USE OF TRIPS FLEXIBILITIES TO INCREASE AFFORDABILITY OF TREATMENT FOR HIV, TUBERCULOSIS AND HEPATITIS C VIRUS IN MIDDLE-INCOME COUNTRIES

2021 ANNUAL REPORT OF FUNDACION GEP (January 1st to December 31st)

Name of the sub-grantee: A.O. «Positive Initiative»

Report submitted by: Cearanovski Constantin

Date of submission: 25.01.2022

SECTION I: Narrative & M&E

1. SUMMARY AND OVERALL ASSESSMENT (1 PAGE MAX)

Highlight key project milestones (<u>if there are any</u>), indicators achieved during the reporting period, (and explain any underachievement in expected milestones and indicators).

There were three key milestones during reporting period:

- 1) Submission of patent opposition on Bedaquiline;
- 2) The first draft legislative amendments were elaborated (although requiring further improvements) and AGEPI attempted (although unsuccessful) to promote them for their further consideration by public institutions.

Due to the synergies with other ongoing projects, medicines procurements for 2021 were monitored, procurement of the original medicine Truvada was stopped, and following the repeated tender a generic medicine was procured thus saving 10,071,718.20 Moldovan Leis, which were about 581,504.62 USD.¹ In addition to this, generic is going to be procured (the procurement process has not been finalised yet) for 2022, the expected saving is amounted to 4,471,602.63 Moldovan Leis, which is about 249,531.397 USD.² In total, 831,036.01 USD were saved.

Explain noteworthy (if there are any) changes in the grant's political/public health context that occurred during the reporting period.

¹ The amount in USD is calculated here and further at the average exchange rate of the National Bank of Moldova for 2020: 1 USD = 17.3201 MDL: https://www.bnm.md/en/content/official-exchange-rates

 $^{^2}$ The amount in USD is calculated here and further at the average exchange rate of the National Bank of Moldova for January 2022: 1 USD = 17.92 MDL.

The Republic of Moldova continued to be affected by COVID-19 pandemic during 2021. All this again led to the decrease in the speed of decision-making in government agencies and restrictions on holding meetings, several key staff persons in AGEPI were infected with COVID-19 and were on medical leave during 2021. All this affected the implementation of the project, but the Positive Initiative is making every possible effort to continue the project implementation remotely and conducting events online. In addition to this, Positive Initiative promoted COVID-19 vaccination and agreed with the authorities to vaccinate the staff in order of priority taking that Positive Initiative is communicating physically with a large number of beneficiaries belonging to HIV affected and other vulnerable groups.

The political sphere continued to be unstable and turbulent during 2021. Thus, early Parliamentary elections took place on 11 July 2021.3 On 06 August the new Government was invested.4 In addition to this, some personnel shifts of the heads of core agencies continued during the reporting period: the new Director General of AGEPI was appointed by the new Government On 8 September.5

Thus, the COVID-19 pandemic, periodic restriction measures, AGEPI staff illness, some personnel shifts and political turbulence postponed or extended the timeframes of the project implementation. Because of the above-described situation in the country, the implementation of programmatic activities was slower during the reporting period than expected.

Describe your key priorities for the grant in the next six months. Please indicate for which medicines you plan to file patent oppositions or push for compulsory license in upcoming 6 months.

The key priorities for 2022 as follows:

- To support further the patent opposition on Bedaquiline;
- To follow up with the AGEPI on the improvement of the draft legislative amendments on intellectual property;
- To identify one more new priority medicine, to make patent search and patents analysis with the expert in chemistry and intellectual property;
- To contribute to the elaboration of the new project application taking the achievements and challenges within the actual project cycle.

Summarize any key new opportunities you see and/or risks you see emerging and how would you address/mitigate it

Opportunities:

- Patients NGOs are supporting the patent opposition on Bedaquiline and elaboration of legislative amendments on intellectual property;
- Setting up contacts with the new Director General of AGEPI;
- Availability of the "100% LIFE" expert support in case of a need.

