	Tablets, 30x(200mg+ 245mg+25mg)	140	47599,4	452,2	6663,9	63,3	Ino-pharm d.o.o.
lopinavir, ritonavir	Aluvia	Abbvie Deutschland GMBH & Co. KG	Tablets, 120x(200mg+ 50mg)	787	7865,0	74,7	6189,8	58,8	Medica Linea Pharm
lopinavir, ritonavir	Aluvia	Abbvie Deutschland GMBH & Co. KG	Tablets, 60x(100mg+ 25mg)	50	3962,5	37,6	198,1	1,9	Medica Linea Pharm
lamivudin, abakavir, dolutegravir	Triumeq	Glaxo Wellcome S.A	Tablets, 30x(300mg+ 600mg+50mg)	520	55185,5	524,3	28696,5	272,6	Phoenix Pharma d.o.o.
darunavir, kobicistat	Rezolsta	Janssen-Cilag S.P.A	Tablets, 30x(800mg+ 150mg)	252	54259,3	515,5	13673,3	129,9	Phoenix Pharma d.o.o.
raltegravir	Isentress	Merck Sharp & Dohme B.V.	Tablets, 60x400mg	242	57849,0	549,6	13999,5	133,0	Phoenix Pharma d.o.o.
maravirok	Celsentri	Pfizer Manufacturing Deutschland GmbH	Tablets, 60x150mg	50	76346,2	725,3	3817,3	36,3	Phoenix Pharma d.o.o.
maravirok	Celsentri	Pfizer Manufacturing Deutschland GmbH	Tablets, 60x300mg	50	76346,2	725,3	3817,3	36,3	Phoenix Pharma d.o.o.
dolutegravir	Tivicay	Glaxo Wellcome S.A.	Tablets, 30x50mg	190	63336,7	601,7	12034,0	114,3	Phoenix Pharma d.o.o.
Total							**274 206,9**	**2605,0**	

ATC Code	Name	INN	Form, quantity in packing and dosage	Producer	License holder
J05AF06	Abacavir sandoz 300 mg	abacavirum	Tablets 60 x 300mg	Salutas pharma gmbh - germania	Sandoz s.r.l. - romania
J05AF06	Abacavir sandoz 300 mg	abacavirum	Tablets 180 x 300mg	Salutas pharma gmbh - germania	Sandoz s.r.l. - romania
J05AR02	Abacavir/lamivudina Aurobindo 600 mg/300mg	abacavirum+ lamivudinum	Tablets 30 x 600mg/300mg	Apl swift services (malta) limited - malta	Aurobindo pharma romania s.r.l. - romania
J05AR02	Abacavir/lamivudina Aurobindo 600 mg/300mg	abacavirum+ lamivudinum	Tablets 50 x 600mg/300mg	Apl swift services (malta) limited - malta	Aurobindo pharma romania s.r.l. - romania
J05AR02	Abacavir/lamivudina Aurobindo 600 mg/300mg	abacavirum+ lamivudinum	Tablets 60 x 600mg/300mg	Apl swift services (malta) limited - malta	Aurobindo pharma romania s.r.l. - romania
J05AR02	Abacavir/lamivudina Aurobindo 600 mg/300mg	abacavirum+ lamivudinum	Tablets 90 x 600mg/300mg	Apl swift services (malta) limited - malta	Aurobindo pharma romania s.r.l. - romania
J05AR02	Abacavir/lamivudina Aurobindo 600 mg/300mg	abacavirum+ lamivudinum	Tablets 30 x 600mg/300mg	Apl swift services (malta) limited - malta	Aurobindo pharma romania s.r.l. - romania
J05AR02	Abacavir/lamivudina Aurobindo 600 mg/300mg	abacavirum+ lamivudinum	Tablets 100 x 600mg/300mg	Apl swift services (malta) limited - malta	Aurobindo pharma romania s.r.l. - romania
J05AR02	Abacavir/lamivudina Glenmark 600 mg/300 mg	abacavirum+ lamivudinum	Tablets 30 x 600mg/300mg	Lupin (europe) limited - marea britanie	Glenmark pharmaceuticals s.r.o. - republica ceha
J05AR02	Abacavir/lamivudina Glenmark 600 mg/300 mg	abacavirum+ lamivudinum	Tablets 60 x 600mg/300mg	Lupin (europe) limited - marea britanie	Glenmark pharmaceuticals s.r.o. - republica ceha
J05AR02	Abacavir/lamivudina Glenmark 600 mg/300 mg	abacavirum+ lamivudinum	Tablets 90 x 600mg/300mg	Lupin (europe) limited - marea britanie	Glenmark pharmaceuticals s.r.o. - republica ceha
J05AR02	Abacavir/lamivudina Glenmark 600 mg/300 mg	abacavirum+ lamivudinum	Tablets 30 x 600mg/300mg	Lupin (europe) limited - marea britanie	Glenmark pharmaceuticals s.r.o. - republica ceha
J05AR02	Abacavir/lamivudina Glenmark 600 mg/300 mg	abacavirum+ lamivudinum	Tablets 60 x 600mg/300mg	Lupin (europe) limited - marea britanie	Glenmark pharmaceuticals s.r.o. - republica ceha
J05AR02	Abacavir/lamivudina Glenmark 600 mg/300 mg	abacavirum+ lamivudinum	Tablets 90 x 600mg/300mg	Lupin (europe) limited - marea britanie	Glenmark pharmaceuticals s.r.o. - republica ceha
J05AR02	Abacavir/lamivudina Glenmark 600 mg/300 mg	abacavirum+ lamivudinum	Tablets 30 x 600mg/300mg	Lupin (europe) limited - marea britanie	Glenmark pharmaceuticals s.r.o. - republica ceha
J05AR02	Abacavir/lamivudina Glenmark 600 mg/300 mg	abacavirum+ lamivudinum	Tablets 90 x 600mg/300mg	Lupin (europe) limited - marea britanie	Glenmark pharmaceuticals s.r.o. - republica ceha
J05AR02	Abacavir/lamivudina Glenmark 600 mg/300 mg	abacavirum+ lamivudinum	Tablets 30 x 600mg/300mg	Lupin (europe) limited - marea britanie	Glenmark pharmaceuticals s.r.o. - republica ceha
J05AR02	Abacavir/lamivudina Glenmark 600 mg/300 mg	abacavirum+ lamivudinum	Tablets 90 x 600mg/300mg	Lupin (europe) limited - marea britanie	Glenmark pharmaceuticals s.r.o. - republica ceha
J05AR02	Abacavir/lamivudina Glenmark 600 mg/300 mg	abacavirum+ lamivudinum	Tablets 90 x 600mg/300mg	Lupin (europe) limited - marea britanie	Glenmark pharmaceuticals s.r.o. - republica ceha
J05AR02	Abacavir/lamivudina Glenmark 600 mg/300 mg	abacavirum+ lamivudinum	Tablets 60 x 600mg/300mg	Lupin (europe) limited - marea britanie	Glenmark pharmaceuticals s.r.o. - republica ceha
J05AR02	Abacavir/lamivudina Glenmark 600 mg/300 mg	abacavirum+ lamivudinum	Tablets 90 x 600mg/300mg	Lupin (europe) limited - marea britanie	Glenmark pharmaceuticals s.r.o. - republica ceha
J05AR02	Abacavir/lamivudina Glenmark 600 mg/300 mg	abacavirum+ lamivudinum	Tablets 60 x 600mg/300mg	Lupin (europe) limited - marea britanie	Glenmark pharmaceuticals s.r.o. - republica ceha
J05AR02	Abacavir/lamivudina Glenmark 600 mg/300 mg	abacavirum+ lamivudinum	Tablets 90 x 600mg/300mg	Lupin (europe) limited - marea britanie	Glenmark pharmaceuticals s.r.o. - republica ceha
J05AR02	Abacavir/lamivudina Glenmark 600 mg/300 mg	abacavirum+ lamivudinum	Tablets 30 x 600mg/300mg	Lupin (europe) limited - marea britanie	Glenmark pharmaceuticals s.r.o. - republica ceha
J05AR02	Abacavir/lamivudina Glenmark 600 mg/300 mg	abacavirum+ lamivudinum	Tablets 30 x 600mg/300mg	Lupin (europe) limited - marea britanie	Glenmark pharmaceuticals s.r.o. - republica ceha
J05AR02	Abacavir/lamivudina Mylan 600 mg/300 mg	abacavirum+ lamivudinum	Tablets 30 x 600mg/300mg	Mylan s.a.s. (saint priest) - franta	Mylan s.a.s. - franta
J05AR02	Abacavir/lamivudina Mylan 600 mg/300 mg	abacavirum+ lamivudinum	Tablets 60 x 600mg/300mg	Mylan s.a.s. (saint priest) - franta	Mylan s.a.s. - franta

ATC Code	Name	INN	Form, quantity in packing and dosage	Producer	License holder
J05AR02	Abacavir/lamivudina Mylan 600 mg/300 mg	abacavirum+ lamivudinum	Tablets 90 x 600mg/300mg	Mylan s.a.s. (saint priest) - franta	Mylan s.a.s. - franta
J05AR02	Abacavir/lamivudina Mylan 600 mg/300 mg	abacavirum+ lamivudinum	Tablets 30 x 600mg/300mg	Mylan s.a.s. (saint priest) - franta	Mylan s.a.s. - franta
J05AR02	Abacavir/lamivudina Mylan 600 mg/300 mg	abacavirum+ lamivudinum	Tablets 60 x 600mg/300mg	Mylan s.a.s. (saint priest) - franta	Mylan s.a.s. - franta
J05AR02	Abacavir/lamivudina Mylan 600 mg/300 mg	abacavirum+ lamivudinum	Tablets 90 x 600mg/300mg	Mylan s.a.s. (saint priest) - franta	Mylan s.a.s. - franta
J05AR02	Abacavir/lamivudina Mylan 600 mg/300 mg	abacavirum+ lamivudinum	Tablets 30 x 600mg/300mg	Mylan s.a.s. (saint priest) - franta	Mylan s.a.s. - franta
J05AR02	Abacavir/lamivudina Mylan 600 mg/300 mg	abacavirum+ lamivudinum	Tablets 30 x 600mg/300mg	Mylan s.a.s. (saint priest) - franta	Mylan s.a.s. - franta
J05AR02	Abacavir/lamivudina Sandoz 600 mg/300mg	abacavirum+ lamivudinum	Tablets 30 x 600mg/300mg	Lupin (europe) ltd - marea britanie	Sandoz s.r.l. - romania
J05AR02	Abacavir/lamivudina Sandoz 600 mg/300mg	abacavirum+ lamivudinum	Tablets 60 x 600mg/300mg	Lupin (europe) ltd - marea britanie	Sandoz s.r.l. - romania
J05AR02	Abacavir/lamivudina Sandoz 600 mg/300mg	abacavirum+ lamivudinum	Tablets 90 x 600mg/300mg	Lupin (europe) ltd - marea britanie	Sandoz s.r.l. - romania
J05AR02	Abacavir/lamivudina Sandoz 600 mg/300mg	abacavirum+ lamivudinum	Tablets 30 x 600mg/300mg	Lupin (europe) ltd - marea britanie	Sandoz s.r.l. - romania
J05AR02	Abacavir/lamivudina Sandoz 600 mg/300mg	abacavirum+ lamivudinum	Tablets 60 x 600mg/300mg	Lupin (europe) ltd - marea britanie	Sandoz s.r.l. - romania
J05AR02	Abacavir/lamivudina Sandoz 600 mg/300mg	abacavirum+ lamivudinum	Tablets 90 x 600mg/300mg	Lupin (europe) ltd - marea britanie	Sandoz s.r.l. - romania
J05AR02	Abacavir/lamivudina Sandoz 600 mg/300mg	abacavirum+ lamivudinum	Tablets 60 x 600mg/300mg	Lupin (europe) ltd - marea britanie	Sandoz s.r.l. - romania
J05AR02	Abacavir/lamivudina Sandoz 600 mg/300mg	abacavirum+ lamivudinum	Tablets 90 x 600mg/300mg	Lupin (europe) ltd - marea britanie	Sandoz s.r.l. - romania
J05AR02	Abacavir/lamivudina Sandoz 600 mg/300mg	abacavirum+ lamivudinum	Tablets 60 x 600mg/300mg	Lupin (europe) ltd - marea britanie	Sandoz s.r.l. - romania
J05AR02	Abacavir/lamivudina Sandoz 600 mg/300mg	abacavirum+ lamivudinum	Tablets 90 x 600mg/300mg	Lupin (europe) ltd - marea britanie	Sandoz s.r.l. - romania
J05AR02	Abacavir/lamivudina Sandoz 600 mg/300mg	abacavirum+ lamivudinum	Tablets 30 x 600mg/300mg	Lupin (europe) ltd - marea britanie	Sandoz s.r.l. - romania
J05AR02	Abacavir/lamivudina Terapia 600 mg/300 mg	abacavirum+ lamivudinum	Tablets 30 x 600mg/300mg	S.c. terapia s.a. - romania	S.c. terapia s.a. - romania
J05AR02	Abacavir/lamivudina Terapia 600 mg/300 mg	abacavirum+ lamivudinum	Tablets 90 x 600mg/300mg	S.c. terapia s.a. - romania	S.c. terapia s.a. - romania
J05AR02	Abacavir/lamivudina Terapia 600 mg/300 mg	abacavirum+ lamivudinum	Tablets 30 x 600mg/300mg	S.c. terapia s.a. - romania	S.c. terapia s.a. - romania
J05AR02	Abacavir/lamivudina Terapia 600 mg/300 mg	abacavirum+ lamivudinum	Tablets 30 x 600mg/300mg	S.c. terapia s.a. - romania	S.c. terapia s.a. - romania
J05AR02	Abacavir/lamivudina Teva 600 mg/300 mg	abacavirum+ lamivudinum	Tablets 10 x 600mg/300mg	Pliva hrvatska d.o.o. (pliva croatia ltd.) - croatia	Teva pharmaceuticals s.r.l. - romania
J05AR02	Abacavir/lamivudina Teva 600 mg/300 mg	abacavirum+ lamivudinum	Tablets 10 x 600mg/300mg	Pliva hrvatska d.o.o. (pliva croatia ltd.) - croatia	Teva pharmaceuticals s.r.l. - romania
J05AR02	Abacavir/lamivudina Teva 600 mg/300 mg	abacavirum+ lamivudinum	Tablets 30 x 600mg/300mg	Pliva hrvatska d.o.o. (pliva croatia ltd.) - croatia	Teva pharmaceuticals s.r.l. - romania
J05AR02	Abacavir/lamivudina Teva 600 mg/300 mg	abacavirum+ lamivudinum	Tablets 30 x 600mg/300mg	Pliva hrvatska d.o.o. (pliva croatia ltd.) - croatia	Teva pharmaceuticals s.r.l. - romania
J05AR02	Abacavir/lamivudina Teva 600 mg/300 mg	abacavirum+ lamivudinum	Tablets 90 x 600mg/300mg	Pliva hrvatska d.o.o. (pliva croatia ltd.) - croatia	Teva pharmaceuticals s.r.l. - romania
J05AR02	Abacavir/lamivudina Teva 600 mg/300 mg	abacavirum+ lamivudinum	Tablets 90 x 600mg/300mg	Pliva hrvatska d.o.o. (pliva croatia ltd.) - croatia	Teva pharmaceuticals s.r.l. - romania
J05AR02	Abacavir/lamivudina Vale 600 mg/300 mg	abacavirum+ lamivudinum	Tablets 30 x 600mg/300mg	Mcdermott laboratories limited t/a - irlanda	Vale pharmaceuticals ltd. - irlanda
J05AR02	Abacavir/lamivudina Vale 600 mg/300 mg	abacavirum+ lamivudinum	Tablets 30 x 600mg/300mg	Mcdermott laboratories limited t/a - irlanda	Vale pharmaceuticals ltd. - irlanda
J05AR02	Abacavir/lamivudina Vale 600 mg/300 mg	abacavirum+ lamivudinum	Tablets 90 x 600mg/300mg	Mcdermott laboratories limited t/a - irlanda	Vale pharmaceuticals ltd. - irlanda
J05AR02	Abacavir/lamivudina Vale 600 mg/300 mg	abacavirum+ lamivudinum	Tablets 90 x 600mg/300mg	Mcdermott laboratories limited t/a - irlanda	Vale pharmaceuticals ltd. - irlanda
J05AR02	Abacavir/lamivudina Vale 600 mg/300 mg	abacavirum+ lamivudinum	Tablets 30 x 600mg/300mg	Mcdermott laboratories limited t/a - irlanda	Vale pharmaceuticals ltd. - irlanda

ATC Code	Name	INN	Form, quantity in packing and dosage	Producer	License holder
J05AR02	Abacavir/lamivudina Zentiva 600 mg/300 mg	abacavirum+ lamivudinum	Tablets 30 x 600mg/300mg	Zentiva, k.s. - republica ceha	Zentiva, k.s. - republica ceha
J05AE08	Atazanavir accord 150 mg	atazanavirum	Capsules 30 x 150mg	Accord healthcare limited - marea britanie	Accord healthcare polska sp. Z o.o. - polonia
J05AE08	Atazanavir accord 150 mg	atazanavirum	Capsules 60 x 150mg	Accord healthcare limited - marea britanie	Accord healthcare polska sp. Z o.o. - polonia
J05AE08	Atazanavir accord 150 mg	atazanavirum	Capsules 90 x 150mg	Accord healthcare limited - marea britanie	Accord healthcare polska sp. Z o.o. - polonia
J05AE08	Atazanavir accord 150 mg	atazanavirum	Capsules 60 x 150mg	Accord healthcare limited - marea britanie	Accord healthcare polska sp. Z o.o. - polonia
J05AE08	Atazanavir accord 200 mg	atazanavirum	Capsules 30 x 200mg	Accord healthcare limited - marea britanie	Accord healthcare polska sp. Z o.o. - polonia
J05AE08	Atazanavir accord 200 mg	atazanavirum	Capsules 60 x 200mg	Accord healthcare limited - marea britanie	Accord healthcare polska sp. Z o.o. - polonia
J05AE08	Atazanavir accord 200 mg	atazanavirum	Capsules 90 x 200mg	Accord healthcare limited - marea britanie	Accord healthcare polska sp. Z o.o. - polonia
J05AE08	Atazanavir accord 200 mg	atazanavirum	Capsules 60 x 200mg	Accord healthcare limited - marea britanie	Accord healthcare polska sp. Z o.o. - polonia
J05AE08	Atazanavir accord 300 mg	atazanavirum	Capsules 30 x 300mg	Accord healthcare limited - marea britanie	Accord healthcare polska sp. Z o.o. - polonia
J05AE08	Atazanavir accord 300 mg	atazanavirum	Capsules 60 x 300mg	Accord healthcare limited - marea britanie	Accord healthcare polska sp. Z o.o. - polonia
J05AE08	Atazanavir accord 300 mg	atazanavirum	Capsules 90 x 300mg	Accord healthcare limited - marea britanie	Accord healthcare polska sp. Z o.o. - polonia
J05AE08	Atazanavir accord 300 mg	atazanavirum	Capsules 60 x 300mg	Accord healthcare limited - marea britanie	Accord healthcare polska sp. Z o.o. - polonia
J05AE08	Atazanavir alvogen 150 mg	atazanavirum	Capsules 60 x 150mg	Remedica ltd - cipru	Alvogen malta operations (row) ltd. - malta
J05AE08	Atazanavir alvogen 150 mg	atazanavirum	Capsules 60 x 150mg	Remedica ltd - cipru	Alvogen malta operations (row) ltd. - malta
J05AE08	Atazanavir alvogen 200 mg	atazanavirum	Capsules 60 x 200mg	Remedica ltd - cipru	Alvogen malta operations (row) ltd. - malta
J05AE08	Atazanavir alvogen 200 mg	atazanavirum	Capsules 60 x 200mg	Remedica ltd - cipru	Alvogen malta operations (row) ltd. - malta
J05AE08	Atazanavir alvogen 300 mg	atazanavirum	Capsules 30 x 300mg	Remedica ltd - cipru	Alvogen malta operations (row) ltd. - malta
J05AE08	Atazanavir alvogen 300 mg	atazanavirum	Capsules 30 x 300mg	Remedica ltd - cipru	Alvogen malta operations (row) ltd. - malta
J05AE08	Atazanavir krka 150 mg	atazanavirum	Capsules 60 x 150mg	Krka, d.d., novo mesto - slovenia	Krka, d.d., novo mesto - slovenia
J05AE08	Atazanavir krka 200 mg	atazanavirum	Capsules 60 x 200mg	Krka, d.d., novo mesto - slovenia	Krka, d.d., novo mesto - slovenia
J05AE08	Atazanavir krka 300 mg	atazanavirum	Capsules 30 x 300mg	Krka, d.d., novo mesto - slovenia	Krka, d.d., novo mesto - slovenia
J05AE08	Atazanavir krka 300 mg	atazanavirum	Capsules 30 x 300mg	Krka, d.d., novo mesto - slovenia	Krka, d.d., novo mesto - slovenia
J05AE08	Atazanavir mylan 150 mg	atazanavirum	Capsules 60 x 1 x 150mg	Mylan hungary kft - ungaria	Mylan s.a.s. - franta
J05AE08	Atazanavir mylan 300 mg	atazanavirum	Capsules 30 x 300mg	Mylan hungary kft - ungaria	Mylan s.a.s. - franta
J05AE08	Atazanavir mylan 300 mg	atazanavirum	Capsules 30 x 300mg	Mylan hungary kft - ungaria	Mylan s.a.s. - franta
J05AE08	Atazanavir mylan 300 mg	atazanavirum	Capsules 30 x 1 x 300mg	Mylan hungary kft - ungaria	Mylan s.a.s. - franta
J05AE08	Atazanavir sandoz 100 mg	atazanavirum	Capsules 12 x 100mg	Remedica ltd - cipru	Sandoz s.r.l. - romania
J05AE08	Atazanavir sandoz 100 mg	atazanavirum	Capsules 24 x 100mg	Remedica ltd - cipru	Sandoz s.r.l. - romania
J05AE08	Atazanavir sandoz 150 mg	atazanavirum	Capsules 60 x 1 x 150mg	Remedica ltd - cipru	Sandoz s.r.l. - romania
J05AE08	Atazanavir sandoz 150 mg	atazanavirum	Capsules 60 x 150mg	Remedica ltd - cipru	Sandoz s.r.l. - romania
J05AE08	Atazanavir sandoz 150 mg	atazanavirum	Capsules 60 x 150mg	Remedica ltd - cipru	Sandoz s.r.l. - romania
J05AE08	Atazanavir sandoz 200 mg	atazanavirum	Capsules 60 x 1 x 200mg	Remedica ltd - cipru	Sandoz s.r.l. - romania
J05AE08	Atazanavir sandoz 200 mg	atazanavirum	Capsules 60 x 200mg	Remedica ltd - cipru	Sandoz s.r.l. - romania
J05AE08	Atazanavir sandoz 200 mg	atazanavirum	Capsules 60 x 200mg	Remedica ltd - cipru	Sandoz s.r.l. - romania
J05AE08	Atazanavir sandoz 300 mg	atazanavirum	Capsules 30 x 1 x 300mg	Remedica ltd - cipru	Sandoz s.r.l. - romania

