

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

**2022 ANNUAL REPORT OF 100% LIFE
(January 1st to December 31st)**

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

Report submitted by: Serghei Craveti

Date of submission: 13.02.2023

SECTION I: Narrative & M&E

1. SUMMARY AND OVERALL ASSESSMENT (1 PAGE MAX)

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

There were two key milestones during the reporting period:

- 1) The Impact Analysis Governmental Committee has finally approved the draft of amendments to the Law no. 50/2008 on the protection of inventions with some recommendations.
- 2) During the National Dialog on HIV with the participation of the MP Ms. Liliana Grosu, the member of the Parliamentary Social Protection, Health and Family Commission the agreement was made to explore the possibility to organise an information session for the members of the Parliament Commission.

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

The war in Ukraine, which is neighbouring Moldova, and the massive flow of refugees from Ukraine to Moldova, as well as ongoing energy crisis coupled with the severe rise of prices on energy sources and high rate of inflation (about 30% in 2022), have changed the priorities and the agenda of the Government and public institutions. Two states of emergency were declared in Moldova in terms of the refugee crisis and energy crisis. The state of emergency in health because of COVID-19 pandemic was finalised on 16 April 2022.

Moldova received an EU candidate country status on 23 June 2022 and thus the efforts of the public institutions were focused on the implementation of the corresponding reforms.

The justice reform performed by the Government has slowed down multiple court hearing processes, including the patent opposition on Bedaquiline submitted by Positive Initiative.

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 licence in upcoming 6 months.

The key priorities for 2023 as follows:

- To support further the patent opposition on Bedaquiline;
- To follow up with the AGEPI on promotion 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 prepare the documentation for filing a new patent opposition after identifying appropriate patent protected medication.

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

There are several opportunities which might appear in the next 6 months:

- The improvement of the amendments to the Law no. 50/2008 on the protection of inventions. Publication of the draft Law for public consultations;
- Court hearings on 20 March 2023 on the submitted Bedaquiline patent opposition;
- Identification of the new medicine for the elaboration and submission of eventual patent opposition.

There are following risks which might affect project implementation in the next 6 months.

- Escalation of the military conflict in Ukraine can affect decision making priorities of the local Government, which can slow down the implementation of project priorities. (In order to address this risk, there would be more communication with stakeholders and general public in order to raise awareness in matter of IP legislation and importance of access to treatment)
- There would be no positive court verdict on Bedaquiline patent opposition, after the March 20 hearing. (There would be further support of legal actions as well as mediatization to put public pressure on the decision making institutions)

2. PROGRAMMATIC PERFORMANCE

2.1 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 implications if there are any. If no reporting of programmatic results is expected for the output, please instead provide a brief narrative describing progress. [Half page max]

2.1 Research to gather data and evidence to inform national strategies

Although the key activities under this output were performed during the previous project

¹ https://drive.google.com/drive/folders/1gKY9IAC17AJpvAHhbsA5_sP04eMTM6Yo?usp=sharing

reporting periods, the Positive Initiative has undertaken some further follow-up and new activities:

- Results analysis of retrospective procurement in regards of key drug manufacturer countries was held in the framework of National HIV/AIDS/STI and TB programs. The drugs that may be difficult to procure due to the country of manufacture have been identified²:
 - * *Sirturo (DCI – Bedaquilinum), 100 mg, pills, prod.: Farmstandart-UfaVita SAD, Russia;*
 - * *Methadoni hydrochloridum, 5 mg/ml, Oral solution, prod.: Zdorovie Narodu SRL, Harkov, Ukraine.*
- Collected information was presented to key national actors, both public institutions and NGOs in order to ensure continued access to treatment.
- 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;

Summarise 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 war in Ukraine and its effects on project implementation in the Republic of Moldova. First semester of the year all resources for both NGOs and government representatives were thrown to address the refugee crisis in Moldova. Most planned activities had to be postponed or slowed down due to unforeseen pressure on human resources.