Risks:

³ https://www.dw.com/ru/dosrochnye-parlamentskie-vybory-v-moldove-samoe-glavnoe/a-58218153

⁴ https://gov.md/en/content/prime-minister-new-cabinet-sworn

⁵ https://agora.md/stiri/92887/un-nou-sef-la-agepi-eugeniu-rusu-numit-in-fotoliul-de-director

- Continuation of COVID-19 pandemic;
- Project's ending in the middle of 2022 while the patent opposition on Bedaquiline is ongoing in the court;
- AGEPI's lack of willingness to further improve the draft law amendments on intellectual property and integrating there TRIPS flexibilities;
- Insufficient political will to promote and approve legislative amendments.

2. PROGRAMMATIC PERFORMANCE

2.1 Output 1: Patent and Market Intelligence

What did you accomplish under Output 1? Describe any activities conducted during the reporting period. Link the narrative to programmatic results for each milestone, outcome and output indicators, i.e, explicitly list the indicator to which the narrative speaks to and explain any underachievement in expected milestones and indicators. Insist on activities with budget implication if there are any. If no reporting of programmatic results is expected for the output, please instead provide a brief narrative

1.2 Market and patent data collection, analysis and dissemination

Although the key activities under this output were performed during the previous project reporting periods, the Positive Initiative has undertaken some further follow-up and new activities:

- Bedaquiline procurement, including prices, were monitored and documented in order to keep track with the developments and to operate with the collected data where necessary;
- Briefing note on Bedaquiline procurement, including prices, was presented at the CCM Technical Working Group on Tuberculosis in order to disseminate the collected data and to inform key national actors, both public institutions and NGOs, about the related
- In October the collection and analysis of information in relation to COVID-19 vaccines was performed following the project's donor request (Annex xx6);
- More detailed data on COVID-19 vaccines in Moldova were collected, made public and periodically updated on the portal www.tender.health.7

Summarize key challenges to implementing planned activities during the reporting period. Describe changes to planned activities that you would recommend to better facilitate the achievement of planned results and any associated changes to future resource needs.

The key challenge consisted in the COVID-19 pandemic which slowed down the interaction with public institutions and experts, collection of data and decision making. Building sustainable internal capacities of the Positive Initiative in the sphere of intellectual property and patents, as well as patent examination on other priority medicines, continue to be relevant.

⁶ https://docs.google.com/document/d/1n6ehSaktCByW45mErkf4eRT3JYHWbD0e/edit

⁷ https://www.tender.health/vaccin-anti-covid-19-

[%]D0%B2%D0%B0%D0%BA%D1%86%D0%B8%D0%BD%D1%8B-

[%]D0%BF%D1%80%D0%BE%D1%82%D0%B8%D0%B2-covid-19

2.2 Output 2: Strategic Policy Dialogue and Demand Creation to create an enabling environment at national, regional and global levels

What did you accomplish under Output 2? Describe any activities conducted during the reporting period. Link the narrative to programmatic results for each milestone, outcome and output indicators, i.e, explicitly list the indicator to which the narrative speaks to and explain any underachievement in expected milestones and indicators. Insist on activities with budget implication if there are any. If no reporting of programmatic results is expected for the output, please instead provide a brief narrative describing progress.

2.1 Research on existing technical barriers to market entry of generics and TRIPS flexibilities

This output was completed under the previous project implementation period.

2.2 National Level Technical Meetings

Most of the technical meetings and consultations took place with AGEPI (see report on the Output 4 below for more details).

In addition to this, the 8-year long Intellectual Property National Strategy in Moldova expired at the end of 2020.8 This is providing the Positive Initiative with the opportunity to be involved into the elaboration of the new Intellectual Property National Strategy in Moldova thus promoting the inclusion of objectives related to the protection of public health and the implementation of TRIPS flexibilities in Moldova. By the end of the reporting period the elaboration of the new Strategy was not initiated by AGEPI or the Government. Therefore, Positive Initiative is monitoring the developments and is planning to intervene once the elaboration of the new Strategy will be announced.

Summarize key challenges to implementing planned activities during the reporting period. Describe changes to planned activities that you would recommend to better facilitate the achievement of planned results and any associated changes to future resource needs.

Not applicable taking that activities under this output were completed under the previous project implementation period.

2.3 Output 3: Remove IP Barriers

What did you accomplish under Output 3? Describe any activities conducted during the reporting period. Link the narrative to programmatic results for each milestone, outcome and output indicators, i.e, explicitly list the indicator to which the narrative speaks to and explain any underachievement in expected milestones and indicators. Insist on activities with budget implication if there are any. If no reporting of programmatic results is expected for the output, please instead provide a brief narrative describing progress.