ATC Code	Name	INN	Form, quantity in packing and dosage	Producer	License holder
J05AE08	Atazanavir sandoz 300 mg	atazanavirum	Capsules 30 x 300mg	Remedica ltd - cipru	Sandoz s.r.l. - romania
J05AE08	Atazanavir sandoz 300 mg	atazanavirum	Capsules 30 x 300mg	Remedica ltd - cipru	Sandoz s.r.l. - romania
J05AE08	Atazanavir sandoz 300 mg	atazanavirum	Capsules 60 x 1 x 300mg	Remedica ltd - cipru	Sandoz s.r.l. - romania
J05AE08	Atazanavir sandoz 300 mg	atazanavirum	Capsules 60 x 300mg	Remedica ltd - cipru	Sandoz s.r.l. - romania
J05AE08	Atazanavir sandoz 300 mg	atazanavirum	Capsules 90 x 1 x 300mg	Remedica ltd - cipru	Sandoz s.r.l. - romania
J05AE08	Atazanavir sandoz 300 mg	atazanavirum	Capsules 90 x 300mg	Remedica ltd - cipru	Sandoz s.r.l. - romania
J05AE08	Atazanavir sandoz 300 mg	atazanavirum	Capsules 120 x 300mg	Remedica ltd - cipru	Sandoz s.r.l. - romania
J05AE08	Atazanavir sandoz 300 mg	atazanavirum	Capsules 120 x 300mg	Remedica ltd - cipru	Sandoz s.r.l. - romania
J05AE08	Atazanavir sandoz 300 mg	atazanavirum	Capsules 60 x 300mg	Remedica ltd - cipru	Sandoz s.r.l. - romania
J05AE08	Atazanavir sandoz 300 mg	atazanavirum	Capsules 90 x 300mg	Remedica ltd - cipru	Sandoz s.r.l. - romania
J05AE08	Atazanavir sandoz 300 mg	atazanavirum	Capsules 120 x 30 x 300mg	Remedica ltd - cipru	Sandoz s.r.l. - romania
J05AE08	Atazanavir teva 150 mg	atazanavirum	Capsules 60 x 150mg	Teva gyogyszergyar zrt. (teva pharm. Works private) - ungaria	Teva pharmaceuticals s.r.l. - romania
J05AE08	Atazanavir teva 150 mg	atazanavirum	Capsules 60 x 1 x 150mg	Teva gyogyszergyar zrt. (teva pharm. Works private) - ungaria	Teva pharmaceuticals s.r.l. - romania
J05AE08	Atazanavir teva 150 mg	atazanavirum	Capsules 60 x 150mg	Teva gyogyszergyar zrt. (teva pharm. Works private) - ungaria	Teva pharmaceuticals s.r.l. - romania
J05AE08	Atazanavir teva 200 mg	atazanavirum	Capsules 60 x 200mg	Teva gyogyszergyar zrt. (teva pharm. Works private) - ungaria	Teva pharmaceuticals s.r.l. - romania
J05AE08	Atazanavir teva 200 mg	atazanavirum	Capsules 60 x 1 x 200mg	Teva gyogyszergyar zrt. (teva pharm. Works private) - ungaria	Teva pharmaceuticals s.r.l. - romania
J05AE08	Atazanavir teva 200 mg	atazanavirum	Capsules 60 x 200mg	Teva gyogyszergyar zrt. (teva pharm. Works private) - ungaria	Teva pharmaceuticals s.r.l. - romania
J05AE08	Atazanavir teva 300 mg	atazanavirum	Capsules 30 x 300mg	Teva gyogyszergyar zrt. (teva pharm. Works private) - ungaria	Teva pharmaceuticals s.r.l. - romania
J05AE08	Atazanavir teva 300 mg	atazanavirum	Capsules 30 x 1 x 300mg	Teva gyogyszergyar zrt. (teva pharm. Works private) - ungaria	Teva pharmaceuticals s.r.l. - romania
J05AE08	Atazanavir teva 300 mg	atazanavirum	Capsules 60 x 300mg	Teva gyogyszergyar zrt. (teva pharm. Works private) - ungaria	Teva pharmaceuticals s.r.l. - romania
J05AE08	Atazanavir teva 300 mg	atazanavirum	Capsules 90 x 300mg	Teva gyogyszergyar zrt. (teva pharm. Works private) - ungaria	Teva pharmaceuticals s.r.l. - romania
J05AE08	Atazanavir teva 300 mg	atazanavirum	Capsules 30 x 300mg	Teva gyogyszergyar zrt. (teva pharm. Works private) - ungaria	Teva pharmaceuticals s.r.l. - romania
J05AE08	Atazanavir teva 300 mg	atazanavirum	Capsules 3 x 30 x 300mg	Teva gyogyszergyar zrt. (teva pharm. Works private) - ungaria	Teva pharmaceuticals s.r.l. - romania
J05AE08	Atazanavir zentiva 150 mg	atazanavirum	Capsules 60 x 150mg	Zentiva, k.s. - republica ceha	Zentiva, k.s. - republica ceha
J05AE08	Atazanavir zentiva 150 mg	atazanavirum	Capsules 60 x 150mg	Zentiva, k.s. - republica ceha	Zentiva, k.s. - republica ceha
J05AE08	Atazanavir zentiva 200 mg	atazanavirum	Capsules 60 x 200mg	Zentiva, k.s. - republica ceha	Zentiva, k.s. - republica ceha
J05AE08	Atazanavir zentiva 200 mg	atazanavirum	Capsules 60 x 200mg	Zentiva, k.s. - republica ceha	Zentiva, k.s. - republica ceha
J05AE08	Atazanavir zentiva 300 mg	atazanavirum	Capsules 30 x 300mg	Zentiva, k.s. - republica ceha	Zentiva, k.s. - republica ceha
J05AE08	Atazanavir zentiva 300 mg	atazanavirum	Capsules 60 x 300mg	Zentiva, k.s. - republica ceha	Zentiva, k.s. - republica ceha
J05AE08	Atazanavir zentiva 300 mg	atazanavirum	Capsules 30 x 300mg	Zentiva, k.s. - republica ceha	Zentiva, k.s. - republica ceha
J05AE08	Atazanavir zentiva 300 mg	atazanavirum	Capsules 30 x 300mg	Zentiva, k.s. - republica ceha	Zentiva, k.s. - republica ceha
J05AE08	Atazanavir zentiva 300 mg	atazanavirum	Capsules 60 x 300mg	Zentiva, k.s. - republica ceha	Zentiva, k.s. - republica ceha

ATC Code	Name	INN	Form, quantity in packing and dosage	Producer	License holder
J05AR06	Atripla 600mg/200mg/245mg	efavirenzum+ emtricitabinum+ tenofovirum disoproxil	Tablets 30 x 600mg/200mg/245mg	Gilead science limited - irlanda	Bristol-myers squibb gilead sciences and msd - irlanda
J05AR06	Atripla 600mg/200mg/245mg	efavirenzum+ emtricitabinum+ tenofovirum disoproxil	Tablets 30 x 600mg/200mg/245mg	Gilead science limited - irlanda	Bristol-myers squibb gilead sciences and msd - irlanda
J05AR20	Biktarvy 50 mg/200 mg/25 mg	bictegravirum+ emtricitabinum+ tenofovirum	Tablets 30 x 50mg/200mg/25mg	Gilead sciences ireland uc - irlanda	Gilead sciences ireland uc - irlanda
J05AR20	Biktarvy 50 mg/200 mg/25 mg	bictegravirum+ emtricitabinum+ tenofovirum	Tablets 30 x 50mg/200mg/25mg	Gilead sciences ireland uc - irlanda	Gilead sciences ireland uc - irlanda
J05AX09	Celsentri 150 mg	maravirocum	Tablets 180 x 150mg	Pfizer manufacturing deutschland gmbh - germania	Viiv healthcare bv - olanda
J05AX09	Celsentri 150 mg	maravirocum	Tablets 30 x 150mg	Pfizer manufacturing deutschland gmbh - germania	Viiv healthcare bv - olanda
J05AX09	Celsentri 150 mg	maravirocum	Tablets 60 x 150mg	Pfizer manufacturing deutschland gmbh - germania	Viiv healthcare bv - olanda
J05AX09	Celsentri 150 mg	maravirocum	Tablets 90 x 150mg	Pfizer manufacturing deutschland gmbh - germania	Viiv healthcare bv - olanda
J05AX09	Celsentri 150 mg	maravirocum	Tablets 180 x 150mg	Pfizer manufacturing deutschland gmbh - germania	Viiv healthcare bv - olanda
J05AX09	Celsentri 20 mg/ml	maravirocum	Oral suspension 20mg/ml	Pfizer service company - belgia	Viiv healthcare bv - olanda
J05AX09	Celsentri 25 mg	maravirocum	Tablets 120 x 25mg	Pfizer manufacturing deutschland gmbh - germania	Viiv healthcare bv - olanda
J05AX09	Celsentri 300 mg	maravirocum	Tablets 180 x 300mg	Pfizer manufacturing deutschland gmbh - germania	Viiv healthcare bv - olanda
J05AX09	Celsentri 300 mg	maravirocum	Tablets 30 x 300mg	Pfizer manufacturing deutschland gmbh - germania	Viiv healthcare bv - olanda
J05AX09	Celsentri 300 mg	maravirocum	Tablets 60 x 300mg	Pfizer manufacturing deutschland gmbh - germania	Viiv healthcare bv - olanda
J05AX09	Celsentri 300 mg	maravirocum	Tablets 90 x 300mg	Pfizer manufacturing deutschland gmbh - germania	Viiv healthcare bv - olanda
J05AX09	Celsentri 300 mg	maravirocum	Tablets 180 x 300mg	Pfizer manufacturing deutschland gmbh - germania	Viiv healthcare bv - olanda
J05AX09	Celsentri 75 mg	maravirocum	Tablets 120 x 75mg	Pfizer manufacturing deutschland gmbh - germania	Viiv healthcare bv - olanda
J05AR01	Combivir 150 mg/300 mg	combinatii (lamivudinum+ zidovudinum)	Tablets 10 x 150mg/300mg	Glaxo wellcome operations ltd. - marea britanie	Viiv healthcare bv - olanda
J05AR01	Combivir 150 mg/300 mg	combinatii (lamivudinum+ zidovudinum)	Tablets 60 x 150mg/300mg	Glaxo wellcome operations ltd. - marea britanie	Viiv healthcare bv - olanda
J05AE10	Darunavir alvogen 400 mg	darunavirum	Tablets 60 x 400mg	Alvogen malta operations (row) limited - malta	Alvogen malta operations (row) limited - malta
J05AE10	Darunavir alvogen 600 mg	darunavirum	Tablets 60 x 600mg	Alvogen malta operations (row) limited - malta	Alvogen malta operations (row) limited - malta
J05AE10	Darunavir alvogen 800 mg	darunavirum	Tablets 30 x 800mg	Alvogen malta operations (row) limited - malta	Alvogen malta operations (row) limited - malta
J05AE10	Darunavir flomi 400 mg	darunavirum	Tablets 60 x 400mg	Pharmathen s.a - grecia	Flomi farma s.r.l. - romania
J05AE10	Darunavir flomi 600 mg	darunavirum	Tablets 60 x 600mg	Pharmathen s.a - grecia	Flomi farma s.r.l. - romania
J05AE10	Darunavir flomi 800 mg	darunavirum	Tablets 60 x 800mg	Pharmathen s.a - grecia	Flomi farma s.r.l. - romania
J05AE10	Darunavir flomi 800 mg	darunavirum	Tablets 60 x 800mg	Pharmathen s.a - grecia	Flomi farma s.r.l. - romania

ATC Code	Name	INN	Form, quantity in packing and dosage	Producer	License holder
J05AE10	Darunavir krka 400 mg	darunavirum	Tablets 30 x 400mg	Krka, d.d., novo mesto - slovenia	Krka, d.d., novo mesto - slovenia
J05AE10	Darunavir krka 600 mg	darunavirum	Tablets 30 x 600mg	Krka, d.d., novo mesto - slovenia	Krka, d.d., novo mesto - slovenia
J05AE10	Darunavir krka 800 mg	darunavirum	Tablets 30 x 800mg	Krka, d.d., novo mesto - slovenia	Krka, d.d., novo mesto - slovenia
J05AE10	Darunavir mylan 600 mg	darunavirum	Tablets 60 x 600mg	Mylan hungary kft - ungaria	Mylan s.a.s. - franta
J05AE10	Darunavir mylan 800 mg	darunavirum	Tablets 30 x 800mg	Mylan hungary kft - ungaria	Mylan s.a.s. - franta
J05AE10	Darunavir sandoz 400 mg	darunavirum	Tablets 10 x 400mg	Lek pharmaceuticals d.d. - slovenia	Sandoz s.r.l. - romania
J05AE10	Darunavir sandoz 400 mg	darunavirum	Tablets 30 x 400mg	Lek pharmaceuticals d.d. - slovenia	Sandoz s.r.l. - romania
J05AE10	Darunavir sandoz 400 mg	darunavirum	Tablets 60 x 400mg	Lek pharmaceuticals d.d. - slovenia	Sandoz s.r.l. - romania
J05AE10	Darunavir sandoz 400 mg	darunavirum	Tablets 90 x 400mg	Lek pharmaceuticals d.d. - slovenia	Sandoz s.r.l. - romania
J05AE10	Darunavir sandoz 400 mg	darunavirum	Tablets 120 x 400mg	Lek pharmaceuticals d.d. - slovenia	Sandoz s.r.l. - romania
J05AE10	Darunavir sandoz 400 mg	darunavirum	Tablets 60 x 1 x 400mg	Lek pharmaceuticals d.d. - slovenia	Sandoz s.r.l. - romania
6J05AE10	Darunavir sandoz 400 mg	darunavirum	Tablets 60 x 400mg	Lek pharmaceuticals d.d. - slovenia	Sandoz s.r.l. - romania
J05AE10	Darunavir sandoz 400 mg	darunavirum	Tablets 120 x 400mg	Lek pharmaceuticals d.d. - slovenia	Sandoz s.r.l. - romania
J05AE10	Darunavir sandoz 600 mg	darunavirum	Tablets 10 x 600mg	Lek pharmaceuticals d.d. - slovenia	Sandoz s.r.l. - romania
J05AE10	Darunavir sandoz 600 mg	darunavirum	Tablets 30 x 600mg	Lek pharmaceuticals d.d. - slovenia	Sandoz s.r.l. - romania
J05AE10	Darunavir sandoz 600 mg	darunavirum	Tablets 60 x 600mg	Lek pharmaceuticals d.d. - slovenia	Sandoz s.r.l. - romania
J05AE10	Darunavir sandoz 600 mg	darunavirum	Tablets 90 x 600mg	Lek pharmaceuticals d.d. - slovenia	Sandoz s.r.l. - romania
J05AE10	Darunavir sandoz 600 mg	darunavirum	Tablets 120 x 600mg	Lek pharmaceuticals d.d. - slovenia	Sandoz s.r.l. - romania
J05AE10	Darunavir sandoz 600 mg	darunavirum	Tablets 60 x 1 x 600mg	Lek pharmaceuticals d.d. - slovenia	Sandoz s.r.l. - romania
J05AE10	Darunavir sandoz 600 mg	darunavirum	Tablets 60 x 600mg	Lek pharmaceuticals d.d. - slovenia	Sandoz s.r.l. - romania
J05AE10	Darunavir sandoz 600 mg	darunavirum	Tablets 120 x 600mg	Lek pharmaceuticals d.d. - slovenia	Sandoz s.r.l. - romania
J05AE10	Darunavir sandoz 600 mg	darunavirum	Tablets 180 x 600mg	Lek pharmaceuticals d.d. - slovenia	Sandoz s.r.l. - romania
J05AE10	Darunavir sandoz 600 mg	darunavirum	Tablets 240 x 600mg	Lek pharmaceuticals d.d. - slovenia	Sandoz s.r.l. - romania
J05AE10	Darunavir sandoz 800 mg	darunavirum	Tablets 10 x 800mg	Lek pharmaceuticals d.d. - slovenia	Sandoz s.r.l. - romania
J05AE10	Darunavir sandoz 800 mg	darunavirum	Tablets 30 x 800mg	Lek pharmaceuticals d.d. - slovenia	Sandoz s.r.l. - romania
J05AE10	Darunavir sandoz 800 mg	darunavirum	Tablets 60 x 800mg	Lek pharmaceuticals d.d. - slovenia	Sandoz s.r.l. - romania
J05AE10	Darunavir sandoz 800 mg	darunavirum	Tablets 90 x 800mg	Lek pharmaceuticals d.d. - slovenia	Sandoz s.r.l. - romania
J05AE10	Darunavir sandoz 800 mg	darunavirum	Tablets 120 x 800mg	Lek pharmaceuticals d.d. - slovenia	Sandoz s.r.l. - romania
J05AE10	Darunavir sandoz 800 mg	darunavirum	Tablets 30 x 1 x 800mg	Lek pharmaceuticals d.d. - slovenia	Sandoz s.r.l. - romania
J05AE10	Darunavir sandoz 800 mg	darunavirum	Tablets 30 x 800mg	Lek pharmaceuticals d.d. - slovenia	Sandoz s.r.l. - romania
J05AE10	Darunavir sandoz 800 mg	darunavirum	Tablets 60 x 800mg	Lek pharmaceuticals d.d. - slovenia	Sandoz s.r.l. - romania
J05AE10	Darunavir sandoz 800 mg	darunavirum	Tablets 90 x 800mg	Lek pharmaceuticals d.d. - slovenia	Sandoz s.r.l. - romania