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2.2 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 implications if there are any. If no reporting of programmatic results is expected for the output, please instead provide a brief narrative describing progress. [Half page max]

3.1. Files patent challenges/legal interventions

During the reporting period a number of activities were conducted to support the lawsuit over the Bedaquiline patent:

- A process of mobilisation of the patient community in the field of TB and HIV was organised at the national level to strengthen advocacy and support litigation in matters of

²<https://www.facebook.com/initiativapozitiva/posts/pfbid0PoeAejGnQuRLmPCwK2peZ9ZXpjWYdWEus9LVYUw5bE9Az5YmCLGenRAghkTKciFwI>

³ https://docs.google.com/document/d/1IFU0MVbxMol24DSXcNDYN9yA6_Bj4IOKRQdXWR1V0s4/edit?usp=sharing

⁴ https://docs.google.com/document/d/118mCh8Gog7ipGL9cCy_d_jtCeBYwQeCIBcOGWhqm1uU/edit?usp=sharing

⁵<https://www.facebook.com/initiativapozitiva/posts/pfbid037sjpbSruKuovjHNQt6QaxYwiMxr8MavzSUu21NoMDxo1ZFTh3nqzGZVZU7A6oftI>

⁶<https://newsmaker.md/ro/doc-maia-sandu-a-respins-candidaturile-a-13-magistrati-pentru-a-fi-numiti-pana-ating-plafonul-de-varsta/>

- invalidation of patent for the “Bedaquiline” in the Republic of Moldova.
- On August 12, a meeting was held with organisations working in the field of tuberculosis in Moldova². At the meeting, representatives of the Positive Initiative held an information session on the problem of evergreen patents and their impact on access to life-saving medicines. Representatives of the organisations expressed their willingness to join forces to support the litigation to challenge the patent for Bedaquiline as well as changes in patent law.



- On September 1 a letter³ to the Ministry of Health was submitted with the request to:
 - * Monitor with special attention the process of the court examination of the invalidation of patents on BDQ on the territory of the Republic of Moldova.
 - * Address the JANSSEN PHARMACEUTICA on the provision of voluntary licence for Bedaquiline in Moldova.
 - * Support the pharmaceutical company Macleods Pharmaceuticals and other generic manufacturers to move forward with submissions to the national regulatory authority;
 - * Support the draft Law for the amendment of normative acts (Law no. 50/2008 on the protection of inventions and Law no. 1456/1993 on pharmaceutical activity) developed by AGEPI.
- At the same time a letter⁴ to Macleods Pharmaceuticals was elaborated and submitted on behalf of KAP community with the request for information regarding the plans of Macleods on accessing Moldovan market with the generic version of BDQ.
- On September 12, the next hearing on the lawsuit challenging the patent renewal of the Bedaquiline medicine, filed by the Positive Initiative, was scheduled. Representatives of the civil sector as well as the patient community took to the rally⁵ in front of the courthouse to support the trial and also attract representatives of the media, to give more publicity to the issue of evergreen patents and in particular the patent for the drug Bedaquiline.
- The hearing didn't take place. Because of the Justice sector reform, the mandate of the



Summarise 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 justice reform implemented by the Government has led to the extension of the hearing process. Unforeseen hearing cancellation of the court hearing led to an extension of activities related to the support of the lawsuit and drawing public attention to the case.

2.3 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 implications if there are any. If no reporting of programmatic results is expected for the output, please instead provide a brief narrative describing progress. [Half page max]

4.1 Support national law and policy reform efforts for use of flexibilities/ Patent law reform promotion in Ukraine, Moldova and Georgia

During the reporting period the Positive Initiative had continued to support the national IP legislation reform and implementation of TRIPS flexibilities. Communication with the AGEPI (the national patent office) in terms of finalisation of the amendments drafting to the Law no. 50/2008 on the protection of inventions. By the end of the reporting period the draft amendments were on their final stage of the elaboration, they are expected to be submitted to the Government during the first quarter of 2023.

4.2. Reduce negative impact of FTAs on use of flexibilities/ In Moldova The Network will develop legislative proposals/ Official event to be organised in the parliament in Moldova and Morocco to support law reform

Public institutions in Moldova, including the Parliament, worked in the regime of emergency during 2022 because of the refugee crisis and energy crisis. The Parliament has also prioritised working on the anti-corruption, as well as on the legislation related to the EU integration taking Moldova to receive the status of EU candidate country on 23 June 2022⁷.

In this context other issues, including IP legislation, were considered of a lower priority and could be hardly promoted and included into the MPs agendas. Therefore, the Positive Initiative had explored other options to draw attention of the MPs to the IP law reform and implementation of TRIPS flexibilities in Moldova. In this respect National Dialogue on HIV was organised on 19-20 December 2022 with the participation of the MP Ms. Liliana Grosu, the member of the Parliamentary Social Protection, Health and Family Commission⁸.