3.1. Files patent challenges/legal interventions

1. EA 009779 81 2008.04.28;

Summarize key challenges to implementing planned activities during the reporting period. Describe changes to planned activities that you would recommend to better facilitate the achievement of planned results and any associated changes to future resource needs.

Unforeseen expenses were made in terms of the patent opposition's translation into French (52 pages of text were translated). In addition, taking the JANSSEN PHARMACEUTICA N.V. (BE) is registered in Belgium, it might make the consideration of the patent opposition longer because of the need to keep international communication with the company.

11 https://instante.justice.md/ru/agenda-

sedintelor?Instance=All&Denumire dosar=initiativa+pozitiva&Numarul cazului=&Obiectul cauzei=& Tipul dosarului=All

12 https://drive.google.com/drive/folders/1SjBTkplt-xFfwXu8Z6ww8 fe3QhnrFD

https://drive.google.com/drive/folders/1SjBTkplt-xFfwXu8Z6ww8 fe3QhnrFD

¹⁰ https://drive.google.com/drive/folders/1SjBTkplt-xFfwXu8Z6ww8 fe3QhnrFD

2.4 Output 4: Create sustainable results and generate systemic, sustainable, replicable outcomes to move the market for ARVs, DAAs and TB medicines

What did you accomplish under Output 4? Describe any activities conducted during the reporting period. Link the narrative to programmatic results for each milestone, outcome and output indicators, i.e, explicitly list the indicator to which the narrative speaks to and explain any underachievement in expected milestones and indicators. Insist on activities with budget implication if there are any. If no reporting of programmatic results is expected for the output, please instead provide a brief narrative describing progress.

4.1. Support national law and policy reform efforts for use of flexibilities

During the reporting period the Positive Initiative had actively supported the national dialogue on the use of flexibilities and on reform of the patents' related legislation.

On 23 March 2021 an online working meeting on the amendment of the legislation governing the patent rights took place. Possibility to amend the Law no. 50/2008 on the Protection of Inventions were discussed. The meeting was organized by the State Agency for Intellectual Property (AGEPI). The discussion was attended by the representatives of AGEPI, the Ministries of Health, Ministry of

https://docs.google.com/document/d/1ilcsjYKDP_rO5NcdBRNXXswRnZI3IV8S/edit?usp=sharing&ouid=102948 961197892378509&rtpof=true&sd=true

17 https://docs.google.com/presentation/d/1mwH1DqrJ8K-

qcvChZjn7mjjYBTh5ksyR/edit?usp=sharing&ouid=102948961197892378509&rtpof=true&sd=true

- ¹⁸ https://positivepeople.md/publichnoe-obsuzhdenie-izmenenij-zakonodatelistva-reguliruyuschegointellektualinuyu-sobstvennosti1/
- ¹⁹ https://www.twn.my/title2/intellectual_property/trips_waiver_proposal/CSOLetter_Dr.%20Ngozi.pdf
- ²⁰ https://positivepeople.md/strany-veca-obmenyalisi-opytom-po-zakupkam-i-postavkam-arv-preparatov/
- ²¹ https://drive.google.com/drive/folders/1zVY08S-shdMDJcDIuWQ9_hD-RFc-prWi?usp=sharing ²² https://docs.google.com/document/d/1W_wlil7dwgnipP3T5N-J2-

W0Hva7fVGQ/edit?usp=sharing&ouid=102948961197892378509&rtpof=true&sd=true

02948961197892378509&rtpof=true&sd=true

https://docs.google.com/document/d/1Byrdh_64b1tcp6AbQrYP7czbsNUxYAjc/edit?usp=sharing&ouid=102948 961197892378509&rtpof=true&sd=true

¹⁴ https://www.facebook.com/initiativapozitiva/posts/3851036891681031

¹⁵ https://www.facebook.com/initiativapozitiva/posts/3915155031935883

²⁵ https://drive.google.com/file/d/1a8zuxkmaYrpg0ok58697bfGZYfb6PLEW/view?usp=sharing

²⁶ https://drive.google.com/file/d/13mlcs8OnYlGqdOAZCNhBdlwKEzQ4LMwo/view?usp=sharing