ATC Code	Name	INN	Form, quantity in packing and dosage	Producer	License holder
J05AE10	Darunavir sandoz 800 mg	darunavirum	Tablets 120 x 800mg	Lek pharmaceuticals d.d. - slovenia	Sandoz s.r.l. - romania
J05AE10	Darunavir sandoz 800 mg	darunavirum	Tablets 240 x 800mg	Lek pharmaceuticals d.d. - slovenia	Sandoz s.r.l. - romania
J05AE10	Darunavir teva 600 mg	darunavirum	Tablets 20 x 600mg	Teva operations poland sp. Z.o.o. - polonia	Teva pharmaceuticals s.r.l. - romania
J05AE10	Darunavir teva 600 mg	darunavirum	Tablets 60 x 600mg	Teva operations poland sp. Z.o.o. - polonia	Teva pharmaceuticals s.r.l. - romania
J05AE10	Darunavir teva 600 mg	darunavirum	Tablets 200 x 600mg	Teva operations poland sp. Z.o.o. - polonia	Teva pharmaceuticals s.r.l. - romania
J05AE10	Darunavir teva 600 mg	darunavirum	Tablets 240 x 600mg	Teva operations poland sp. Z.o.o. - polonia	Teva pharmaceuticals s.r.l. - romania
J05AE10	Darunavir teva 600 mg	darunavirum	Tablets 20 x 1 x 600mg	Teva operations poland sp. Z.o.o. - polonia	Teva pharmaceuticals s.r.l. - romania
J05AE10	Darunavir teva 600 mg	darunavirum	Tablets 60 x 1 x 600mg	Teva operations poland sp. Z.o.o. - polonia	Teva pharmaceuticals s.r.l. - romania
J05AE10	Darunavir teva 600 mg	darunavirum	Tablets 200 x 1 x 600mg	Teva operations poland sp. Z.o.o. - polonia	Teva pharmaceuticals s.r.l. - romania
J05AE10	Darunavir teva 600 mg	darunavirum	Tablets 240 x 1 x 600mg	Teva operations poland sp. Z.o.o. - polonia	Teva pharmaceuticals s.r.l. - romania
J05AE10	Darunavir teva 600 mg	darunavirum	Tablets 20 x 600mg	Teva operations poland sp. Z.o.o. - polonia	Teva pharmaceuticals s.r.l. - romania
J05AE10	Darunavir teva 600 mg	darunavirum	Tablets 60 x 600mg	Teva operations poland sp. Z.o.o. - polonia	Teva pharmaceuticals s.r.l. - romania
J05AE10	Darunavir teva 600 mg	darunavirum	Tablets 200 x 600mg	Teva operations poland sp. Z.o.o. - polonia	Teva pharmaceuticals s.r.l. - romania
J05AE10	Darunavir teva 600 mg	darunavirum	Tablets 240 x 600mg	Teva operations poland sp. Z.o.o. - polonia	Teva pharmaceuticals s.r.l. - romania
J05AE10	Darunavir teva 600 mg	darunavirum	Tablets 20 x 1 x 600mg	Teva operations poland sp. Z.o.o. - polonia	Teva pharmaceuticals s.r.l. - romania
J05AE10	Darunavir teva 600 mg	darunavirum	Tablets 60 x 1 x 600mg	Teva operations poland sp. Z.o.o. - polonia	Teva pharmaceuticals s.r.l. - romania
J05AE10	Darunavir teva 600 mg	darunavirum	Tablets 200 x 1 x 600mg	Teva operations poland sp. Z.o.o. - polonia	Teva pharmaceuticals s.r.l. - romania
J05AE10	Darunavir teva 600 mg	darunavirum	Tablets 240 x 1 x 600mg	Teva operations poland sp. Z.o.o. - polonia	Teva pharmaceuticals s.r.l. - romania
J05AE10	Darunavir teva 600 mg	darunavirum	Tablets 20 x 600mg	Teva operations poland sp. Z.o.o. - polonia	Teva pharmaceuticals s.r.l. - romania
J05AE10	Darunavir teva 600 mg	darunavirum	Tablets 60 x 600mg	Teva operations poland sp. Z.o.o. - polonia	Teva pharmaceuticals s.r.l. - romania
J05AE10	Darunavir teva 600 mg	darunavirum	Tablets 200 x 600mg	Teva operations poland sp. Z.o.o. - polonia	Teva pharmaceuticals s.r.l. - romania
J05AE10	Darunavir teva 600 mg	darunavirum	Tablets 240 x 600mg	Teva operations poland sp. Z.o.o. - polonia	Teva pharmaceuticals s.r.l. - romania
J05AE10	Darunavir teva 600 mg	darunavirum	Tablets 20 x 1 x 600mg	Teva operations poland sp. Z.o.o. - polonia	Teva pharmaceuticals s.r.l. - romania
J05AE10	Darunavir teva 600 mg	darunavirum	Tablets 60 x 1 x 600mg	Teva operations poland sp. Z.o.o. - polonia	Teva pharmaceuticals s.r.l. - romania
J05AE10	Darunavir teva 600 mg	darunavirum	Tablets 200 x 1 x 600mg	Teva operations poland sp. Z.o.o. - polonia	Teva pharmaceuticals s.r.l. - romania
J05AE10	Darunavir teva 600 mg	darunavirum	Tablets 240 x 1 x 600mg	Teva operations poland sp. Z.o.o. - polonia	Teva pharmaceuticals s.r.l. - romania
J05AE10	Darunavir teva 600 mg	darunavirum	Tablets 60 x 600mg	Teva operations poland sp. Z.o.o. - polonia	Teva pharmaceuticals s.r.l. - romania
J05AE10	Darunavir teva 600 mg	darunavirum	Tablets 180 (60 x 3) x 600mg	Teva operations poland sp. Z.o.o. - polonia	Teva pharmaceuticals s.r.l. - romania
J05AE10	Darunavir teva 600 mg	darunavirum	Tablets 200 x 600mg	Teva operations poland sp. Z.o.o. - polonia	Teva pharmaceuticals s.r.l. - romania
J05AE10	Darunavir teva 800 mg	darunavirum	Tablets 10 x 800mg	Teva operations poland sp. Z.o.o - polonia	Teva b.v. - olanda
J05AE10	Darunavir teva 800 mg	darunavirum	Tablets 30 x 800mg	Teva operations poland sp. Z.o.o - polonia	Teva b.v. - olanda
J05AE10	Darunavir teva 800 mg	darunavirum	Tablets 30 x 1 x 800mg	Teva operations poland sp. Z.o.o - polonia	Teva b.v. - olanda

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J05AE10	Darunavir teva 800 mg	darunavirum	Tablets 60 x 800mg	Teva operations poland sp. Z.o.o - polonia	Teva b.v. - olanda
J05AE10	Darunavir teva 800 mg	darunavirum	Tablets 60 x 1 x 800mg	Teva operations poland sp. Z.o.o - polonia	Teva b.v. - olanda
J05AE10	Darunavir teva 800 mg	darunavirum	Tablets 90 x 800mg	Teva operations poland sp. Z.o.o - polonia	Teva b.v. - olanda
J05AE10	Darunavir teva 800 mg	darunavirum	Tablets 90 x 1 x 800mg	Teva operations poland sp. Z.o.o - polonia	Teva b.v. - olanda
J05AE10	Darunavir teva 800 mg	darunavirum	Tablets 100 x 800mg	Teva operations poland sp. Z.o.o - polonia	Teva b.v. - olanda
J05AE10	Darunavir teva 800 mg	darunavirum	Tablets 100 x 1 x 800mg	Teva operations poland sp. Z.o.o - polonia	Teva b.v. - olanda
J05AE10	Darunavir teva 800 mg	darunavirum	Tablets 30 x 800mg	Teva operations poland sp. Z.o.o - polonia	Teva b.v. - olanda
J05AE10	Darunavir teva 800 mg	darunavirum	Tablets 90 (3 x 30) x 800mg	Teva operations poland sp. Z.o.o - polonia	Teva b.v. - olanda
J05AE10	Darunavir teva 800 mg	darunavirum	Tablets 100 x 800mg	Teva operations poland sp. Z.o.o - polonia	Teva b.v. - olanda
J05AE10	Darunavir teva 800 mg	darunavirum	Tablets 30 x 800mg	Teva operations poland sp. Z.o.o - polonia	Teva b.v. - olanda
J05AE10	Darunavir teva 800 mg	darunavirum	Tablets 90 (3 x 30) x 800mg	Teva operations poland sp. Z.o.o - polonia	Teva b.v. - olanda
J05AE10	Darunavir teva 800 mg	darunavirum	Tablets 100 x 800mg	Teva operations poland sp. Z.o.o - polonia	Teva b.v. - olanda
J05AE10	Darunavir zentiva 400 mg	darunavirum	Tablets 60 x 400mg	Zentiva, k.s. - republica ceha	Zentiva, k.s. - republica ceha
J05AE10	Darunavir zentiva 600 mg	darunavirum	Tablets 60 x 600mg	Zentiva, k.s. - republica ceha	Zentiva, k.s. - republica ceha
J05AE10	Darunavir zentiva 75 mg	darunavirum	Tablets 480 x 75mg	Zentiva, k.s. - republica ceha	Zentiva, k.s. - republica ceha
J05AE10	Darunavir zentiva 800 mg	darunavirum	Tablets 30 x 800mg	Zentiva, k.s. - republica ceha	Zentiva, k.s. - republica ceha
J05AE10	Darunavir zentiva 800 mg	darunavirum	Tablets 30 x 800mg	Zentiva, k.s. - republica ceha	Zentiva, k.s. - republica ceha
J05AG24	Delstrigo 100 mg/300 mg/ 245 mg	doravirinum+ lamivudinum+ tenofovirum disoproxil	Tablets 30 x 100mg/300mg/245mg	Merck sharp & dohme b.v. - olanda	Merck sharp & dohme b.v. - olanda
J05AG24	Delstrigo 100 mg/300 mg/ 245 mg	doravirinum+ lamivudinum+ tenofovirum disoproxil	Tablets 90 (3 x 30) x 100mg/300mg/245mg	Merck sharp & dohme b.v. - olanda	Merck sharp & dohme b.v. - olanda
J05AR17	Descovy 200 mg/10 mg	emtricitabinum+ tenofovirum alafenamida	Tablets 30 x 200mg/10mg	Gilead sciences ireland uc - irlanda	Gilead sciences ireland uc - irlanda
J05AR17	Descovy 200 mg/10 mg	emtricitabinum+ tenofovirum alafenamida	Tablets 90 (3 x30) x 200mg/10mg	Gilead sciences ireland uc - irlanda	Gilead sciences ireland uc - irlanda
J05AR17	Descovy 200 mg/25 mg	emtricitabinum+ tenofovirum alafenamida	Tablets 30 x 200mg/25mg	Gilead sciences ireland uc - irlanda	Gilead sciences ireland uc - irlanda
J05AR17	Descovy 200 mg/25 mg	emtricitabinum+ tenofovirum alafenamida	Tablets 90 (3 x 30) x 200mg/25mg	Gilead sciences ireland uc - irlanda	Gilead sciences ireland uc - irlanda
J05AR25	Dovato 50 mg/300 mg	combinatii (dolutegravirum+ lamivudinum)	Tablets 30 x 50mg/300mg	Glaxo wellcome, s.a. - spania	Viiv healthcare bv - olanda
J05AR03	Dunotrisin 200 mg/245 mg	emtricitabinum+ tenofovirum disoproxil	Tablets 30 x 200mg/245mg	Remedica ltd. - cipru	Alvogen ipco s.ar.l. - luxemburg
J05AR03	Dunotrisin 200 mg/245 mg	emtricitabinum+ tenofovirum disoproxil	Tablets 30 x 200mg/245mg	Remedica ltd. - cipru	Alvogen ipco s.ar.l. - luxemburg
J05AG05	Edurant	rilpivirinum	Tablets 30 x 25mg	Janssen cilag spa - italia	Janssen-cilag international nv - belgia

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J05AR06	Efavirenz/emtricitabina/ Tenofovir disoproxil krka 600 mg/200 mg/245 mg	efavirenzum+ emtricitabinum+ tenofovirum disoproxil	Tablets 30 x 600mg/200mg/245mg	Tad pharma gmbh - germania	Krka, d.d., novo mesto - slovenia
J05AR06	Efavirenz/emtricitabina/ Tenofovir disoproxil mylan 600 mg/200 mg/245 mg	efavirenzum+ emtricitabinum+ tenofovirum disoproxil	30 x Tablets 600mg/200mg/245mg	Mcdermott lab. Ltd. T/a gerard lab. T/a mylan - irlanda	Mylan s.a.s - franta
J05AR06	Efavirenz/emtricitabina/ Tenofovir disoproxil mylan 600 mg/200 mg/245 mg	efavirenzum+ emtricitabinum+ tenofovirum disoproxil	Tablets 90 (3 x 30) x 600mg/200mg/245mg	Mcdermott lab. Ltd. T/a gerard lab. T/a mylan - irlanda	Mylan s.a.s - franta
J05AR06	Efavirenz/emtricitabina /tenofovir disoproxil zentiva 600 mg/200 mg/245 mg	efavirenzum+ emtricitabinum+ tenofovirum disoproxil	Tablets 30 x 600mg/200mg/245mg	Zentiva s.a. - romania	Zentiva, k.s. - republica ceha
J05AR03	Emtricitabina/tenofovir disoproxil accord 200 mg/ 245 mg	emtricitabinum+ tenofovirum disoproxil	Tablets 30 x 200mg/245mg	Accord healthcare polska sp. Z o.o. - marea britanie	Accord healthcare polska sp. Z o.o. - polonia
J05AR03	Emtricitabina/tenofovir disoproxil accord 200 mg/ 245 mg	emtricitabinum+ tenofovirum disoproxil	Tablets 60 x 200mg/245mg	Accord healthcare polska sp. Z o.o. - marea britanie	Accord healthcare polska sp. Z o.o. - polonia
J05AR03	Emtricitabina/tenofovir disoproxil accord 200 mg/ 245 mg	emtricitabinum+ tenofovirum disoproxil	Tablets 90 x 200mg/245mg	Accord healthcare polska sp. Z o.o. - marea britanie	Accord healthcare polska sp. Z o.o. - polonia
J05AR03	Emtricitabina/tenofovir disoproxil accord 200 mg/ 245 mg	emtricitabinum+ tenofovirum disoproxil	Tablets 30 x 1 x 200mg/245mg	Accord healthcare polska sp. Z o.o. - marea britanie	Accord healthcare polska sp. Z o.o. - polonia
J05AR03	Emtricitabina/tenofovir disoproxil accord 200 mg/ 245 mg	emtricitabinum+ tenofovirum disoproxil	Tablets 60 x 1 x 200mg/245mg	Accord healthcare polska sp. Z o.o. - marea britanie	Accord healthcare polska sp. Z o.o. - polonia
J05AR03	Emtricitabina/tenofovir disoproxil accord 200 mg/ 245 mg	emtricitabinum+ tenofovirum disoproxil	Tablets 90 x 1 x 200mg/245mg	Accord healthcare polska sp. Z o.o. - marea britanie	Accord healthcare polska sp. Z o.o. - polonia
J05AR03	Emtricitabina/tenofovir disoproxil accord 200 mg/ 245 mg	emtricitabinum+ tenofovirum disoproxil	Tablets 30 x 200mg/245mg	Accord healthcare polska sp. Z o.o. - marea britanie	Accord healthcare polska sp. Z o.o. - polonia
J05AR03	Emtricitabina/tenofovir disoproxil accord 200 mg/ 245 mg	emtricitabinum+ tenofovirum disoproxil	Tablets 90 (3 x 30) x 200mg/245mg	Accord healthcare polska sp. Z o.o. - marea britanie	Accord healthcare polska sp. Z o.o. - polonia
J05AR03	Emtricitabina/tenofovir disoproxil accordpharma 200 mg/245 mg	combinatii (emtricitabinum+ tenofovirum)	Tablets 30 x 1 x 200mg/245mg	Pharmadox healthcare ltd - malta	Accord healthcare polska sp. Z.o.o. - polonia
J05AR03	Emtricitabina/tenofovir disoproxil mylan 200 mg/ 245 mg	emtricitabinum+ tenofovirum disoproxil	Tablets 30 x 200 mg/245 mg	Mylan hungary kft. - ungaria	Mylan s.a.s - franta
J05AR03	Emtricitabina/tenofovir disoproxil sandoz 200 mg/ 245 mg	emtricitabinum+ tenofovirum disoproxil	Tablets 30 x 200mg/245mg	Pharmadox healthcare ltd. - malta	Sandoz s.r.l. - romania
J05AR03	Emtricitabina/tenofovir disoproxil sandoz 200 mg/ 245 mg	emtricitabinum+ tenofovirum disoproxil	Tablets 60 x 200mg/245mg	Pharmadox healthcare ltd. - malta	Sandoz s.r.l. - romania
J05AR03	Emtricitabina/tenofovir disoproxil sandoz 200 mg/ 245 mg	emtricitabinum+ tenofovirum disoproxil	Tablets 90 x 200mg/245mg	Pharmadox healthcare ltd. - malta	Sandoz s.r.l. - romania
J05AR03	Emtricitabina/tenofovir disoproxil sandoz 200 mg/ 245 mg	emtricitabinum+ tenofovirum disoproxil	Tablets 30 x 200mg/245mg	Pharmadox healthcare ltd. - malta	Sandoz s.r.l. - romania
J05AR03	Emtricitabina/tenofovir disoproxil sandoz 200 mg/ 245 mg	emtricitabinum+ tenofovirum disoproxil	Tablets 60 (2 x 30) x 200mg/245mg	Pharmadox healthcare ltd. - malta	Sandoz s.r.l. - romania
J05AR03	Emtricitabina/tenofovir disoproxil sandoz 200 mg/ 245 mg	emtricitabinum+ tenofovirum disoproxil	Tablets 90 (3V30) x 200mg/245mg	Pharmadox healthcare ltd. - malta	Sandoz s.r.l. - romania
J05AR03	Emtricitabina/tenofovir disoproxil teva 200 mg/ 245 mg	emtricitabinum+ tenofovirum disoproxil	Tablets 30 x 200mg/245mg	Pliva hrvatska d.o.o. (pliva croatia ltd.) - croatia	Teva pharmaceuticals s.r.l. - romania
J05AR03	Emtricitabina/tenofovir disoproxil teva 200 mg/ 245 mg	emtricitabinum+ tenofovirum disoproxil	Tablets 30 x 200mg/245mg	Pliva hrvatska d.o.o. (pliva croatia ltd.) - croatia	Teva pharmaceuticals s.r.l. - romania