⁷ <https://www.consilium.europa.eu/en/policies/eastern-partnership/moldova/#candidate>

⁸ <https://www.parlament.md/StructuraParlamentului/Deputa%8c8%9bii/tabid/87/Id/1040/language/ro-RO/Default.aspx>

IP law reform in Moldova was discussed during the National Dialogue. As a result, preliminary understanding with Ms. Grosu was held regarding the need to inform the members of the Parliamentary Commission on the IP law reform and implementation of TRIPS flexibilities. It was agreed to explore during the first quarter of 2023 the possibility to organise an information session for the members of the Commission.

Summarise 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 war in Ukraine, which is neighbouring Moldova, and the massive flow of refugees from Ukraine to Moldova, as well as ongoing energy crisis coupled with the severe rise of prices on energy sources and high rate of inflation (about 30% in 2022), have changed the priorities and the agenda of the Government and public institutions. Two states of emergency were declared in Moldova in terms of the refugee crisis and energy crisis. The state of emergency in health because of COVID-19 pandemic was finalised on 16 April 2022.

Moldova received an EU candidate country status on 23 June 2022 and thus the efforts of the public institutions were focused on the implementation of the corresponding reforms.

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

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2.4 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 implications 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

Project and ITPC visibility were ensured throughout the events organised: information on key project's activities were placed on the Facebook page of the Positive Initiative and its website. Links to the released news were included in the report above.

- 1) Saving on drugs, not on health: the difference between original drugs and generics.
<https://positivepeople.md/ekonomiya-na-lekarstvah-a-ne-na-zdorovie-otlichie-originalinyh-lekarstv-ot-dzhenerikov/>
- 2) How "evergreen patents" drive up drug prices even in the world's largest country.
<https://positivepeople.md/kak-vechnozelenye-patenty-povyshayut-ceny-na-lekarstva-dazhe-v-samoj-bolishoj-v-mire-strane>
- 3) Treatment of drug-resistant tuberculosis within 24 weeks.
https://www.facebook.com/permalink.php?story_fbid=4909024122548964&id=24551796566293
- 4) Generics and originals. One year after filing a Bedaquiline application.
<https://www.facebook.com/initiativapozitiva/posts/353132993513149>
- 5) 14 important questions to the phthysiatrician about TB
<https://www.facebook.com/initiativapozitiva/posts/pfbid02VcHxJ3tq2X53CYZadKgwVHU9U18JemXTnV57XgGzWK6QpYtmnagVGwaZmdw7Bqql>