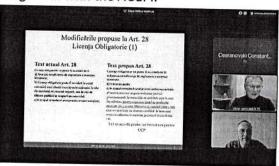
Agriculture, Ministry of Economy, Ministry of Defense and the Competition Council. Dr. Vladimir Grosu, the expert of Positive Initiative, took part in the meeting as one of the key experts in this field.¹⁴

On 15 April 2021 a meeting of the working group on the elaboration of amendments to the Law no. 50/2008 on the Protection of Inventions was held. The meeting was also attended (online) by the European expert Mr. Bojan Pretnar. The participants discussed the proposals and recommendations that were included in the draft law, and agreed on the need to change the rules regarding compulsory licenses so that Moldova could purchase more generics, which will reduce the price of purchased medicines. The representative of the Ministry of Health, Labour and Social Protection, Mr. Gheorghe Gorceag, noted that, during the pandemic, this is especially important, and that the government must have effective tools to be able to respond in situations where public health is at risk. Dr. Vladimir Grosu, the expert of the Positive Initiative, took part in the meeting and advocated for the legislative amendments drafted by the Positive Initiative.

On 16 July 2021 AGEPI submitted to the Positive Initiative a draft law¹⁶ for the amendment of the Law no. 50/2008 on the Protection of Inventions and requested the opinion of the Positive Initiative. Following the analysis of the submitted draft the Positive Initiative concluded that many of the proposals elaborated by Dr. Vladimir Grosu were not integrated into the draft. Therefore, the Positive Initiative had submitted these proposals to the AGEPI again requesting their integration into the draft law. The Positive Initiative had learned later that the AGEPI made a preliminary Impact Analysis of the draft law and submitted it to the Governmental Committee as a first step for the promotion of the draft law. However, the Committee had returned the Impact Analysis back to the AGEPI with the recommendation to improve it and to provide additional justification for the amendment of the legal framework.

In this respect, AGEPI has organised on 15 November 2021 online public hearings on the elaborated draft amendments.¹⁷ Following the analysis the Positive Initiative came to the conclusion that many of the proposals elaborated by the expert Dr. Vladimir Grosu were still not included into the draft. Therefore, the Positive Initiative took active part in the public hearings presenting there detailed proposals and discussing them with the AGEPI.¹⁸





By the end of the reporting period the Positive Initiative had learned that, following the public consultations, the AGEPI had repeatedly submitted the draft law and its Impact Analysis to the Governmental Committee and the Committee had again returned the documents back to the AGEPI for the improvement and additional justification. The Positive Initiative will use this situation for further advocate for the improvement of the draft law in 2022.

4.2. Reduce the negative impact of FTAs on use of flexibilities

In April 2021 the Positive Initiative co-signed a letter addressed to the WTO Director General on the industry controlled bilateral contract manufacturing agreements and voluntary licenses (the "Third Way") as the main approach for expanding production and supply of Covid-19 medical products.19

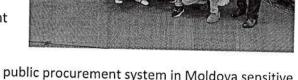
4.3. Create financial sustainability to support the IP interventions

During the reported period the Positive Initiative has organised or supported a number of events and processes aimed at national capacity building in the sustainability of medical public procurement taking into account the related financing and IP issues.

On 02 April 2021, during the online meeting of the CCM Technical Working Group on Tuberculosis meeting, it was proposed to develop a procurement mechanism for two-tier competition, as well as to include the civil society representatives in the technical working group on the procurement of anti-TB drugs and on the initiation of a patent opposition on Bedaquiline.

On 09 August 2021 facilitated the organisation in Moldova of a working meeting of the procurement authorities from Armenia, Moldova and Ukraine.²⁰ During the meeting the following key issues were discussed:21

- 1. Recommendations on procurement and supply of antiretroviral medicines in the EECA region, in particular, based on Armenia's experience and the analysis made by i-Plus Solution;
- 2. Market access for generic medicines and patent opposition;
- 3. Procurement of small quantities of medicines;
- 4. Implementation of category management approaches and principles in centralized public health procurements in Moldova;



- 5. Development of a transparent electronic public procurement system in Moldova sensitive to the needs of centralized public health procurements;
- 6. Perspectives and synergies within the development of an information system for stock management of medicines, medical products and equipment in Moldova and Ukraine.