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J05AR03	Emtricitabina/tenofovir disoproxil teva 200 mg/ 245 mg	emtricitabinum+ tenofovirum disoproxil	Tablets 90 x 200mg/245mg	Pliva hrvatska d.o.o. (pliva croatia ltd.) - croatia	Teva pharmaceuticals s.r.l. - romania
J05AR03	Emtricitabina/tenofovir disoproxil teva 200 mg/ 245 mg	emtricitabinum+ tenofovirum disoproxil	Tablets 30 x 200mg/245mg	Pliva hrvatska d.o.o. (pliva croatia ltd.) - croatia	Teva pharmaceuticals s.r.l. - romania
J05AR03	Emtricitabina/tenofovir disoproxil teva 200 mg/ 245 mg	emtricitabinum+ tenofovirum disoproxil	Tablets 30 x 200mg/245mg	Pliva hrvatska d.o.o. (pliva croatia ltd.) - croatia	Teva pharmaceuticals s.r.l. - romania
J05AR03	Emtricitabina/tenofovir disoproxil teva 200 mg/ 245 mg	emtricitabinum+ tenofovirum disoproxil	Tablets 90 x 200mg/245mg	Pliva hrvatska d.o.o. (pliva croatia ltd.) - croatia	Teva pharmaceuticals s.r.l. - romania
J05AR03	Emtricitabina/tenofovir disoproxil teva 200 mg/ 245 mg	emtricitabinum+ tenofovirum disoproxil	Tablets 30 x 200mg/245mg	Pliva hrvatska d.o.o. (pliva croatia ltd.) - croatia	Teva pharmaceuticals s.r.l. - romania
J05AR03	Emtricitabina/tenofovir disoproxil teva 200 mg/ 245 mg	emtricitabinum+ tenofovirum disoproxil	Tablets 90 (3 x 30) x 200mg/245mg	Pliva hrvatska d.o.o. (pliva croatia ltd.) - croatia	Teva pharmaceuticals s.r.l. - romania
J05AR03	Emtricitabina/tenofovir disoproxil teva 200 mg/ 245 mg	emtricitabinum+ tenofovirum disoproxil	Tablets 30 x 200mg/245mg	Pliva hrvatska d.o.o. (pliva croatia ltd.) - croatia	Teva pharmaceuticals s.r.l. - romania
J05AR03	Emtricitabina/tenofovir disoproxil teva 200 mg/ 245 mg	emtricitabinum+ tenofovirum disoproxil	Tablets 90 (3 x 30) x 200mg/245mg	Pliva hrvatska d.o.o. (pliva croatia ltd.) - croatia	Teva pharmaceuticals s.r.l. - romania
J05AF09	Emtriva 10mg/ml	emtricitabinum	Oral suspension 10mg/ml	Gilead science limited - irlanda	Gilead science international limited - marea britanie
J05AF09	Emtriva 200mg	emtricitabinum	Capsules 30 x 200mg	Gilead science limited - irlanda	Gilead sciences ireland uc - irlanda
J05AF09	Emtriva 200mg	emtricitabinum	Capsules 30 x 200mg	Gilead science limited - irlanda	Gilead sciences ireland uc - irlanda
J05AF05	Epivir 10mg/ml	lamivudinum	Oral suspension 10mg/ml	Aspen bad oldesloe gmbh - germania	Viiv healthcare bv - olanda
J05AF05	Epivir 150mg	lamivudinum	Tablets 60 x 150mg	Glaxo wellcome operations ltd. - marea britanie	Viiv healthcare bv - olanda
J05AF05	Epivir 150mg	lamivudinum	Tablets 60 x 150mg	Glaxo wellcome operations ltd. - marea britanie	Viiv healthcare bv - olanda
J05AF05	Epivir 300mg	lamivudinum	Tablets 30 x 300mg	Glaxo wellcome operations ltd. - marea britanie	Viiv healthcare bv - olanda
J05AF05	Epivir 300mg	lamivudinum	Tablets 30 x 300mg	Glaxo wellcome operations ltd. - marea britanie	Viiv healthcare bv - olanda
J05AR15	Evotaz 300mg/150mg	combinatii (atazanavirum+ cobicistatum)	Tablets 30 x 300mg+150mg	Bristol-myers squibb s.r.l. - italia	Bristol-myers squibb pharma eeig - marea britanie
J05AR15	Evotaz 300mg/150mg	combinatii (atazanavirum+ cobicistatum)	Tablets 90 x 300mg+150mg	Bristol-myers squibb s.r.l. - italia	Bristol-myers squibb pharma eeig - marea britanie
J05AX07	Fuzeon 90mg/ml	enfuvirtidum	Injection 90mg/ml	Roche pharma ag - germania	Roche registration ltd. - marea britanie
J05AX07	Fuzeon 90mg/ml	enfuvirtidum	Injection 90mg/ml	Roche pharma ag - germania	Roche registration ltd. - marea britanie
J05AR18	Genvoya 150 mg/150 mg/ 200 mg/10 mg	elvitegravir+ cobicistat+ emtricitabine+ tenofovir	Tablets 30 x 150mg/150mg/ 200mg/10mg	Gilead sciences ireland uc - irlanda	Gilead sciences ireland uc - irlanda
J05AR18	Genvoya 150 mg/150 mg/ 200 mg/10 mg	elvitegravir+ cobicistat+ emtricitabine+ tenofovir	Tablets 90 x 150mg/150mg/ 200mg/10mg	Gilead sciences ireland uc - irlanda	Gilead sciences ireland uc - irlanda
J05AG04	Intelence 100 mg	etravirinum	Tablets 120 x 100mg	Janssen cilag spa - italia	Janssen-cilag international nv - belgia
J05AG04	Intelence 200 mg	etravirinum	Tablets 60 x 200mg	Janssen cilag spa - italia	Janssen-cilag international nv - belgia
J05AG04	Intelence 25 mg	etravirinum	Tablets 120 x 25mg	Janssen cilag spa - italia	Janssen-cilag international nv - belgia
J05AX08	Isentress 100 mg	raltegravirum	Granules 100mg	Merck sharp & dohme b.v. - olanda	Merck sharp & dohme b.v. - olanda
J05AX08	Isentress 400 mg	raltegravirum	Tablets 60 x 400mg	Merck sharp & dohme b.v. - olanda	Merck sharp & dohme b.v. - olanda

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J05AX08	Isentress 400 mg	raltegravirum	Tablets 60 x 400mg	Merck sharp & dohme b.v. - olanda	Merck sharp & dohme b.v. - olanda
J05AX08	Isentress 600 mg	raltegravirum	Tablets 60 x 600mg	Merck sharp & dohme b.v. - olanda	Merck sharp & dohme b.v. - olanda
J05AR21	Juluca 50 mg/25 mg	combinatii (dolutegravirum+ rilpivirinum)	Tablets 30 x 50mg/25mg	Glaxo wellcome s.a. - spania	Viiv healthcare bv - olanda
J05AR10	Kaletra 200mg/50mg	lopinavirum+ ritonavirum	Tablets 120 x 200mg/50mg	Abbott gmbh & co - germania	Abbvie deutschland gmbh &co. Kg - germania
J05AR10	Kaletra 80mg/ml+20mg/ml	lopinavirum+ ritonavirum	Oral suspension 80mg/ml+20mg/ml	Abbott laboratories ltd. - marea britanie	Abbvie deutschland gmbh &co. Kg - germania
J05AR10	Kaletra 80mg/ml+20mg/ml	lopinavirum+ ritonavirum	Oral suspension 80mg/ml+20mg/ml 120 ml	Abbott laboratories ltd. - marea britanie	Abbvie deutschland gmbh &co. Kg - germania
J05AR02	Kivexa 600mg/300mg	abacavirum+ lamivudinum	Tablets 30 x 600mg/300mg	Glaxo wellcome s.a. - spania	Viiv healthcare bv - olanda
J05AR02	Kivexa 600mg/300mg	abacavirum+ lamivudinum	Tablets 90 (3 x 30) x 600mg/300mg	Glaxo wellcome s.a. - spania	Viiv healthcare bv - olanda
J05AF05	Lamivudina aurobindo 150 mg	lamivudinum	Tablets 14 x 150mg	Apl swift services (malta) limited - malta	Aurobindo pharma romania s.r.l. - romania
J05AF05	Lamivudina aurobindo 150 mg	lamivudinum	Tablets 30 x 150mg	Apl swift services (malta) limited - malta	Aurobindo pharma romania s.r.l. - romania
J05AF05	Lamivudina aurobindo 150 mg	lamivudinum	Tablets 60 x 150mg	Apl swift services (malta) limited - malta	Aurobindo pharma romania s.r.l. - romania
J05AF05	Lamivudina aurobindo 150 mg	lamivudinum	Tablets 120 x 150mg	Apl swift services (malta) limited - malta	Aurobindo pharma romania s.r.l. - romania
J05AF05	Lamivudina aurobindo 150 mg	lamivudinum	Tablets 500 x 150mg	Apl swift services (malta) limited - malta	Aurobindo pharma romania s.r.l. - romania
J05AF05	Lamivudina aurobindo 150 mg	lamivudinum	Tablets 60 x 150mg	Apl swift services (malta) limited - malta	Aurobindo pharma romania s.r.l. - romania
J05AF05	Lamivudina aurobindo 150 mg	lamivudinum	Tablets 500 x 150mg	Apl swift services (malta) limited - malta	Aurobindo pharma romania s.r.l. - romania
J05AF05	Lamivudina mylan 150 mg	lamivudinum	Tablets 30 x 150mg	Mc dermott laboratories ltd. Trading as gerard lab - irlanda	Generics (uk) ltd - marea britanie
J05AF05	Lamivudina mylan 150 mg	lamivudinum	Tablets 60 x 150mg	Mc dermott laboratories ltd. Trading as gerard lab - irlanda	Generics (uk) ltd - marea britanie
J05AF05	Lamivudina mylan 150 mg	lamivudinum	Tablets 90 x 150mg	Mc dermott laboratories ltd. Trading as gerard lab - irlanda	Generics (uk) ltd - marea britanie
J05AF05	Lamivudina mylan 150 mg	lamivudinum	Tablets 120 x 150mg	Mc dermott laboratories ltd. Trading as gerard lab - irlanda	Generics (uk) ltd - marea britanie
J05AF05	Lamivudina mylan 150 mg	lamivudinum	Tablets 30 x 150mg	Mc dermott laboratories ltd. Trading as gerard lab - irlanda	Generics (uk) ltd - marea britanie
J05AF05	Lamivudina mylan 150 mg	lamivudinum	Tablets 60 x 150mg	Mc dermott laboratories ltd. Trading as gerard lab - irlanda	Generics (uk) ltd - marea britanie
J05AF05	Lamivudina mylan 150 mg	lamivudinum	Tablets 30 x 150mg	Mc dermott laboratories ltd. Trading as gerard lab - irlanda	Generics (uk) ltd - marea britanie
J05AF05	Lamivudina mylan 150 mg	lamivudinum	Tablets 60 x 150mg	Mc dermott laboratories ltd. Trading as gerard lab - irlanda	Generics (uk) ltd - marea britanie
J05AF05	Lamivudina mylan 300 mg	lamivudinum	Tablets 30 x 300mg	Mc dermott laboratories ltd. Trading as gerard lab - irlanda	Generics (uk) ltd - marea britanie
J05AF05	Lamivudina mylan 300 mg	lamivudinum	Tablets 60 x 300mg	Mc dermott laboratories ltd. Trading as gerard lab - irlanda	Generics (uk) ltd - marea britanie
J05AF05	Lamivudina mylan 300 mg	lamivudinum	Tablets 90 x 300mg	Mc dermott laboratories ltd. Trading as gerard lab - irlanda	Generics (uk) ltd - marea britanie
J05AF05	Lamivudina mylan 300 mg	lamivudinum	Tablets 120 x 300mg	Mc dermott laboratories ltd. Trading as gerard lab - irlanda	Generics (uk) ltd - marea britanie

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J05AF05	Lamivudina mylan 300 mg	lamivudinum	Tablets 30 x 300mg	Mc dermott laboratories ltd. Trading as gerard lab - irlanda	Generics (uk) ltd - marea britanie
J05AF05	Lamivudina mylan 300 mg	lamivudinum	Tablets 60 x 300mg	Mc dermott laboratories ltd. Trading as gerard lab - irlanda	Generics (uk) ltd - marea britanie
J05AF05	Lamivudina mylan 300 mg	lamivudinum	Tablets 30 x 300mg	Mc dermott laboratories ltd. Trading as gerard lab - irlanda	Generics (uk) ltd - marea britanie
J05AF05	Lamivudina mylan 300 mg	lamivudinum	Tablets 60 x 300mg	Mc dermott laboratories ltd. Trading as gerard lab - irlanda	Generics (uk) ltd - marea britanie
J05AF05	Lamivudina teva 100 mg	lamivudinum	Tablets 28 x 100 mg	Teva pharm. Works private ltd. Company - ungaria	Teva b.v. - olanda
J05AF05	Lamivudina teva 100 mg	lamivudinum	Tablets 30 x 100 mg	Teva pharm. Works private ltd. Company - ungaria	Teva b.v. - olanda
J05AF05	Lamivudina teva 100 mg	lamivudinum	Tablets 84 x 100 mg	Teva pharm. Works private ltd. Company - ungaria	Teva b.v. - olanda
J05AF05	Lamivudina teva 100 mg	lamivudinum	Tablets 100 x 100 mg	Teva pharm. Works private ltd. Company - ungaria	Teva b.v. - olanda
J05AF05	Lamivudina teva 100 mg	lamivudinum	Tablets 60 x 100 mg	Teva pharm. Works private ltd. Company - ungaria	Teva b.v. - olanda
J05AF05	Lamivudina teva Pharma b.v. 300 mg	lamivudinum	Tablets 20 x 300 mg	Teva pharm. Works private ltd. Company - ungaria	Teva b.v. - olanda
J05AF05	Lamivudina teva Pharma b.v. 300 mg	lamivudinum	Tablets 30 x 300 mg	Teva pharm. Works private ltd. Company - ungaria	Teva b.v. - olanda
J05AF05	Lamivudina teva Pharma b.v. 300 mg	lamivudinum	Tablets 60 x 300 mg	Teva pharm. Works private ltd. Company - ungaria	Teva b.v. - olanda
J05AF05	Lamivudina teva Pharma b.v. 300 mg	lamivudinum	Tablets 90 x 300 mg	Teva pharm. Works private ltd. Company - ungaria	Teva b.v. - olanda
J05AF05	Lamivudina teva Pharma b.v. 300 mg	lamivudinum	Tablets 100 x 300 mg	Teva pharm. Works private ltd. Company - ungaria	Teva b.v. - olanda
J05AF05	Lamivudina teva Pharma b.v. 300 mg	lamivudinum	Tablets 500 x 300 mg	Teva pharm. Works private ltd. Company - ungaria	Teva b.v. - olanda
J05AF05	Lamivudina teva Pharma b.v. 300 mg	lamivudinum	Tablets 30 x 300 mg	Teva pharm. Works private ltd. Company - ungaria	Teva b.v. - olanda
J05AR12	Lamivudina/tenofovir disoproxil cipla 300 mg/ 245 mg	lamivudinum+ tenofovirum disoproxil	Tablets 30 x 300mg/245mg	Cipla (eu) limited - marea britanie	Cipla (eu) limited - marea britanie
J05AR12	Lamivudina/tenofovir disoproxil cipla 300 mg/ 245 mg	lamivudinum+ tenofovirum disoproxil	Tablets 30 x 300mg/245mg	Cipla (eu) limited - marea britanie	Cipla (eu) limited - marea britanie
J05AR12	Lamivudina/tenofovir disoproxil cipla 300 mg/ 245 mg	lamivudinum+ tenofovirum disoproxil	Tablets 30 x 300mg/245mg	Cipla (eu) limited - marea britanie	Cipla (eu) limited - marea britanie
J05AR12	Lamivudina/tenofovir disoproxil cipla 300 mg/ 245 mg	lamivudinum+ tenofovirum disoproxil	Tablets 30 x 300mg/245mg	Cipla (eu) limited - marea britanie	Cipla (eu) limited - marea britanie
J05AR01	Lamivudina/zidovudina accord 150 mg/300 mg	combinatii (lamivudinum+ zidovudinum)	Tablets 60 x 150mg/300mg	Accord healthcare limited - marea britanie	Accord healthcare polska sp. Z o.o. - polonia
J05AR01	Lamivudina/zidovudina accord 150 mg/300 mg	combinatii (lamivudinum+ zidovudinum)	Tablets 120 x 150mg/300mg	Accord healthcare limited - marea britanie	Accord healthcare polska sp. Z o.o. - polonia
J05AR01	Lamivudina/zidovudina accord 150 mg/300 mg	combinatii (lamivudinum+ zidovudinum)	Tablets 200 x 150mg/300mg	Accord healthcare limited - marea britanie	Accord healthcare polska sp. Z o.o. - polonia
J05AR01	Lamivudina/zidovudina accord 150 mg/300 mg	combinatii (lamivudinum+ zidovudinum)	Tablets 60 x 150mg/300mg	Accord healthcare limited - marea britanie	Accord healthcare polska sp. Z o.o. - polonia
J05AR01	Lamivudina/zidovudina accord 150 mg/300 mg	combinatii (lamivudinum+ zidovudinum)	Tablets 500 x 150mg/300mg	Accord healthcare limited - marea britanie	Accord healthcare polska sp. Z o.o. - polonia
J05AR01	Lamivudina/zidovudina aurobindo 150 mg/300 mg	combinatii (lamivudinum+ zidovudinum)	Tablets 60 x 150mg/300mg	Apl swift services (malta) limited - malta	Aurobindo pharma românia srl - romania
J05AR01	Lamivudina/zidovudina aurobindo 150 mg/300 mg	combinatii (lamivudinum+ zidovudinum)	Tablets 60 x 150mg/300mg	Apl swift services (malta) limited - malta	Aurobindo pharma românia srl - romania