On 15 September 2021 the Positive Initiative took part in the Regional Seminar "The Role of Patent System in dealing with Public Health Challenges"22 organised by AGEPI and WIPE for patent offices from Armenia, Belarus, Kazakhstan, Moldova, Russian Federation, Tajikistan, Uzbekistan and Ukraine. The Positive Initiative made a presentation there on the compulsory licences, access to medicines and the possibilities for the improvement of the national legal frameworks of the participating countries,23 thus advocating further for the use of TRIPS flexibilities.

At the end of September, following the proposal of the "100% Life", the Positive Initiative launched a number of actions aimed at the following:

- To start negotiations with Medicines Patent Pool in order to extent the Bedaquiline license to the territory of Moldova or by any other means to enable access to generics in Moldova;
- To reconsider price policy for Bedaquiline in Moldova in order to achieve reduction of price for the medicine;
- To take steps that would enable generics to enter Moldovan market as soon as they become available.

In this respect the Positive Initiative undertook the following:

- On 04 October a letter to the National TB Programme was submitted with the request to support the communication with the JANSSEN PHARMACEUTICA on the provision of voluntary licence for Bedaquiline in Moldova;
- On 12 October a letter to the Ministry of Health was submitted with the request to address the JANSSEN PHARMACEUTICA on the provision of voluntary licence for Bedaquiline in Moldova. More that, the Ministry was provided with the draft address to the company;²⁴
- On 29 November the Positive Initiative had repeatedly requested the Ministry of Health to address to the the JANSSEN PHARMACEUTICA on the provision of voluntary licence for Bedaquiline in Moldova;
- On 3 December the Positive Initiative received an official response from the Ministry of Health according to which the Ministry was taking steps to collect the information on the situation with Bedaquiline and was going to to request the Medicines and Medical Devices Agency to contact the JANSSEN PHARMACEUTICA;
- On 07 December the national TB Programme submitted to the Ministry of Health a letter regarding the situation with Bedaquiline in Moldova;²⁵
- On 08 December the Ministry of Health initiated online consultations on Bedaquiline in Moldova;
- On 14 December the online consultations took place with the participation of the following actors:
 - Medicines and Medical Devices Agency;
 - World Health Organisation Country Office in Moldova;
 - Centre for Centralised Public Procurement in Health;
 - IMSP Institute of Phthisiopneumology "Chiril Draganiuc";
 - National TB Program;
 - The specialised commission of the Ministry of Health in the field of phthisiopneumology;
 - NGO "Positive Initiative";
- The following decision were taken on 14 December consultations:
 - To analyse the experience of countries in the EURO/EECA region that can procure medicines through the Global Drug Facility using the public funding;
 - To consider addressing the Janssen Pharmaceutica with the request of creating conditions for the Bedaquiline price reduction.





The Positive Initiative will continue follow up advocacy on the above mentioned priorities.

Summarize key challenges to implementing planned activities during the reporting period. Describe changes to planned activities that you would recommend to better facilitate the achievement of planned results and any associated changes to future resource needs.

COVID-19 pandemic slowed down the working and decision-making processes.

Traditional way of thinking about intellectual property as a value superior to the right to health is making it harder the elaboration and promotion of the draft amendments to the intellectual property legislation.

2.5 Output 5: Amplifying visibility, coordination, effectiveness and support for the consortium's work

What did you accomplish under Output 5? Describe any activities conducted during the reporting period. Link the narrative to programmatic results for each milestone, outcome and output indicators, i.e, explicitly list the indicator to which the narrative speaks to and explain any underachievement in expected milestones and indicators. Insist on activities with budget implication if there are any. If no reporting of programmatic results is expected for the output, please instead provide a brief narrative describing progress.