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J05AR01	Lamivudina/zidovudina Mylan 150 mg/300 mg	combinatii (lamivudinum+ zidovudinum)	Tablets 30 x 150mg/300mg	Mc dermott laboratories ltd. Trading as gerard lab - irlanda	Mylan s.a.s. - franta
J05AR01	Lamivudina/zidovudina Mylan 150 mg/300 mg	combinatii (lamivudinum+ zidovudinum)	Tablets 60 x 150mg/300mg	Mc dermott laboratories ltd. Trading as gerard lab - irlanda	Mylan s.a.s. - franta
J05AR01	Lamivudina/zidovudina Mylan 150 mg/300 mg	combinatii (lamivudinum+ zidovudinum)	Tablets 100 x 150mg/300mg	Mc dermott laboratories ltd. Trading as gerard lab - irlanda	Mylan s.a.s. - franta
J05AR01	Lamivudina/zidovudina Mylan 150 mg/300 mg	combinatii (lamivudinum+ zidovudinum)	Tablets 200 x 150mg/300mg	Mc dermott laboratories ltd. Trading as gerard lab - irlanda	Mylan s.a.s. - franta
J05AR01	Lamivudina/zidovudina Mylan 150 mg/300 mg	combinatii (lamivudinum+ zidovudinum)	Tablets 60 x 150mg/300mg	Mc dermott laboratories ltd. Trading as gerard lab - irlanda	Mylan s.a.s. - franta
J05AR01	Lamivudina/zidovudina Mylan 150 mg/300 mg	combinatii (lamivudinum+ zidovudinum)	Tablets 60 x 150mg/300mg	Mc dermott laboratories ltd. Trading as gerard lab - irlanda	Mylan s.a.s. - franta
J05AR01	Lamivudina/zidovudina sandoz 150 mg/300 mg	combinatii (lamivudinum+ zidovudinum)	Tablets 60 x 150mg/300mg	Pharmadox healthcare ltd. - malta	Sandoz s.r.l. - romania
J05AR01	Lamivudina/zidovudina sandoz 150 mg/300 mg	combinatii (lamivudinum+ zidovudinum)	Tablets 120 x 150mg/300mg	Pharmadox healthcare ltd. - malta	Sandoz s.r.l. - romania
J05AR01	Lamivudina/zidovudina sandoz 150 mg/300 mg	combinatii (lamivudinum+ zidovudinum)	Tablets 180 x 150mg/300mg	Pharmadox healthcare ltd. - malta	Sandoz s.r.l. - romania
J05AR01	Lamivudina/zidovudina Teva	combinatii (lamivudinum+ zidovudinum)	Tablets 60 x 150mg/300mg	Teva pharm. Works private ltd. Company - ungaria	Teva b.v. - olanda
J05AR01	Lamivudina/zidovudina Teva	combinatii (lamivudinum+ zidovudinum)	Tablets 60 x 150mg/300mg	Teva pharm. Works private ltd. Company - ungaria	Teva b.v. - olanda
J05AR10	Lopinavir/ritonavir accord 200 mg/50 mg	lopinavirum+ ritonavirum	Tablets 3 x 40 x 200mg/50mg	Accord healthcare limited - marea britanie	Accord healthcare polska sp. Z o.o. - polonia
J05AR10	Lopinavir/ritonavir accord 200 mg/50 mg	lopinavirum+ ritonavirum	Tablets 60 x 200mg/50mg	Accord healthcare limited - marea britanie	Accord healthcare polska sp. Z o.o. - polonia
J05AR10	Lopinavir/ritonavir accord 200 mg/50 mg	lopinavirum+ ritonavirum	Tablets 120 x 200mg/50mg	Accord healthcare limited - marea britanie	Accord healthcare polska sp. Z o.o. - polonia
J05AR10	Lopinavir/ritonavir accord 200 mg/50 mg	lopinavirum+ ritonavirum	Tablets 120 x 200mg/50mg	Accord healthcare limited - marea britanie	Accord healthcare polska sp. Z o.o. - polonia
J05AR10	Lopinavir/ritonavir accord 200 mg/50 mg	lopinavirum+ ritonavirum	Tablets 120 x 200mg/50mg	Accord healthcare limited - marea britanie	Accord healthcare polska sp. Z o.o. - polonia
J05AR10	Lopinavir/ritonavir mylan 100 mg/25 mg	lopinavirum+ ritonavirum	Tablets 60 x 100mg/25mg	Mylan hungary kft - ungaria	Mylan s.a.s. - franta
J05AR10	Lopinavir/ritonavir mylan 100 mg/25 mg	lopinavirum+ ritonavirum	Tablets 60 x 100mg/25mg	Mylan hungary kft - ungaria	Mylan s.a.s. - franta
J05AR10	Lopinavir/ritonavir mylan 100 mg/25 mg	lopinavirum+ ritonavirum	Tablets 60 x 100mg/25mg	Mylan hungary kft - ungaria	Mylan s.a.s. - franta
J05AR10	Lopinavir/ritonavir mylan 200 mg/50 mg	lopinavirum+ ritonavirum	Tablets 120 x 200mg/50mg	Mylan hungary kft - ungaria	Mylan s.a.s. - franta
J05AR10	Lopinavir/ritonavir mylan 200 mg/50 mg	lopinavirum+ ritonavirum	Tablets 360 x 200mg/50mg	Mylan hungary kft - ungaria	Mylan s.a.s. - franta
J05AR10	Lopinavir/ritonavir mylan 200 mg/50 mg	lopinavirum+ ritonavirum	Tablets 120 x 200mg/50mg	Mylan hungary kft - ungaria	Mylan s.a.s. - franta
J05AR10	Lopinavir/ritonavir mylan 200 mg/50 mg	lopinavirum+ ritonavirum	Tablets 120 x 200mg/50mg	Mylan hungary kft - ungaria	Mylan s.a.s. - franta
J05AR10	Lopinavir/ritonavir mylan 200 mg/50 mg	lopinavirum+ ritonavirum	Tablets 120 x 200mg/50mg	Mylan hungary kft - ungaria	Mylan s.a.s. - franta
J05AR10	Lopinavir/ritonavir terapia 200mg/50 mg	lopinavirum+ ritonavirum	Tablets 120 x 200mg/50mg	Ranbaxy ireland limited - irlanda	Terapia s.a. - romania
J05AR10	Lopinavir/ritonavir terapia 200mg/50 mg	lopinavirum+ ritonavirum	Tablets 120 x 200mg/50mg	Ranbaxy ireland limited - irlanda	Terapia s.a. - romania
J05AR10	Lopinavir/ritonavir terapia 200mg/50 mg	lopinavirum+ ritonavirum	Tablets 120 x 200mg/50mg	Ranbaxy ireland limited - irlanda	Terapia s.a. - romania
J05AR10	Lopinavir/ritonavir terapia 200mg/50 mg	lopinavirum+ ritonavirum	Tablets 40 x 200mg/50mg	Ranbaxy ireland limited - irlanda	Terapia s.a. - romania

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J05AG01	Nevirapina accord 400 mg	nevirapinum	Tablets 30 x 400mg	Pharmadox healthcare ltd. - malta	Accord healthcare polska sp. Z o.o. - polonia
J05AG01	Nevirapina accord 400 mg	nevirapinum	Tablets 30 x 1 x 400mg	Pharmadox healthcare ltd. - malta	Accord healthcare polska sp. Z o.o. - polonia
J05AG01	Nevirapina accord 400 mg	nevirapinum	Tablets 90 x 1 x 400mg	Pharmadox healthcare ltd. - malta	Accord healthcare polska sp. Z o.o. - polonia
J05AG01	Nevirapina sandoz 200 mg	nevirapinum	Tablets 14 x 200mg	Pharmadox healthcare ltd. - malta	Sandoz s.r.l. - romania
J05AG01	Nevirapina sandoz 200 mg	nevirapinum	Tablets 200mg Cutie cu blist. PVC/Al x 60 Tablets	Pharmadox healthcare ltd. - malta	Sandoz s.r.l. - romania
J05AG01	Nevirapina sandoz 200 mg	nevirapinum	Tablets 120 x 200mg	Pharmadox healthcare ltd. - malta	Sandoz s.r.l. - romania
J05AG01	Nevirapina teva 200mg	nevirapinum	Tablets 60 x 200mg	Teva pharmaceuticals works private ltd. Company - ungaria	Teva b.v. - olanda
J05AG01	Nevirapina teva 200mg	nevirapinum	Tablets 120 x 200mg	Teva pharmaceuticals works private ltd. Company - ungaria	Teva b.v. - olanda
J05AG01	Nevirapina teva 200mg	nevirapinum	Tablets 60 x 200mg	Teva pharmaceuticals works private ltd. Company - ungaria	Teva b.v. - olanda
J05AG01	Nevirapina teva 200mg	nevirapinum	Tablets 120 x 200mg	Teva pharmaceuticals works private ltd. Company - ungaria	Teva b.v. - olanda
J05AE03	Norvir 100 mg	ritonavirum	Tablets 30 x 100mg	Abbott gmbh & co. Kg - germania	Abbvie deutschland gmbh & co. Kg - germania
J05AR19	Odefsey 200 mg/25 mg/ 25 mg	emtricitabinum+ rilpivirinum+ tenofovirum alafenamid	Tablets 30 x 200mg/25mg/25mg	Gilead sciences ireland uc - irlanda	Gilead sciences international ltd - marea britanie
J05AR06	Padviram 600 mg/200 mg/ 245 mg	efavirenzum+ emtricitabinum+ tenofovirum disoproxil	Tablets 30 x 600mg/200mg/245mg	Remedica ltd. - cipru	Sandoz s.r.l. - romania
J05AR06	Padviram 600 mg/200 mg/ 245 mg	efavirenzum+ emtricitabinum+ tenofovirum disoproxil	Tablets 90 (3 x 30) x 600mg/200mg/245mg	Remedica ltd. - cipru	Sandoz s.r.l. - romania
J05AG06	Pifeltro 100 mg	doravirinum	Tablets 30 x 100mg	Merck sharp & dohme b.v. - olanda	Merck sharp & dohme b.v. - olanda
J05AG06	Pifeltro 100 mg	doravirinum	Tablets 90 (3 x 30) x 100mg	Merck sharp & dohme b.v. - olanda	Merck sharp & dohme b.v. - olanda
J05AE10	Prezista 100 mg/ml	darunavirum	Oral suspension 100mg/ml	Janssen pharmaceutica n.v. - belgia	Janssen-cilag international nv - belgia
J05AE10	Prezista 150 mg	darunavirum	Tablets 240 x 150mg	Janssen-cilag s.p.a. - italia	Janssen-cilag international nv - belgia
J05AE10	Prezista 400mg	darunavirum	Tablets 60 x 400mg	Janssen-cilag spa - italia	Janssen-cilag international nv - belgia
J05AE10	Prezista 600mg	darunavirum	Tablets 60 x 600mg	Janssen-cilag spa - italia	Janssen-cilag international nv - belgia
J05AE10	Prezista 75 mg	darunavirum	Tablets 480 x 75mg	Janssen-cilag s.p.a. - italia	Janssen-cilag international nv - belgia
J05AE10	Prezista 800 mg	darunavirum	Tablets 30 x 800mg	Janssen-cilag s.p.a. - italia	Janssen-cilag international nv - belgia
J05AR02	Retrikil 600 mg/300 mg	abacavirum+ lamivudinum	Tablets 30 x 600mg/300mg	Remedica ltd - cipru	Alvogen ipco s.ar.l. - luxemburg
J05AF01	Retrovir 10 mg/ml	zidovudinum	Oral suspension 10mg/ml	Viiv healthcare trading services uk limited - irlanda	Viiv healthcare bv - olanda
J05AF01	Retrovir 10 mg/ml	zidovudinum	Oral suspension 10mg/ml	Viiv healthcare trading services uk limited - irlanda	Viiv healthcare bv - olanda
J05AF01	Retrovir 100 mg	zidovudinum	Capsules 10 x 100mg	Glaxo smithkline pharmaceuticals s.a. - polonia	Viiv healthcare bv - olanda
J05AF01	Retrovir 100 mg	zidovudinum	Capsules 100 x 100mg	Glaxo smithkline pharmaceuticals s.a. - polonia	Viiv healthcare bv - olanda

ATC Code	Name	INN	Form, quantity in packing and dosage	Producer	License holder
J05AF01	Retrovir 100 mg	zidovudinum	Capsules 100 x 100mg	Glaxo smithkline pharmaceuticals s.a. - polonia	Viiv healthcare bv - olanda
J05AE08	Reyataz 150 mg	atazanavirum	Capsules 60 x 150mg	Bristol-myers squibb - franta	Bristol-myers squibb pharma eeig - irlanda
J05AE08	Reyataz 150 mg	atazanavirum	Capsules 60 x 150mg	Bristol-myers squibb - franta	Bristol-myers squibb pharma eeig - irlanda
J05AE08	Reyataz 200 mg	atazanavirum	Capsules 60 x 200mg	Bristol-myers squibb - franta	Bristol-myers squibb pharma eeig - irlanda
J05AE08	Reyataz 200 mg	atazanavirum	Capsules 60 x 200mg	Bristol-myers squibb - franta	Bristol-myers squibb pharma eeig - irlanda
J05AE08	Reyataz 300 mg	atazanavirum	Capsules 30 x 300mg	Bristol-myers squibb - franta	Bristol-myers squibb pharma eeig - irlanda
J05AE08	Reyataz 300 mg	atazanavirum	Capsules 5 x 6 x 300mg	Bristol-myers squibb - franta	Bristol-myers squibb pharma eeig - irlanda
J05AE08	Reyataz 300 mg	atazanavirum	Capsules 30 x 300mg	Bristol-myers squibb - franta	Bristol-myers squibb pharma eeig - irlanda
J05AR14	Rezolsta 800 mg/150 mg	combinatii (darunavirum+ cobicistatum)	Tablets 30 x 800mg/150mg	Janssen-cilag spa - italia	Janssen-cilag international nv - belgia
J05AE03	Ritonavir accord 100 mg	ritonavirum	Tablets 30 x 100mg	Accord healthcare limited - marea britanie	Accord healthcare polska sp. Z o.o. - polonia
J05AE03	Ritonavir accord 100 mg	ritonavirum	Tablets 120 x 100mg	Accord healthcare limited - marea britanie	Accord healthcare polska sp. Z o.o. - polonia
J05AE03	Ritonavir mylan 100 mg	ritonavirum	Tablets 30 x 100mg	Generics uk limited - marea britanie	Mylan s.a.s. - franta
J05AE03	Ritonavir mylan 100 mg	ritonavirum	Tablets 90 x 100mg	Generics uk limited - marea britanie	Mylan s.a.s. - franta
J05AE03	Ritonavir mylan 100 mg	ritonavirum	Tablets 100 x 100mg	Generics uk limited - marea britanie	Mylan s.a.s. - franta
J05AE03	Ritonavir sandoz 100 mg	ritonavirum	Tablets 30 x 100mg	Pharmadox healthcare ltd. - malta	Sandoz s.r.l. - romania
J05AE03	Ritonavir sandoz 100 mg	ritonavirum	Tablets 60 x 100mg	Pharmadox healthcare ltd. - malta	Sandoz s.r.l. - romania
J05AE03	Ritonavir sandoz 100 mg	ritonavirum	Tablets 90 x 100mg	Pharmadox healthcare ltd. - malta	Sandoz s.r.l. - romania
J05AE03	Ritonavir sandoz 100 mg	ritonavirum	Tablets 120 x 100mg	Pharmadox healthcare ltd. - malta	Sandoz s.r.l. - romania
J05AG03	Stocrin 600 mg	efavirenzum	Tablets 30 x 600mg	Merck sharp & dohme bv - olanda	Merck sharp & dohme b.v. - olanda
J05AR22	Symtuza 800 mg/150 mg/ 200 mg/10 mg	combinatii (darunavirum+ cobicistatum+ emtricitabinum+ tenofovirum alafenamida)	Tablets 30 x 800mg/150mg/ 200mg/10mg	Janssen-cilag spa - italia	Janssen-cilag international nv - belgia
J05AE07	Telzir 700mg	fosamprenavirum	Tablets 60 x 700mg	Glaxo wellcome operations ltd. - marea britanie	Viiv healthcare bv - olanda
J05AF07	Tenofovir disoproxil accord 245 mg	tenofovirum disoproxil	Tablets 30 x 1 x 245mg	Accord healthcare limited - marea britanie	Accord healthcare polska sp. Z o.o. - polonia
J05AF07	Tenofovir disoproxil accord 245 mg	tenofovirum disoproxil	Tablets 30 x 245mg	Accord healthcare limited - marea britanie	Accord healthcare polska sp. Z o.o. - polonia
J05AF07	Tenofovir disoproxil accordpharma 245 mg	tenofovirum disoproxil	Tablets 30 x 1 x 245mg	Accord healthcare limited - marea britanie	Accord healthcare polska sp. Z o.o. - polonia
J05AF07	Tenofovir disoproxil aurobindo 245 mg	tenofovirum disoproxil	Tablets 30 x 245mg	Apl swift services (malta) limited - malta	Aurobindo pharma romania s.r.l. - romania
J05AF07	Tenofovir disoproxil aurobindo 245 mg	tenofovirum disoproxil	Tablets 30 x 245mg	Apl swift services (malta) limited - malta	Aurobindo pharma romania s.r.l. - romania
J05AF07	Tenofovir disoproxil aurobindo 245 mg	tenofovirum disoproxil	Tablets 30 x 245mg	Apl swift services (malta) limited - malta	Aurobindo pharma romania s.r.l. - romania
J05AF07	Tenofovir disoproxil aurobindo 245 mg	tenofovirum disoproxil	Tablets 90 x 245mg	Apl swift services (malta) limited - malta	Aurobindo pharma romania s.r.l. - romania
J05AF07	Tenofovir disoproxil cipla 245 mg	tenofovirum disoproxil	Tablets 30 x 245mg	Cipla (eu) limited - marea britanie	Cipla europe nv - belgia
J05AF07	Tenofovir disoproxil cipla 245 mg	tenofovirum disoproxil	Tablets 90 x 245mg	Cipla (eu) limited - marea britanie	Cipla europe nv - belgia

ATC Code	Name	INN	Form, quantity in packing and dosage	Producer	License holder
J05AF07	Tenofovir disoproxil cipla 245 mg	tenofovirum disoproxil	Tablets 30 x 245mg	Cipla (eu) limited - marea britanie	Cipla europe nv - belgia
J05AF07	Tenofovir disoproxil cipla 245 mg	tenofovirum disoproxil	Tablets 30 x 245mg	Cipla (eu) limited - marea britanie	Cipla europe nv - belgia
J05AF07	Tenofovir disoproxil Glenmark 245 mg	tenofovirum disoproxil	Tablets 30 x 245mg	Lupin (europe) limited - marea britanie	Glenmark pharmaceuticals s.r.o. - republica ceha
J05AF07	Tenofovir disoproxil Glenmark 245 mg	tenofovirum disoproxil	Tablets 90 (3 x 30) x 245mg	Lupin (europe) limited - marea britanie	Glenmark pharmaceuticals s.r.o. - republica ceha
J05AF07	Tenofovir disoproxil Mylan	tenofovirum disoproxil	Tablets 30 x 245mg	Mylan hungary kft - ungaria	Mylan s.a.s - franta
J05AF07	Tenofovir disoproxil Sandoz 245 mg	tenofovirum disoproxil	Tablets 30 x 1 x 245mg	Salutas pharma gmbh - germania	Sandoz s.r.l. - romania
J05AF07	Tenofovir disoproxil Sandoz 245 mg	tenofovirum disoproxil	Tablets 60 x 1 x 245mg	Salutas pharma gmbh - germania	Sandoz s.r.l. - romania
J05AF07	Tenofovir disoproxil Sandoz 245 mg	tenofovirum disoproxil	Tablets 90 x 1 x 245mg	Salutas pharma gmbh - germania	Sandoz s.r.l. - romania
J05AF07	Tenofovir disoproxil Sandoz 245 mg	tenofovirum disoproxil	Tablets 30 x 245mg	Salutas pharma gmbh - germania	Sandoz s.r.l. - romania
J05AF07	Tenofovir disoproxil Sandoz 245 mg	tenofovirum disoproxil	Tablets 30 x 245mg	Salutas pharma gmbh - germania	Sandoz s.r.l. - romania
J05AF07	Tenofovir disoproxil Sandoz 245 mg	tenofovirum disoproxil	Tablets 30 x 245mg	Salutas pharma gmbh - germania	Sandoz s.r.l. - romania
J05AF07	Tenofovir disoproxil Teva 245 mg	tenofovirum disoproxil	Tablets 30 x 245mg	Teva pharm. Works private ltd. Company - ungaria	Teva pharmaceuticals s.r.l. - romania
J05AF07	Tenofovir disoproxil Teva 245 mg	tenofovirum disoproxil	Tablets 30 x 245mg	Teva pharm. Works private ltd. Company - ungaria	Teva pharmaceuticals s.r.l. - romania
J05AF07	Tenofovir disoproxil Teva 245 mg	tenofovirum disoproxil	Tablets 90 x 245mg	Teva pharm. Works private ltd. Company - ungaria	Teva pharmaceuticals s.r.l. - romania
J05AF07	Tenofovir disoproxil Teva 245 mg	tenofovirum disoproxil	Tablets 90 x 1 x 245mg	Teva pharm. Works private ltd. Company - ungaria	Teva pharmaceuticals s.r.l. - romania
J05AF07	Tenofovir disoproxil Teva 245 mg	tenofovirum disoproxil	Tablets 30 x 245mg	Teva pharm. Works private ltd. Company - ungaria	Teva pharmaceuticals s.r.l. - romania
J05AF07	Tenofovir disoproxil Teva 245 mg	tenofovirum disoproxil	Tablets 30 x 1 x 245mg	Teva pharm. Works private ltd. Company - ungaria	Teva pharmaceuticals s.r.l. - romania
J05AF07	Tenofovir disoproxil Teva 245 mg	tenofovirum disoproxil	Tablets 90 x 245mg	Teva pharm. Works private ltd. Company - ungaria	Teva pharmaceuticals s.r.l. - romania
J05AF07	Tenofovir disoproxil Teva 245 mg	tenofovirum disoproxil	Tablets 90 x 1 x 245mg	Teva pharm. Works private ltd. Company - ungaria	Teva pharmaceuticals s.r.l. - romania
J05AF07	Tenofovir disoproxil Teva 245 mg	tenofovirum disoproxil	Tablets 30 x 245mg	Teva pharm. Works private ltd. Company - ungaria	Teva pharmaceuticals s.r.l. - romania
J05AF07	Tenofovir disoproxil Teva 245 mg	tenofovirum disoproxil	Tablets 30 x 1 x 245mg	Teva pharm. Works private ltd. Company - ungaria	Teva pharmaceuticals s.r.l. - romania
J05AF07	Tenofovir disoproxil Teva 245 mg	tenofovirum disoproxil	Tablets 90 x 245mg	Teva pharm. Works private ltd. Company - ungaria	Teva pharmaceuticals s.r.l. - romania
J05AF07	Tenofovir disoproxil Teva 245 mg	tenofovirum disoproxil	Tablets 90 x 1 x 245mg	Teva pharm. Works private ltd. Company - ungaria	Teva pharmaceuticals s.r.l. - romania
J05AF07	Tenofovir disoproxil Teva 245 mg	tenofovirum disoproxil	Tablets 30 x 1 x 245mg	Teva pharm. Works private ltd. Company - ungaria	Teva pharmaceuticals s.r.l. - romania
J05AF07	Tenofovir disoproxil Teva 245 mg	tenofovirum disoproxil	Tablets 90 x 1 x 245mg	Teva pharm. Works private ltd. Company - ungaria	Teva pharmaceuticals s.r.l. - romania
J05AF07	Tenofovir disoproxil Teva 245 mg	tenofovirum disoproxil	Tablets 30 x 245mg	Teva pharm. Works private ltd. Company - ungaria	Teva pharmaceuticals s.r.l. - romania
J05AF07	Tenofovir disoproxil Teva 245 mg	tenofovirum disoproxil	Tablets 30 x 245mg	Teva pharm. Works private ltd. Company - ungaria	Teva pharmaceuticals s.r.l. - romania
J05AF07	Tenofovir disoproxil Teva 245 mg	tenofovirum disoproxil	Tablets 30 x 245mg	Teva pharm. Works private ltd. Company - ungaria	Teva pharmaceuticals s.r.l. - romania
J05AF07	Tenofovir disoproxil Teva 245 mg	tenofovirum disoproxil	Tablets 30 x 245mg	Teva pharm. Works private ltd. Company - ungaria	Teva pharmaceuticals s.r.l. - romania
J05AF07	Tenofovir disoproxil Zentiva 245 mg	tenofovirum disoproxil	Tablets 30 x 245 mg	Zentiva s.a. - romania	Zentiva, k.s. - republica ceha
J05AF07	Tenofovir stada 245 mg	tenofovirum disoproxil	Tablets 30 x 245mg	Stada arzneimittel ag - austria	Stada m&d srl - romania

ATC Code	Name	INN	Form, quantity in packing and dosage	Producer	License holder
J05AF07	Tenofovir stada 245 mg	tenofovirum disoproxil	Tablets 90 (3 x 30) x 245mg	Stada arzneimittel ag - austria	Stada m&d srl - romania
J05AX12	Tivicay 10 mg	dolutegravirum	Tablets 30 x 10mg	Glaxo wellcome, s.a. - spania	Viiv healthcare bv - olanda
J05AX12	Tivicay 10 mg	dolutegravirum	Tablets 90 x 10mg	Glaxo wellcome, s.a. - spania	Viiv healthcare bv - olanda
J05AX12	Tivicay 25 mg	dolutegravirum	Tablets 30 x 25mg	Glaxo wellcome, s.a. - spania	Viiv healthcare bv - olanda
J05AX12	Tivicay 25 mg	dolutegravirum	Tablets 90 x 25mg	Glaxo wellcome, s.a. - spania	Viiv healthcare bv - olanda
J05AX12	Tivicay 50 mg	dolutegravirum	Tablets 30 x 50mg	Glaxo wellcome s.a. - spania	Viiv healthcare bv - olanda
J05AR13	Triumeq 50 mg/600 mg/ 300mg	combinatii (dolutegravirum+ abacavirum+ lamivudinum)	Tablets 30 x 50mg/600mg/300mg	Glaxo wellcome, s.a. - spania	Viiv healthcare bv - olanda
J05AR13	Triumeq 50 mg/600 mg/ 300mg	combinatii (dolutegravirum+ abacavirum+ lamivudinum)	Tablets 90 x 50mg/600mg/300mg	Glaxo wellcome, s.a. - spania	Viiv healthcare bv - olanda
J05AR04	Trizivir 300mg/150mg/ 300mg	abacavirum+ lamivudinum+ zidovudinum	Tablets 60 x 300mg/150mg/300mg)	Glaxo wellcome operations u.k. ltd. - marea britanie	Viiv healthcare bv - olanda
J05AR04	Trizivir 300mg/150mg/ 300mg	abacavirum+ lamivudinum+ zidovudinum	Tablets 60 x 300mg/150mg/300mg	Glaxo wellcome operations u.k. ltd. - marea britanie	Viiv healthcare bv - olanda
J05AF13	Vemlidy 25 mg	tenofovirum alafenamida	Tablets 30 x 25mg	Gilead sciences ireland uc - irlanda	Gilead sciences ireland uc - irlanda
J05AG01	Viramune 400mg	nevirapinum	Tablets 30 x 400mg	Boehringer ingelheim pharma gmbh & co. Kg - germania	Boehringer ingelheim international gmbh - germania
J05AG01	Viramune 400mg	nevirapinum	Tablets 30 x 400mg	Boehringer ingelheim pharma gmbh & co. Kg - germania	Boehringer ingelheim international gmbh - germania
J05AG01	Viramune 400mg	nevirapinum	Tablets 90 x 400mg	Boehringer ingelheim pharma gmbh & co. Kg - germania	Boehringer ingelheim international gmbh - germania
J05AG01	Viramune 50mg	nevirapinum	Tablets 180 x 50mg	Boehringer ingelheim pharma gmbh & co. Kg - germania	Boehringer ingelheim international gmbh - germania
J05AG01	Viramune 50mg/ml	nevirapinum	Oral suspension 50mg/5ml	Boehringer ingelheim pharma gmbh & co. Kg - germania	Boehringer ingelheim int. Gmbh - germania
J05AF07	Viread 245mg	tenofovirum disoproxil	Tablets 30 x 245mg	Altana pharma oranienburg gmbh - germania	Gilead science international limited - marea britanie
J05AF07	Viread 245mg	tenofovirum disoproxil	Tablets 30 x 245mg	Altana pharma oranienburg gmbh - germania	Gilead science international limited - marea britanie
J05AF07	Virofob 245 mg	tenofovirum disoproxil	Tablets 30 x 245mg	Remedica ltd. - cipru	Alvogen ipco s.ar.l. - luxemburg
J05AF07	Virofob 245 mg	tenofovirum disoproxil	Tablets 30 x 245mg	Remedica ltd. - cipru	Alvogen ipco s.ar.l. - luxemburg
J05AF05	Zeffix 100 mg	lamivudinum	Tablets 28 x 100mg	Glaxo wellcome operations ltd. - marea britanie	Glaxosmithkline (ireland) limited - irlanda
J05AF05	Zeffix 100 mg	lamivudinum	Tablets 84 x 100mg	Glaxo wellcome operations ltd. - marea britanie	Glaxosmithkline (ireland) limited - irlanda
J05AF04	Zerit 200 mg	stavudinum	Oral suspension 200mg	Bristol-myers squibb - franta	Bristol-myers squibb pharma eeig - marea britanie
J05AF04	Zerit 30 mg	stavudinum	Capsules 14 x 4 x 30mg	Bristol-myers squibb - franta	Bristol-myers squibb pharma eeig - marea britanie
J05AF04	Zerit 30 mg	stavudinum	Capsules 60 x 30mg	Bristol-myers squibb - franta	Bristol-myers squibb pharma eeig - marea britanie
J05AF04	Zerit 40 mg	stavudinum	Capsules 14 x 4 x 40mg	Bristol-myers squibb - franta	Bristol-myers squibb pharma eeig - marea britanie

ATC Code	Name	INN	Form, quantity in packing and dosage	Producer	License holder
J05AF04	Zerit 40 mg	stavudinum	Capsules 60 x 40mg	Bristol-myers squibb - franta	Bristol-myers squibb pharma eeig - marea britanie
J05AF06	Ziagen 20 mg/ml	abacavirum	Oral suspension 20mg/ml	Glaxo wellcome gmbh & co. Kg - germania	Viiv healthcare bv - olanda
J05AF06	Ziagen 300 mg	abacavirum	Tablets 60 x 300mg	Glaxo operations uk limited - marea britanie	Viiv healthcare bv - olanda

INN	Form and dosage	Max. quantity I of tablets/ vials, pcs.	Max cost, ex VAT		Supplier
			RON	USD	
Number of procurement notice— CN1007139 of 08.12.2018. Consumer— 4055750 Spitalul Județean de Urgență Buzău. Contract number — CAN1017167 of 13.06.2019[1].					
115. atazanavirum	Capsules 300mg	-	1768699,20	442174,80	Pharmafarm s.a. / ro 200106 Mediplus exim / ro 9311280 Farmexpert d.c.i. s.r.l. / ro 8955860
116. darunavirum	Tablets 600mg	-	1847161,95	461790,49	Mediplus exim / ro 9311280 Farmexpert d.c.i. s.r.l. / ro 8955860 Farmaceutica remedia distribution & logistics s.r.l. / 3572074
117. didanosinum 250 mg	The lot was canceled administratively.				
118. didanosinum 400 mg	The lot was canceled administratively.				
119. lopinavirum + ritonavirum 200 mg/50 mg	Tablets 200mg/50mg	-	4034680,65	1008670,16	Farmexpert d.c.i. s.r.l. / ro 8955860 Mediplus exim / ro 9311280
120. raltegravirum	Tablets 400mg	-	3872670,75	968167,69	Pharmafarm s.a. / ro 200106 Farmexpert d.c.i. s.r.l. / ro 8955860 Mediplus exim / ro 9311280
121. tenofovirum	Tablets 245mg	-	801020,25	200255,06	Fidelio farm s.r.l. / ro 15399342 Mediplus exim / ro 9311280 Farmexpert d.c.i. s.r.l. / ro 8955860
Number of procurement notice — CN1007138 of 08.12.2018. Consumer— 9524980 Institutul National de Boli Infectioase «Prof. Dr. Matei Bals». Contract number — CAN1019215 of 24.07.2019[2].					
1. darunavir 600mg	Tablets 600mg	756000	30875040,00	7718760,00	Mediplus exim / ro 9311280 Farmexpert d.c.i. s.r.l. / ro 8955860
2. efavirenz 600mg	Tablets 600mg	432000	1062720,00	265680,00	Mediplus exim / ro 9311280 Farmexpert d.c.i. s.r.l. / ro 8955860 Pharmafarm s.a. / ro 200106
3. lopinavir 80mg + ritonavir 20mg soluție 60ml	Oral solution 80mg+20mg	540	138450,60	34612,65	Mediplus exim / ro 9311280 Farmexpert d.c.i. s.r.l. / ro 8955860
4. maraviroc 300mg	Tablets 300mg	21600	980856,00	245214,00	Mediplus exim / ro 9311280 Farmexpert d.c.i. s.r.l. / ro 8955860 Pharmafarm s.a. / ro 200106
5. nevirapin 400mg	The lot was canceled administratively.				
6. nevirapin susp. orală 50mg/5ml 240ml	Oral solution 50mg/5ml	2160	228484,80	57121,20	Mediplus exim / ro 9311280 Farmexpert d.c.i. s.r.l. / ro 8955860
7. ritonavir 100mg	Tablets 100mg	1944000	6959520,00	1739880,00	Mediplus exim / ro 9311280 Farmexpert d.c.i. s.r.l. / ro 8955860
8. zidovudina 100mg	Capsules 100mg	108000	414720,00	103680,00	Mediplus exim / ro 9311280 Farmexpert d.c.i. s.r.l. / ro 8955860 Pharmafarm s.a. / ro 200106
Number of procurement notice — CN1006487 of 22.11.2018. Consumer— 4240898 Spitalul Clinic Judetean de Urgenta Sibiu. Contract number— CAN1019235 of 25.07.2019[3].					
292. dolutegravirum	Tablets 50mg	12600	1024758,00	256189,50	Mediplus exim / ro 9311280
Number of procurement notice — SCN1022050 of 24.10.2018. Consumer— 5453860 Spitalul Municipal «Dr.Alexandru Simionescu» Hunedoara. Contract number— SCNA1009150 of 29.11.2018[4].					
1.lamivudinum+ zidovudinum 150mg / 300mg	Tablets 150mg/300mg	3960	21423,60	5355,90	Mediplus exim / ro 9311280 Pharmafarm s.a. / ro 200106 Farmexpert d.c.i. s.r.l. / ro 8955860

1 https://sicap-prod.e-licitatie.ro/pub/notices/ca-notices/view-c/100073386
2 https://sicap-prod.e-licitatie.ro/pub/notices/ca-notices/view-c/100081384
3 https://sicap-prod.e-licitatie.ro/pub/notices/ca-notices/view-c/100072536
4 https://sicap-prod.e-licitatie.ro/pub/notices/ca-notices/view-rfq/100034507

INN	Form and dosage	Max. quantity l of tablets/ vials, pcs.	Max cost, ex VAT		Supplier
			RON	USD	
2. emtricitabinum 200 mg	The lot was canceled due to inappropriate offers.				
3. lamivudinum 10mg/ml sol. orala*200ml	Oral solution 10mg/ml	24	1987,68	496,92	Mediplus exim / ro 9311280 Pharmafarm s.a. / ro 200106
4. raltegravirum 400 mg	Tablets 400mg	3600	146520,00	36630,00	Farmexpert d.c.i. s.r.l. / ro 8955860 Pharmafarm s.a. / ro 200106 Farmexim s.a. / ro 335278
5. lopinavirum+ ritonavirum 200 mg/ 50mg	Tablets 200mg/50mg	7200	85248,00	21312,00	Farmexim s.a. / ro 335278 Farmexpert d.c.i. s.r.l. / ro 8955860 Mediplus exim / ro 9311280
6. abacavirum+ lamivudinum	Tablets	1260	56700,00	14175,00	Mediplus exim / ro 9311280 Farmexpert d.c.i. s.r.l. / ro 8955860 Pharmafarm s.a. / ro 200106
7. ritonavirum 100 mg	Tablets 100mg	1620	74387,16	18596,79	Farmexpert d.c.i. s.r.l. / ro 8955860 Mediplus exim / ro 9311280 Farmexim s.a. / ro 335278
8. darunavirum 400 mg	Tablets 400mg	360	9374,40	2343,60	Farmexpert d.c.i. s.r.l. / ro 8955860 Fildas trading s.r.l. / ro 4851409 Mediplus exim / ro 9311280
9. darunavirum 600 mg	Tablets 600mg	720	27943,20	6985,80	Farmexpert d.c.i. s.r.l. / ro 8955860 Mediplus exim / ro 9311280 Fildas trading s.r.l. / ro 4851409
10. zidovudinum 10 mg / ml 200 mg	Oral solution 10mg/ml	30	1335,00	333,75	Farmexim s.a. / ro 335278 Mediplus exim / ro 9311280 Pharmafarm s.a. / ro 200106
11. atazanavirum 150 mg	Capsules 150mg	180	4545,00	1136,25	Mediplus exim / ro 9311280 Farmexpert d.c.i. s.r.l. / ro 8955860 Pharmafarm s.a. / ro 200106
12. atazanavirum 300 mg	Capsules 300mg	720	33796,80	8449,20	Mediplus exim / ro 9311280 Pharmafarm s.a. / ro 200106 Farmexpert d.c.i. s.r.l. / ro 8955860
13. nevirapirum 50 mg / 5 ml	Oral solution 50mg/5ml	24	2410,56	602,64	Farmexpert d.c.i. s.r.l. / ro 8955860 Mediplus exim / ro 9311280
14. tenofovirum disoproxil fumarate 245 mg	Tablets 245mg	1260	30290,40	7572,60	Pharmafarm s.a. / ro 200106 Farmexpert d.c.i. s.r.l. / ro 8955860 Mediplus exim / ro 9311280
15. dolutegravirum 50 mg	Tablets 50mg	180	14653,80	3663,45	Mediplus exim / ro 9311280 Farmexpert d.c.i. s.r.l. / ro 8955860 Pharmafarm s.a. / ro 200106
Number of procurement notice — SCN1021932 of 24.10.2018. Consumer— 4202010 Spitalul Judetean Dr. Fogolyan Kristof Sfantu Gheorghe. Contract number— SCNA1009437 of 05.12.2018[5].					
2. dolutegravirum comprimate 50mg	Tablets 50mg	2000	162820,00	40705,00	Pharmafarm s.a. / ro 200106
3. combinatii (dolutegravirum+ abacavirum+ lamivudinum) comprimate 50mg/ 600mg/300mg	Tablets 50mg/600mg/ 300mg	1000	106790,00	26697,50	Pharmafarm s.a. / ro 200106
Number of procurement notice — CN1005062 of 11.10.2018. Consumer— 4374873 Spitalul de Urgenta Petrosani. Contract number— CAN1011736 of 30.07.2019[6].					
1. abacavirum 300 mg	Tablets 300mg	3000	40530,00	10132,50	Mediplus exim / ro 9311280 Pharmafarm s.a. / ro 200106 Farmexim s.a. / ro 335278

5 http://sicap-prod.e-licitatie.ro/pub/notices/ca-notices/view-rfq/100035972
6 http://sicap-prod.e-licitatie.ro/pub/notices/ca-notices/view-c/100082019

INN	Form and dosage	Max. quantity I of tablets/ vials, pcs.	Max cost, ex VAT		Supplier
			RON	USD	
2. abacavirum 300 mg + lamivudinum 150 mg+ zidovudina 300 mg	Tablets 300mg/150mg/300mg	3000	83730,00	20932,50	Mediplus exim / ro 9311280 Pharmafarm s.a. / ro 200106 Farmexim s.a. / ro 335278
3. abacavirum 600mg + lamivudinum 300 mg	Tablets 600mg/300mg	45000	2066400,00	516600,00	Pharmafarm s.a. / ro 200106 Farmexpert d.c.i. s.r.l. / ro 8955860 Mediplus exim / ro 9311280
4. atazanavirum 300 mg	The lot was canceled due to inappropriate offers.				
5. darunavirum 400mg	Tablets 400mg	18000	468720,00	117180,00	Farmexpert d.c.i. s.r.l. / ro 8955860 Mediplus exim / ro 9311280 Farmexim s.a. / ro 335278
6. darunavirum 600mg	Tablets 600mg	54000	2095740,00	523935,00	Farmexim s.a. / ro 335278 Mediplus exim / ro 9311280 Farmexpert d.c.i. s.r.l. / ro 8955860
7. efavirenzum 600mg	The lot was canceled due to inappropriate offers.				
8. emtricitabinum cps 200 mg	Capsules 200mg	22500	463275,00	115818,75	Romastru trading / ro 6769462
9. etravirinum x100 mg	Tablets 100mg	60000	748800,00	187200,00	Mediplus exim / ro 9311280 Farmexpert d.c.i. s.r.l. / ro 8955860 Farmexim s.a. / ro 335278
10. lamivudina+ zidovudina (combinatii) 150mg/300mg	Tablets 150mg/300mg	72000	547200,00	136800,00	Pharmafarm s.a. / ro 200106 Farmexim s.a. / ro 335278 Farmexpert d.c.i. s.r.l. / ro 8955860
11. lamivudinum 10 mg/ml	Oral solution 10mg/ml	10	828,20	207,05	Mediplus exim / ro 9311280 Pharmafarm s.a. / ro 200106 Farmexim s.a. / ro 335278
12. lamivudinum 150mg	Tablets 150mg	15000	76200,00	19050,00	Pharmafarm s.a. / ro 200106 Farmexim s.a. / ro 335278 Farmexpert d.c.i. s.r.l. / ro 8955860
13. lopinavirum+ ritonavirum 200mg/50mg	Tablets 200mg/50mg	180000	2129400,00	532350,00	Farmexim s.a. / ro 335278 Mediplus exim / ro 9311280 Farmexpert d.c.i. s.r.l. / ro 8955860
14. nevirapinum 200 mg	Tablets 200mg	3600	20340,00	5085,00	Farmexim s.a. / ro 335278
15. raltegravirum x 400 mg	Tablets 400mg	72000	2929680,00	732420,00	Farmexpert d.c.i. s.r.l. / ro 8955860 Farmexim s.a. / ro 335278 Pharmafarm s.a. / ro 200106
16. ritonavirum 100mg	Tablets 100mg	78000	248820,00	62205,00	Farmexpert d.c.i. s.r.l. / ro 8955860 Mediplus exim / ro 9311280 Farmexim s.a. / ro 335278
17. tenofovirum x 245 mg	Tablets 245mg	36000	1312200,00	328050,00	Mediplus exim / ro 9311280 Fidelio farm s.r.l. / ro 15399342 Farmexpert d.c.i. s.r.l. / ro 8955860
18. zidovudinum 100 mg	Capsules 100mg	11000	40260,00	10065,00	Mediplus exim / ro 9311280 Pharmafarm s.a. / ro 200106 Farmexim s.a. / ro 335278
19. zidovudinum solutie orala	Oral solution	10	445,00	111,25	Mediplus exim / ro 9311280 Pharmafarm s.a. / ro 200106 Farmexim s.a. / ro 335278
Number of procurement notice — CN1004649 of 29.09.2018. Consumer— 2487647 Spitalul Clinic de Boli Infectioase si Pneumoftiziologie «Dr.Victor Babes». Contract number— CAN1022589 of 05.10.2019[7].					
1. abacavirum 300mg	Tablets 300mg	1000	13500,00	3375,00	Pharmafarm s.a. / ro 200106
2. atazanavirum 150mg	Capsules 150mg	1000	25240,00	6310,00	Pharmafarm s.a. / ro 200106
3. atazanavirum 300mg	Capsules 300mg	30000	1407900,00	351975,00	Alliance healthcare romania / ro 8955860