5.4 Promote the work of the consortium through traditional and social media

During the reporting period the Positive Initiative had covered extensively the project activities in social media, which include the following:

- 1. Activists from Belarus, Kazakhstan and Kyrgyzstan fight for access to the TB treatment: https://www.facebook.com/initiativapozitiva/posts/3849955291789191
- Online Workshop on Changes to the Patent Laws: https://www.facebook.com/initiativapozitiva/posts/3851036891681031
- Online meeting of the TB Technical Working Group https://www.facebook.com/initiativapozitiva/posts/3887014291416624
- Ruslan Poverga on the Patent Law https://www.facebook.com/initiativapozitiva/posts/3913114158806637
- Infographic Original vs Generic https://www.facebook.com/initiativapozitiva/posts/3889854204465966
- Wheel patent comparison with the Bedaquiline Patent https://www.facebook.com/initiativapozitiva/posts/3909370015847718
- 7. International fight against one of the "evergreen" patents https://www.facebook.com/initiativapozitiva/posts/3926478267470226
- 8. Washington supports the suspension of patents that were in effect on preventive drugs for coronavirus https://www.facebook.com/initiativapozitiva/posts/3972045606246825
- O.A. "Positive Initiative" filed a claim against the pharmaceutical company JANSSEN PHARMACEUTICA N.V. in the court of the Chisinau City Center sector. (BE) https://www.facebook.com/initiativapozitiva/posts/3910260602425326
- Meeting of the Working Group on Amendments to Law No. 50/2008 on the Protection of Inventions https://www.facebook.com/initiativapozitiva/posts/3915155031935883
- 11. Interview with Nikita Trofimenko, Intellectual Property Lawyer https://www.facebook.com/initiativapozitiva/posts/3948285411956178
- 12. What's good about compulsory licensing for people living with HIV

https://www.facebook.com/initiativapozitiva/posts/3875397612578292

- 13. Civil society in Moldova spoke out against high prices for TB treatment https://www.facebook.com/initiativapozitiva/posts/4245784645539585
- 14. Efficient procurement as a tool to expand access to treatment https://www.facebook.com/initiativapozitiva/posts/4246634102121306
- 15. How are major HIV drug manufacturers holding back generics from entering the market? https://www.facebook.com/initiativapozitiva/posts/4399482576836457
- On November 17, 2021, a court hearing was held on the case of invalidating the patents for the drug bedaquiline of the pharmaceutical company JANSSEN PHARMACEUTICA N.V. in the Republic of Moldova. (BE).

https://www.facebook.com/initiativapozitiva/posts/4549150145203032

- The Ministry of Health reports that three innovations aimed at reducing the prices of medicines have come into force today. https://www.facebook.com/initiativapozitiva/posts/4479228968861817
- 18. Public discussion of changes in the legislation governing intellectual property https://www.facebook.com/initiativapozitiva/posts/4551408401643873

Summarize key challenges to implementing planned activities during the reporting period. Describe changes to planned activities that you would recommend to better facilitate the achievement of planned results and any associated changes to future resource needs.

COVID-19 pandemic decreased the number of activities which could be communicated for the public.

Complexity of the issue and slow progress with the elaboration of the legislative amendments limited the possibilities for communication work.

3. COMPLEMENTARY FINANCIAL INFORMATION

SECTION II: Financial Performance Narrative

Please fill in the following table:

Budget	Reporting period			Grant start to reporting year end			
implementation	2021 budget	January to December 2021 expenditure	%	Cumulative budget	Total expenditure to date	%	
Proportion of budget spent	62448.78	52582.39	-84	62448.78	52582.39	-84	

Please fill in the following table:

		Reporting period	Grant start to reporting period end			
	2021 budget	January to December 2021 expenditure	%	Cumulative budget	Total expenditure to date	%
Output 1:	0	0	0	0	0	0

	Reporting period			Grant start to reporting period end		
	2021 budget	January to December 2021 expenditure	%	Cumulative budget	Total expenditure to date	%
Output 2:	1 989.12	1989.00	-100	1 989.12	1989.00	-100

	Reporting period			Grant start to reporting period end			
	2021 budget	January to December 2021 expenditure	%	Cumulative budget	Total expenditure to date	%	
Output 3:	19 904.96	14 904.84	-75	19 904.96	14 904.84	-75	

	Reporting period			Grant start to reporting period end		
	2021 budget	January to December 2021 expenditure	%	Cumulative budget	Total expenditure to date	%
Output 4:	11 003.30	9 925.62	-90	11 003.30	9 925.62	-90

	Reporting period			Grant start to reporting period end		
	2021 budget	January to December 2021 expenditure	%	Cumulative budget	Total expenditure to date	%
Output 5:	6 449.00	7 603.96	+118	6 449.00	7 603.96	+118