7 http://sicap-prod.e-licitatie.ro/pub/notices/ca-notices/view-c/100093918

INN	Form and dosage	Max. quantity I of tablets/ vials, pcs.	Max cost, ex VAT		Supplier
			RON	USD	
4. abacavirum + lamivudinum + zidovudinum 300mg/150mg/300mg	Tablets 300mg/150mg/300mg	1500	41865,00	10466,25	Pharmafarm s.a. / ro 200106
5. combinatii (abacavirum + lamivudinum) 600mg/300mg	Tablets 600mg/300mg	90000	4131900,00	1032975,00	Pharmafarm s.a. / ro 200106
6. combinatii (darunavirum + cobicistatum) 800mg/150mg	Tablets 800mg/150mg	14400	1009296,00	252324,00	Mediplus exim / ro 9311280
7. combinatii (dolutegravirum + abacavirum + lamivudinum) 50mg/600mg/300mg	Tablets 50mg/600mg/300mg	36000	3844080,00	961020,00	Mediplus exim / ro 9311280
8. (elvitegravirum + cobicistatum + emtricitabinum + tenofovirum) 150mg/150mg/200mg/10mg	Tablets 150mg/150mg/ 200mg/10mg	36000	4915080,00	1228770,00	Romastru trading / ro 6769462
9. combinatii (emtricitabinum + tenofovirum) 200mg/10mg	Tablets 200mg/10mg	36000	3425040,00	856260,00	Romastru trading / ro 6769462
10. combinatii (emtricitabinum + tenofovirum) 200mg/25mg	Tablets 200mg/25mg	36000	3425040,00	856260,00	Romastru trading / ro 6769462
11. combinatii (emtricitabinum + tenofovirum) 200mg/245mg	Tablets 200mg/245mg	36000	973440,00	243360,00	Alliance healthcare romania / ro 8955860
12. combinatii (lamivudinum + zidovudinum) 150mg/300mg	Tablets 150mg/300mg	210000	930300,00	232575,00	Mediplus exim / ro 9311280
13. combinatii (lopinavirum + ritonavirum) 200mg/50mg	Tablets 200mg/50mg	240000	2839200,00	709800,00	Mediplus exim / ro 9311280
14. darunavirum 800mg	Tablets 800mg	36000	1443600,00	360900,00	Alliance healthcare romania / ro 8955860
15. darunavirum 400mg	Tablets 400mg	90000	1804500,00	451125,00	Alliance healthcare romania / ro 8955860
16. darunavirum 600mg	Tablets 600mg	60000	1801200,00	450300,00	Alliance healthcare romania / ro 8955860
17. efavirenzum 600mg	Tablets 600mg	12000	27960,00	6990,00	Mediplus exim / ro 9311280
18. emtricitabinum 200mg	Capsules 200mg	20000	411800,00	102950,00	Romastru trading / ro 6769462
19. etravirinum 200mg	Tablets 200mg	43200	1150416,00	287604,00	Mediplus exim / ro 9311280
20. etravirinum 100mg	Tablets 100mg	42000	523740,00	130935,00	Mediplus exim / ro 9311280
21. lamivudinum 150mg	The lot was canceled due to inappropriate offers.				
22. maravirocum 150mg	Tablets 150mg	1500	64695,00	16173,75	Pharmafarm s.a. / ro 200106
23. maravirocum 300mg	Tablets 300mg	1500	64695,00	16173,75	Pharmafarm s.a. / ro 200106
24. nevirapinum 200mg	Tablets 200mg	6000	33840,00	8460,00	Alliance healthcare romania / ro 8955860
25. nevirapinum 400mg	Tablets 400mg	1500	24990,00	6247,50	Alliance healthcare romania / ro 8955860
26. raltegravirum 400mg	Tablets 400mg	120000	4882800,00	1220700,00	Pharmafarm s.a. / ro 200106
27. raltegravirum 600mg	Tablets 600mg	120000	4882800,00	1220700,00	Pharmafarm s.a. / ro 200106
28. rilpivirinum 25mg	Tablets 25mg	14400	443376,00	110844,00	Alliance healthcare romania / ro 8955860
29. ritonavirum 100mg	Tablets 100mg	120000	381600,00	95400,00	Alliance healthcare romania / ro 8955860
30. tenofovirum 245mg	Tablets 245mg	24000	558240,00	139560,00	Alliance healthcare romania / ro 8955860
31. zidovudinum 100mg	Capsules 100mg	2000	7320,00	1830,00	Pharmafarm s.a. / ro 200106

Number of procurement notice — CN1004412 of 22.09.2018. Consumer— 4350505 Spitalul Judetean de Urgenta 'Sf. Pantelimon' Focsani. Contract number— CAN1008758 of 29.01.2020[8].

8 http://sicap-prod.e-licitatie.ro/pub/notices/ca-notices/view-c/100117204

INN	Form and dosage	Max. quantity I of tablets/ vials, pcs.	Max cost, ex VAT		Supplier
			RON	USD	
25. dolutegravirum 50mg	Tablets 50mg	5760	467366,40	116841,60	Pharmafarm s.a. / ro 200106
26. darunavirum 800 mg	Tablets 800mg	5400	207846,00	51961,50	Farmexim s.a. / ro 335278
27. raltegravirum 600mg	Tablets 600mg	5760	234374,40	58593,60	Pharmafarm s.a. / ro 200106
Number of procurement notice — CN1004157 of 18.09.2018. Consumer— 15113490 Spitalul Clinic de Boli Infectioase Constanta. Contract number— CAN1012483 of 06.03.2019[9].					
1. lamivudinum 150mg	The lot was canceled because procedures do not conform the legislative provisions.				
2. lamivudinum 300mg cpr film	The lot was canceled because procedures do not conform the legislative provisions.				
3. zidovudinum+ lamivudinum compr. film. 150mg/300mg	The lot was canceled because procedures do not conform the legislative provisions.				
4. abacavirum + lamivudinum compr. film. 600mg/300mg	The lot was canceled because procedures do not conform the legislative provisions.				
5. nevirapinum 400mg cps 400mg	The lot was canceled because procedures do not conform the legislative provisions.				
6. abacavirum + lamivudinum + zidovudinum compr. film. 300mg/150mg/300mg	The lot was canceled because procedures do not conform the legislative provisions.				
7. nevirapinum susp. orala 50mg/5ml-240ml	The lot was canceled because procedures do not conform the legislative provisions.				
8. tenofovirum cpr 245mg	The lot was canceled because procedures do not conform the legislative provisions.				
9. stavudinum 40mg caps.	Capsules 40mg	5376	49781,76	12445,44	PHARMAFARM S.A. / RO 200106
10. fosamprenavirum compr. film. 700mg	Tablets 700mg	14400	289152,00	72288,00	PHARMAFARM S.A. / RO 200106
11. stavudinum 30mg caps.	Capsules 30mg	53	48437,76	12109,44	FARMEXPERT D.C.I. S.R.L. / RO 8955860
12. maravirocum 150mg cpr film 150 mg	The lot was canceled because procedures do not conform the legislative provisions.				
13. lopinavirum + ritonavirum compr. film. 200mg/50mg	The lot was canceled because procedures do not conform the legislative provisions.				
14. atazanavirum caps. 300 mg	The lot was canceled because procedures do not conform the legislative provisions.				
15. efavirenzum compr. film. 600mg	The lot was canceled because procedures do not conform the legislative provisions.				
16. maravirocum 300mg cpr 300 mg 300mg	The lot was canceled because procedures do not conform the legislative provisions.				
17. zidovudinum 100mg caps. 100mg	The lot was canceled because procedures do not conform the legislative provisions.				
18. abacavirum compr. film. 300mg	The lot was canceled because procedures do not conform the legislative provisions.				
19. zidovudinum fl 200ml 1% 10mg/ml	The lot was canceled because procedures do not conform the legislative provisions.				
20. lamivudinum fl sol orala 10mg/ml-240ml	The lot was canceled because procedures do not conform the legislative provisions.				
21. abacavirum fl 240ml-20mg/ml	The lot was canceled because procedures do not conform the legislative provisions.				
22. ritonavirum cpr film 100mg	The lot was canceled because procedures do not conform the legislative provisions.				
23. emtricitabinum cps 200mg	The lot was canceled because procedures do not conform the legislative provisions.				
24. darunavirum 400mg cpr	The lot was canceled because procedures do not conform the legislative provisions.				
25. darunavirum 600mg cpr	The lot was canceled because procedures do not conform the legislative provisions.				
26. raltegravirum compr film 400mg	The lot was canceled because procedures do not conform the legislative provisions.				

9 http://sicap-prod.e-licitatie.ro/pub/notices/ca-notices/view-c/100054435

INN	Form and dosage	Max. quantity l of tablets/ vials, pcs.	Max cost, ex VAT		Supplier
			RON	USD	
27. lopinavirum + ritonavirum fl 80mg/ml/20mg/ml	The lot was canceled because procedures do not conform the legislative provisions.				
28. dolutegravirum cpr 50 mg 50mg	The lot was canceled because procedures do not conform the legislative provisions.				
29. darunavirum fl 200ml 100mg/ml	The lot was canceled because procedures do not conform the legislative provisions.				
30. etravirinum cpr 200mg	The lot was canceled because procedures do not conform the legislative provisions.				
31. rilpivirinum cpr film 25mg	The lot was canceled because procedures do not conform the legislative provisions.				
32. combinatii (dolutegravirum+ abacavirum+ lamivudinum) cpr film 50mg/ 600mg/300mg	The lot was canceled because procedures do not conform the legislative provisions.				
33. combinatii (darunavirum+ cobicistatinum) cpr film 800mg /150mg	The lot was canceled because procedures do not conform the legislative provisions.				
34. combinatii (emtricitabinum+ tenofovirum) cpr film 200mg /10mg	The lot was canceled because procedures do not conform the legislative provisions.				
35. combinatii (emtricitabinum+ tenofovirum) cpr film 200mg /25mg	The lot was canceled because procedures do not conform the legislative provisions.				
36. combinatii (elvitegravir+ cobicistat+ emtricitabine+ tenofovir) cpr film 150mg/150mg /200mg/10mg	The lot was canceled because procedures do not conform the legislative provisions.				
37. combinatii (emtricitabinum+ tenofovir disoprixil) cpr film 200mg/ 245mg	Tablets 200mg/245mg	126000	3408300,00	852075,00	FARMEXPERT D.C.I. S.R.L. / RO 8955860
38. raltegravirum cpr film 600mg	Tablets 600mg	72000	2929680,00	732420,00	PHARMAFARM S.A. / RO 200106
Number of procurement notice — CN1003896 of 08.09.2018. Consumer— 9524980 Institutul National de Boli Infectioase «Prof. Dr. Matei Bals». Contract number— CAN1007587 of 12.02.2020[10].					
1. darunavir 400mg	The lot was canceled because procedures do not conform the legislative provisions.				
Number of procurement notice — CN1003724 of 05.09.2018. Consumer— 4364594 Spitalul Universitar de Urgenta Militar Central «Dr. Carol Davila». Contract number— CAN1019448 of 20.09.2019[11].					
58. maravirocum 150mg	The lot was canceled because procedures do not conform the legislative provisions.				
59. maravirocum 300mg	The lot was canceled because procedures do not conform the legislative provisions.				
60. lamivudinum+ zidovudinum 150mg/300mg	The lot was canceled because procedures do not conform the legislative provisions.				
61. emtricitabinum 200mg	The lot was canceled because procedures do not conform the legislative provisions.				
62. emtricitabinum+ tenofovirum disoproxilum200mg/245mg	The lot was canceled because procedures do not conform the legislative provisions.				
63. etravirinum 100mg	The lot was canceled because procedures do not conform the legislative provisions.				
64. lamivudinum 150mg	The lot was canceled because procedures do not conform the legislative provisions.				
65. lamivudinum 300mg	The lot was canceled because procedures do not conform the legislative provisions.				
66. raltegravirum 400mg	The lot was canceled because procedures do not conform the legislative provisions.				
67. lopinavirum+ ritonavirum 200mg/50mg	The lot was canceled because procedures do not conform the legislative provisions.				
68. abacavirum+ lamivudinum 600mg/300mg	The lot was canceled because procedures do not conform the legislative provisions.				
69. ritonavirum 100mg	The lot was canceled because procedures do not conform the legislative provisions.				

10 http://sicap-prod.e-licitatie.ro/pub/notices/ca-notices/view-c/100119808
11 http://sicap-prod.e-licitatie.ro/pub/notices/ca-notices/view-c/100091075

INN	Form and dosage	Max. quantity I of tablets/ vials, pcs.	Max cost, ex VAT		Supplier
			RON	USD	
70. darunavirum 400mg	The lot was canceled because procedures do not conform the legislative provisions.				
71. darunavirum 600mg	The lot was canceled because procedures do not conform the legislative provisions.				
72. zidovudinum 100mg	The lot was canceled because procedures do not conform the legislative provisions.				
73. atazanavirum 300mg	The lot was canceled because procedures do not conform the legislative provisions.				
74. efavirenzum 600mg	The lot was canceled because procedures do not conform the legislative provisions.				
75. fosamprenavirum 700mg	Tablets 700mg	3000	60240,00	15060,00	Europharm holding s.a. / ro 6567900 Mediplus exim / ro 9311280 Pharmafarm s.a. / ro 200106
76. abacavirum+lamivudinum+zidovudinum 300mg/150mg/300mg	The lot was canceled because procedures do not conform the legislative provisions.				
77. tenofovirum disoproxil fumarate 245mg	The lot was canceled because procedures do not conform the legislative provisions.				
78. abacavirum 300mg	The lot was canceled because procedures do not conform the legislative provisions.				
Number of procurement notice — CN1003533 of 29.08.2018. Consumer— 4206845 Spitalului Judetean de Urgenta Targoviste. Contract number— CAN1018389 of 26.11.2019[12].					
1. abacavirum 300 mg	The lot was canceled because procedures do not conform the legislative provisions.				
2. atazanavirum 300 mg	The lot was canceled due to inappropriate offers.				
3. darunavirum 400 mg	Tablets 400mg	12960	259860,96	64965,24	Farmexpert d.c.i. s.r.l. / ro 8955860 Fildas trading s.r.l. / ro 4851409
4. darunavirum 600 mg	Tablets 600mg	21600	548596,80	137149,20	Fildas trading s.r.l. / ro 4851409
5. darunavirum+ cobicistatum 800/150 mg	The lot was canceled because procedures do not conform the legislative provisions.				
6. dolutegravirum+ abacavirum+ lamivudinum 50/600/300 mg	The lot was canceled because procedures do not conform the legislative provisions.				
7. dolutegravirum 50 mg	The lot was canceled because procedures do not conform the legislative provisions.				
8. efavirenzum 600 mg	Tablets 600mg	7200	16790,40	4197,60	Pharmafarm s.a. / ro 200106 Farmexpert d.c.i. s.r.l. / ro 8955860
9. elvitegravirum+ cobicistatum+ emtricitabinum+ tenofovirum 150/150/200/10 mg	Tablets 150mg/150mg/200mg/10mg	1800	245770,20	61442,55	Romastru trading / ro 6769462
10. emtricitabinum 200 mg	Capsules 200mg	5400	111202,20	27800,55	Romastru trading / ro 6769462 Farmexpert d.c.i. s.r.l. / ro 8955860
11. emtricitabinum + tenofovirum 200/10 mg	Tablets 200mg/10mg	5400	513783,00	128445,75	Romastru trading / ro 6769462
12. emtricitabinum + tenofovirum 200/25 mg	Tablets 200mg/25mg	1800	171261,00	42815,25	Romastru trading / ro 6769462
13. emtricitabinum+ tenofovirum disoproxil 200/245 mg	Tablets 200mg/245mg	10800	332100,00	83025,00	Farmexpert d.c.i. s.r.l. / ro 8955860 Fildas trading s.r.l. / ro 4851409
14. etravirinum 100 mg	The lot was canceled because procedures do not conform the legislative provisions.				
15. etravirinum 200 mg	Tablets 200mg	7200	191757,60	47939,40	Farmexpert d.c.i. s.r.l. / ro 8955860 Fildas trading s.r.l. / ro 4851409
16. fosamprenavirum 700 mg	The lot was canceled because procedures do not conform the legislative provisions.				
17. lamivudinum 150 mg	The lot was canceled because procedures do not conform the legislative provisions.				
18. lamivudinum sol 10 mg/ml	The lot was canceled because procedures do not conform the legislative provisions.				

12 http://sicap-prod.e-licitatie.ro/pub/notices/ca-notices/view-c/100104709

INN	Form and dosage	Max. quantity I of tablets/ vials, pcs.	Max cost, ex VAT		Supplier
			RON	USD	
19. lamivudinum+ zidovidinum 150/300 mg	Tablets 150mg/300mg	43200	191505,60	47876,40	Pharmafarm s.a. / ro 200106 Europharm holding s.a. / ro 6567900 Fildas trading s.r.l. / ro 4851409
20. lamivudinum+ abacavir+zidovidinum 150/300/300 mg	The lot was canceled because procedures do not conform the legislative provisions.				
21. lamivudinum+ abacavirum 300/600 mg	The lot was canceled because procedures do not conform the legislative provisions.				
22. lopinavir/ritonavirum 80mg/20mg	Oral solution 80mg/20mg	36	8774,50	2193,63	Fildas trading s.r.l. / ro 4851409
23. lopinavirum+ ritonavirum 200mg/50mg	Tablets 200mg/50mg	115200	1363161,60	340790,40	Farmexpert d.c.i. s.r.l. / ro 8955860 Fildas trading s.r.l. / ro 4851409
24. nevirapinum 50mg/5ml	The lot was canceled due to inappropriate offers.				
25. nevirapinum 200mg	Tablets 200mg	1440	8134,56	2033,64	Pharmafarm s.a. / ro 200106 Farmexpert d.c.i. s.r.l. / ro 8955860
26. raltegravirum 400 mg	Tablets 400mg	21600	878925,60	219731,40	Pharmafarm s.a. / ro 200106 Farmexpert d.c.i. s.r.l. / ro 8955860
27. raltegravirum 600 mg	The lot was canceled due to inappropriate offers.				
28. rilpivirinum 25 mg	Tablets 25mg	1080	33260,76	8315,19	Fildas trading s.r.l. / ro 4851409
29. ritonavirum 100 mg	Tablets 100mg	39600	126205,20	31551,30	Farmexpert d.c.i. s.r.l. / ro 8955860 Fildas trading s.r.l. / ro 4851409
30. stavudinum 30 mg	The lot was canceled administratively.				
31. tenofovirum 245 mg	Tablets 245mg	10080	234511,20	58627,80	Fildas trading s.r.l. / ro 4851409 Pharmafarm s.a. / ro 200106 Farmexpert d.c.i. S.r.l. / ro 8955860
32. zidovudinum 100 mg	The lot was canceled because procedures do not conform the legislative provisions.				
33. zidovudinum 10 mg/ml	The lot was canceled because procedures do not conform the legislative provisions.				
Number of procurement notice — CN1003520 of 28.08.2018. Consumer— 4352620 Spitalul Judetean Giurgiu. Contract number— CAN1009586 of 29.12.2018[13].					
1. lamivudinum 150 mg	Tablets 150mg	-	206993,88	51748,47	Europharm holding s.a. / ro 6567900 Pharmafarm s.a. / ro 200106 Farmexpert d.c.i. s.r.l. / ro 8955860 Mediplus exim / ro 9311280
2. lamivudinum+ zidovudinum 150/300 mg	Tablets 150mg/300mg	-	247372,56	61843,14	Mediplus exim / ro 9311280 Pharmafarm s.a. / ro 200106 Farmexpert d.c.i. s.r.l. / ro 8955860
3. abacavirum 300 mg	Tablets 300mg	-	777934,08	194483,52	Fildas trading s.r.l. / ro 4851409 Europharm holding s.a. / ro 6567900 Mediplus exim / ro 9311280
4. abacavirum+ lamivudinum 600/300 mg	Tablets 600mg/300mg	-	2810199,96	702549,99	Fildas trading s.r.l. / ro 4851409 Europharm holding s.a. / ro 6567900 Pharmafarm s.a. / ro 200106
5. lopinavirum+ ritonavirum 200/50 mg	Tablets 200mg/50mg	-	1917043,20	479260,80	Farmexim s.a. / ro 335278 Mediplus exim / ro 9311280 Fildas trading s.r.l. / ro 4851409
6. etravirinum 200 mg	Tablets 200mg	-	431459,46	107864,87	Farmexim s.a. / ro 335278 Mediplus exim / ro 9311280 Farmexpert d.c.i. s.r.l. / ro 8955860
7. raltegravirum 400 mg	Tablets 400mg	-	4455752,10	1113938,03	Farmexim s.a. / ro 335278 Mediplus exim / ro 9311280 Pharmafarm s.a. / ro 200106

13 http://sicap-prod.e-licitatie.ro/pub/notices/ca-notices/view-c/100032494

INN	Form and dosage	Max. quantity l of tablets/ vials, pcs.	Max cost, ex VAT		Supplier
			RON	USD	
8. nevirapinum 400 mg	Tablets 400mg	-	134970,30	33742,58	Fildas trading s.r.l. / ro 4851409 Farmexpert d.c.i. s.r.l. / ro 8955860 Mediplus exim / ro 9311280
9. ritonavirum 100 mg	Tablets 100mg	-	441801,36	110450,34	Farmexim s.a. / ro 335278 Mediplus exim / ro 9311280 Farmexpert d.c.i. s.r.l. / ro 8955860
10. darunavirum 600 mg	Tablets 600mg	-	3296503,44	824125,86	Farmexim s.a. / ro 335278 Fildas trading s.r.l. / ro 4851409 Farmexpert d.c.i. s.r.l. / ro 8955860
11. darunavirum 800 mg	Tablets 800mg	-	144372,60	36093,15	Fildas trading s.r.l. / ro 4851409 Farmexpert d.c.i. s.r.l. / ro 8955860 Mediplus exim / ro 9311280
12. atazanavirum 300 mg	Tablets 300mg	-	971566,92	242891,73	Fildas trading s.r.l. / ro 4851409 Farmexpert d.c.i. s.r.l. / ro 8955860 Mediplus exim / ro 9311280
13. efavirenzum 600 mg	Tablets 600mg	-	23092,74	5773,19	Farmexim s.a. / ro 335278 Mediplus exim / ro 9311280 Pharmafarm s.a. / ro 200106
14. fosamprenavirum 700 mg	Tablets 700mg	-	86762,88	21690,72	Europharm holding s.a. / ro 6567900 Pharmafarm s.a. / ro 200106 Mediplus exim / ro 9311280
15. abacavirum+ lamivudinum+ zidovudinum 300/150/300 mg	Tablets 300mg/150mg/300mg	-	80388,86	20097,22	Fildas trading s.r.l. / ro 4851409 Europharm holding s.a. / ro 6567900 Mediplus exim / ro 9311280
16. tenofovirum disoproxil fumarate 245 mg	Tablets 245mg	-	1779818,40	444954,60	Fidelio farm s.r.l. / ro 15399342 Fildas trading s.r.l. / ro 4851409 Mediplus exim / ro 9311280
17. maravirocum 150 mg	Tablets 150mg	-	465866,64	116466,66	Fildas trading s.r.l. / ro 4851409 Europharm holding s.a. / ro 6567900 Mediplus exim / ro 9311280
18. zidovudinum 100 mg	Capsules 100mg	-	18319,00	4579,75	Europharm holding s.a. / ro 6567900 Pharmafarm s.a. / ro 200106 Mediplus exim / ro 9311280
19. zidovudinum 10 mg/ml	Oral solution 10mg/ml	-	1335,00	333,75	Europharm holding s.a. / ro 6567900 Pharmafarm s.a. / ro 200106 Mediplus exim / ro 9311280
20. lamivudinum 10 mg/ml	Oral solution 10mg/ml	-	2484,60	621,15	Europharm holding s.a. / ro 6567900 Pharmafarm s.a. / ro 200106 Mediplus exim / ro 9311280
21. emtricitabinum 200mg	Capsules 200mg	-	185339,70	46334,93	Farmexim s.a. / ro 335278 Mediplus exim / ro 9311280 Fildas trading s.r.l. / ro 4851409
22. emtricitabinum/ tenofovirum 200/245mg	Tablets 200mg/245mg	-	584064,00	146016,00	Fidelio farm s.r.l. / ro 15399342 Fildas trading s.r.l. / ro 4851409 Mediplus exim / ro 9311280
Number of procurement notice — CN1003349 of 24.08.2018. Consumer— 9524980 Institutul National de Boli Infectioase «Prof. Dr. Matei Bals». Contract number— CAN1010206 of 01.08.2019[14].					
1. abacavir 300mg	Tablets 300mg	43200	583632,00	145908,00	Mediplus exim / ro 9311280 Europharm holding s.a. / ro 6567900 Pharmafarm s.a. / ro 200106
2. abacavir 300mg + lamivudina 150mg + zidovudina 300mg	Tablets 300mg/150mg/300mg	172800	4822848,00	1205712,00	Pharmafarm s.a. / ro 200106 Mediplus exim / ro 9311280 Fildas trading s.r.l. / ro 4851409

14 http://sicap-prod.e-licitatie.ro/pub/notices/ca-notices/view-c/100082818

INN	Form and dosage	Max. quantity I of tablets/ vials, pcs.	Max cost, ex VAT		Supplier
			RON	USD	
3. abacavir 600mg + lamivudina 300mg	Tablets 600mg/300mg	1188000	54552960,00	13638240,00	Fildas trading s.r.l. / ro 4851409 Mediplus exim / ro 9311280 Pharmafarm s.a. / ro 200106
4. atazanavir 300mg	Capsules 300mg	216000	10139040,00	2534760,00	Farmexpert d.c.i. s.r.l. / ro 8955860 Fildas trading s.r.l. / ro 4851409 Mediplus exim / ro 9311280
5. darunavir 400mg	Tablets 400mg	432000	11249280,00	2812320,00	Fildas trading s.r.l. / ro 4851409 Farmexpert d.c.i. s.r.l. / ro 8955860 Rubicon pharmaceuticals srl / 30099764
6. emtricitabina 200mg + tenofovir 245mg	Tablets 200mg/245mg	216000	5842800,00	1460700,00	Fildas trading s.r.l. / ro 4851409 Fidelio farm s.r.l. / ro 15399342 Farmexpert d.c.i. s.r.l. / ro 8955860
7. lamivudina 150mg	Tablets 150mg	64800	329184,00	82296,00	Pharmafarm s.a. / ro 200106 Europharm holding s.a. / ro 6567900 Farmexpert d.c.i. s.r.l. / ro 8955860
8. lamivudina 150mg + zidovudina 300mg	Tablets 150mg/300mg	1296000	10497600,00	2624400,00	Farmexpert d.c.i. s.r.l. / ro 8955860 Mediplus exim / ro 9311280 Europharm holding s.a. / ro 6567900
9. lopinavir 200mg + ritonavir 50mg	Tablets 200mg/50mg	2160000	25552800,00	6388200,00	Farmexim s.a. / ro 335278 Fildas trading s.r.l. / ro 4851409 Farmexpert d.c.i. s.r.l. / ro 8955860
10. raltegravir 400mg	Tablets 400mg	972000	39550680,00	9887670,00	Mediplus exim / ro 9311280 Pharmafarm s.a. / ro 200106 Farmexim s.a. / ro 335278
11. tenofovir 245mg	Tablets 245mg	486000	17714700,00	4428675,00	Fildas trading s.r.l. / ro 4851409 Rubicon pharmaceuticals srl / 30099764 Farmexpert d.c.i. s.r.l. / ro 8955860
12. zidovudina 10mg/ml 200ml	Oral solution 10mg/ml	2592	115344,00	28836,00	Pharmafarm s.a. / ro 200106 Mediplus exim / ro 9311280 Fildas trading s.r.l. / ro 4851409
Number of procurement notice — CN1002837 of 02.08.2018. Consumer— 4557951 Spitalul Judetan de Urgenta «Mavromati» Botosani. Contract number— CAN1007935 of 04.07.2019[15].					
1. lamivudinum cp 150 mg	Tablets 150mg	4200	16632,00	4158,00	Pharmafarm s.a. / ro 200106
2. abacavir cp 300 mg	Tablets 300mg	1920	25920,00	6480,00	Pharmafarm s.a. / ro 200106
3. abacavir+ lamivudinum cp.600/300 mg	Tablets 600mg/300mg	16800	771288,00	192822,00	Pharmafarm s.a. / ro 200106
4. zidovudinum + lamivudinum	Tablets	55680	246662,40	61665,60	Pharmafarm s.a. / ro 200106
5. abacavirum + lamivudinum+ zidovudinum cp.300/150/300	Tablets 300mg/150mg/300mg	2160	60285,60	15071,40	Pharmafarm s.a. / ro 200106
6. efavirenzum cp.film.600 mg	Tablets 600mg	7200	16776,00	4194,00	Pharmafarm s.a. / ro 200106
7. ritornavirum cps. 100 mg	Tablets 100mg	24480	77846,40	19461,60	Fildas trading s.r.l. / ro 4851409
8. lopinavirum+ ritonavirum cp.film, 200/50mg	Tablets 200mg/50mg	96360	1139938,80	284984,70	Fildas trading s.r.l. / ro 4851409
9. fosamprenavirum cp.700 mg	Tablets 700mg	1920	38553,60	9638,40	Pharmafarm s.a. / ro 200106
10. atazanavirum cps.150 mg	Capsules 150mg	8160	205958,40	51489,60	Farmexim s.a. / ro 335278
11. darunavir cp.600 mg	Tablets 600mg	15360	461107,20	115276,80	Fildas trading s.r.l. / ro 4851409
12. darunavir cp.400 mg	Tablets 400mg	2880	57744,00	14436,00	Fildas trading s.r.l. / ro 4851409
13. lamivudinum flac	Oral suspension	25	2070,50	517,63	Pharmafarm s.a. / ro 200106

15 http://sicap-prod.e-licitatie.ro/pub/notices/ca-notices/view-c/100077820

INN	Form and dosage	Max. quantity I of tablets/ vials, pcs.	Max cost, ex VAT		Supplier
			RON	USD	
14. raltegravirum cp.film. 400 mg	Tablets 400mg	16800	683592,00	170898,00	Pharmafarm s.a. / ro 200106
15. tenofovir cp.245 mg	Tablets 245mg	2400	55824,00	13956,00	Fildas trading s.r.l. / ro 4851409
16. emtricitabin cp.200 mg	Capsules 200mg	2400	49416,00	12354,00	Romastru trading / ro 6769462
17. etravirinum cp.100 mg	Tablets 100mg	7680	95769,60	23942,40	Farmexim s.a. / ro 335278
18. dolutegravir cp.50 mg	Tablets 50mg	2880	234460,80	58615,20	Pharmafarm s.a. / ro 200106
19. zidovudinum sol. orala	Oral solution	50	2225,00	556,25	Pharmafarm s.a. / ro 200106
Number of procurement notice — CN1002738 of 25.07.2018. Consumer— 9524980 Institutul National de Boli Infectioase «Prof. Dr. Matei Bals». Contract number— CAN1004469 of 08.07.2019[16].					
1. abacavir sol. orală 20mg/ml 240ml	Oral solution 20mg/ml	432	99096,48	24774,12	Fildas trading s.r.l. / ro 4851409 Europharm holding s.a. / ro 6567900 Pharmafarm s.a. / ro 200106
2. lamivudina susp. orală 10mg/ml 240ml	Oral solution 10mg/ml	1680	146546,40	36636,60	Fildas trading s.r.l. / ro 4851409 Europharm holding s.a. / ro 6567900 Pharmafarm s.a. / ro 200106
Number of procurement notice — CN1001521 of 23.06.2018. Consumer— 3627501 Spitalul de Boli infectioase si Psihiatrie Baia Mare. Contract number— CAN1004200 of 14.05.2019[17].					
84. darunavirum 400 mg	Tablets 400mg	10500	200130,00	50032,50	Farmexim s.a. / ro 335278 Farmexpert d.c.i. s.r.l. / ro 8955860 Mediplus exim / ro 9311280
85. darunavirum 600 mg	Tablets 600mg	3960	108583,20	27145,80	Farmexim s.a. / ro 335278 Farmexpert d.c.i. s.r.l. / ro 8955860 Mediplus exim / ro 9311280
86. dolutegravirum 50 mg	Tablets 50mg	3300	264759,00	66189,75	Farmexpert d.c.i. s.r.l. / ro 8955860 Europharm holding s.a. / ro 6567900 Pharmafarm s.a. / ro 200106
Number of procurement notice — CN1000348 of 14.05.2018. Consumer— 3963722 Spitalul Judeţean Satu Mare. Contract number— CAN1005049 of 12.02.2020[18].					
58. abacavirum, 300mg, compr.film	Tablets 300mg	8640	116640,00	29160,00	Mediplus exim / ro 9311280
59. abacavirum, 20mg/ml 240 ml,sol orala	Oral solution 20mg/ml	180	39204,00	9801,00	Mediplus exim / ro 9311280
60. abacavirum + lamivudinum, 600mg/300mg, compr film	Tablets 600mg/300mg	12960	594993,60	148748,40	Fildas trading s.r.l. / ro 4851409
61. abacavirum/ lamivudinum/ zidovudinum,300mg/ 150mg/300mg, compr film	Tablets 300mg/150mg/300mg	8640	241142,40	60285,60	Mediplus exim / ro 9311280
62. atazanavirum , 300mg, compr.film	Tablets 300mg	4320	202737,60	50684,40	Mediplus exim / ro 9311280
63. darunavirum, 400mg, compr film	Tablets 400mg	32400	843372,00	210843,00	Farmexpert d.c.i. s.r.l. / ro 8955860
64. darunavirum, 600mg, compr.film	Tablets 600mg	43200	1676160,00	419040,00	Farmexpert d.c.i. s.r.l. / ro 8955860
65. efavirenzum, 600mg, compr.film	Tablets 600mg	10800	25164,00	6291,00	Mediplus exim / ro 9311280
66. emtricitabinu, 200mg, caps	Capsules 200mg	21600	444744,00	111186,00	Romastru trading / ro 6769462
67. lamivudinum, 150mg, compr.film	Tablets 150 mg	21600	85536,00	21384,00	Europharm holding s.a. / ro 6567900

16 http://sicap-prod.e-licitatie.ro/pub/notices/ca-notices/view-c/100078501
17 http://sicap-prod.e-licitatie.ro/pub/notices/ca-notices/view-c/100068073
18 http://sicap-prod.e-licitatie.ro/pub/notices/ca-notices/view-c/100118739

INN	Form and dosage	Max. quantity l of tablets/ vials, pcs.	Max cost, ex VAT		Supplier
			RON	USD	
68. lamivudinum, 10mg/ml 240ml, sol. orala, flacon	Tablets 10mg/ml	180	14907,60	3726,90	Mediplus exim / ro 9311280
69. lamivudinum/ zidovudina 150mg/ 300mg, compr film	Tablets 150mg/300mg	43200	191376,00	47844,00	Farmexpert d.c.i. s.r.l. / ro 8955860
70. lopinavir/ritornavir , 80mg/ ml+20mg/ml 60ml, sol orala, flacon	Oral solution 80mg/ml, 20mg/ml	180	43871,40	10967,85	Fildas trading s.r.l. / ro 4851409
71. lopinavir/ritornavir, 200mg/50mg, compr film	Tablets 200mg/50mg	43200	511056,00	127764,00	Mediplus exim / ro 9311280
72. nevirapinum, 200mg, compr	Tablets 200mg	12960	73094,40	18273,60	Fidelio farm s.r.l. / ro 15399342
73. raltegravirum, 400mg, compr film	Tablets 400mg	43200	1757808,00	439452,00	Mediplus exim / ro 9311280
74. ritonavirum , 100mg, compr.film	Tablets 100mg	32400	103032,00	25758,00	Mediplus exim / ro 9311280
75. tenofovirum disoproxil fumarate, 245mg, compr film	Tablets 245mg	32400	753624,00	188406,00	Fildas trading s.r.l. / ro 4851409
76. zidovudinum 10mg/ml, sol orala, flacon	Oral solution 10mg/ml	180	8010,00	2002,50	Mediplus exim / ro 9311280
Number of procurement notice — CN1000152 of 02.05.2018. Consumer— 4243983 Spitalul Judetean de Urgenta Sf. Ioan cel Nou Suceava. Contract number— CAN1003022 of 14.08.2018[19].					
68. rilpivirinum 25 mg	Tablets 25mg	780	27175,20	6793,80	Mediplus exim / ro 9311280
69. combinatii (dolutegravirum+ abacavirum+lamivudinum) 50mg/600mg/300mg	Tablets 50mg/600mg/300mg	1560	183565,20	45891,30	Mediplus exim / ro 9311280
70. combinatii (darunavirum+cobicistatum) 800mg/150mg	Tablets 800mg/150mg	1560	121180,80	30295,20	Farmexpert d.c.i. s.r.l. / ro 8955860
71. combinatii (mtricitabinum+tenofovirum) 200mg/10mg	Tablets 200mg/10mg	1560	163768,80	40942,20	Romastru trading s.r.l. / ro 6769462
72. combinatii (mtricitabinum+tenofovirum) 200mg/25mg	Tablets 200mg/25mg	1560	163768,80	40942,20	Romastru trading s.r.l. / ro 6769462
73. combinatii (elvitegravir+ cobicistat+emtricitabine+ tenofovir) 150mg/150mg/200mg/10mg	Tablets 150mg/150mg/200mg/10mg	1560	234140,40	58535,10	Romastru trading s.r.l. / ro 6769462
Total			**340177375,8**	**85044343,94**	

19 http://sicap-prod.e-licitatie.ro/pub/notices/ca-notices/view-c/100006161