- 6) Infographics "evergreen patents"
<https://www.facebook.com/initiativapozitiva/posts/pfbid0C7C9ZEmShV7Lupq7BbfP1YPbYRhsdJmwucukgGhpGHyE4JeEfWsaGxLZK6MdaE7vil>
- 7) All you need to know about pharmaceutical patenting
<https://www.facebook.com/initiativapozitiva/posts/pfbid02hvSBrrh9DmbrJ4G5kenyE1LYf7wr6H2ZyC9kULS34LuWwvp2T3jH5XsJrCHzfHG6l>
- 8) Activists from around the world demand action to improve access to Bedaquiline
<https://www.facebook.com/initiativapozitiva/posts/pfbid02go8SgSvKQvnB4HXMjYcNXLmXYQM12SqHkbqGGqFFDt9pM9M5f8XgfWyaJtkRdt9l>
- 9) Infographic "how you can save money on buying Bedaquiline"
<https://www.facebook.com/initiativapozitiva/posts/pfbid0mg6dM8jYeQUJTDNuL2F9Sx64VkdGpv2aPfrwAMLo5dQVeP4EtBTDxy9e6LaSw7HLl>
- 10) Istanbul hosts Second Global Summit on Intellectual Property and Access to Medicines July 19-21
<https://www.facebook.com/initiativapozitiva/posts/pfbid02HR5NXrotUg9RePqyJBeZEU2Dun2NSqLpkj4mwWMCzjxHu9hMiwcBjNFxykgwWmAzl>
- 11) Pharmaceutical company ViiV Healthcare will provide 90 countries with access to low-cost generic versions of an injectable HIV prevention drug
<https://www.facebook.com/initiativapozitiva/posts/pfbid0AcJAXCT6ZLkxbz2BX8AjESBcvUuaKjTn6ycUZhKgxDCSAsQLJGuPoAZb7XjSs7ol>
- 12) Today an event was held where the process of expanding the circle of partners with organisations from Moldova working in the field of TB was discussed.
<https://www.facebook.com/initiativapozitiva/posts/pfbid0PoeAejGnQuRLmPCwK2peZ9ZXpjWYdWEus9LVYUw5bE9Az5YmCLGenRAghkTKciFwl>
- 13) Generic production is needed. UNAIDS encouraged to share lenacapavir technology
<https://www.facebook.com/initiativapozitiva/posts/pfbid0k7bCHjVgoVVASUxp766dxEBDESxoi53EMnYDHMwa4pFnxiaba3NVRzmAT8hvecS5l>
- 14) Live from the rally to repeal the patent on Bedaquiline
https://www.facebook.com/watch/live/?ref=watch_permalink&v=836457240682634
- 15) Rally in front of the Chisinau court (litigation over the patent for the TB drug Bedaquiline)
<https://www.facebook.com/initiativapozitiva/posts/pfbid037sjpbSruKuovjHNQt6QaxYwiMxr8MavzSUuD21NoMDxo1ZFTh3nqzGZVZU7A6oftl>
- 16) Fighting for equal rights for pharmaceutical companies and patients
<https://www.facebook.com/initiativapozitiva/posts/pfbid0shppWdGKgxAQMQ1RAtv71EmqDwnDyUm453gZW9eg7Q1i7w7weqzHzLciEHDGK8Al>
- 17) 1/4/6x24: How to beat TB?
<https://positivepeople.md/1/4/6h24-kak-pobediti-tuberkulyoz/>
- 18) Supplies of life-saving generic drugs from India under threat
<https://www.facebook.com/initiativapozitiva/posts/pfbid0krffHA9GSyuvWwxh426PHo3nwf1DuzUDTr1TPw3HgWlBQNr4deyTAYLCUNtC5fBDl>
- 19) What's the difference between originals and generics?
<https://www.facebook.com/initiativapozitiva/posts/pfbid0BinegcKNzzNm6XziWAbT1vqakBTStFwFY4cps2capM19RQADsqJEFcRdWaa2ZDF9l>
- 20) One of the topics of yesterday's National Dialogue was patent legislation.
<https://www.facebook.com/initiativapozitiva/posts/pfbid02v8m2YwrKKNCLRMZzYuLj2Q2f7NTGi122C8YGgdJJ26NwrR1CRQIHZ3TWfCfVq1zol>
There were two video spots created in order to raise awareness among key stakeholders and the general population regarding the connection between the power of evergreen patents, patent legislation gaps and lack of access to affordable medicine.
- Video about changes in patent law:
<https://youtu.be/pnSGlgLuhnE>
- Video about evergreen patents:

<https://youtu.be/pnSGIgLuhE>

Due to the change in the date of the court hearing and delay in promotion of the amendments to the IP legislation, a decision was made to postpone the promotion of video materials for the first quarter of 2023.

Summarise 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 war in Ukraine, which is neighbouring Moldova, and the massive flow of refugees from Ukraine to Moldova, as well as ongoing energy crisis coupled with the severe rise of prices on energy sources and high rate of inflation (about 30% in 2022), have changed the priorities and the agenda of the Government and public institutions, as well as media partners.

Traditional way of thinking about intellectual property as a value superior to the right to health makes communication efforts more valuable in implementation of the project. Continuous work on amplifying visibility and efficient communication is crucial for successful implementation of the project.

3. COMPLEMENTARY FINANCIAL INFORMATION

SECTION II: Financial Performance Narrative

Please fill in the following table:

Budget implementation	Reporting period			Grant start to reporting year end		
	2022 budget	January to December 2022 expenditure	%	Cumulative budget	Total expenditure to date	%
<i>Proportion of budget spent</i>	52682.75	52678.77	100	109857.87	52678.77	48

Please fill in the following table:

	Reporting period			Grant start to reporting period end		
	2022 budget	January to December 2022 expenditure	%	Cumulative budget	Total expenditure to date	%
Output 1:	0	0	0	0	0	0

	Reporting period			Grant start to reporting period end		
	2022 budget	January to December 2022 expenditure	%	Cumulative budget	Total expenditure to date	%
Output 2:	2046.08	2051.90	100	4206.08	2051.90	49

⁹ This is the cumulative budget from the start of the grant through the end of the current reporting year.

	Reporting period			Grant start to reporting period end		
	2022 budget	January to December 2022 expenditure	%	Cumulative budget	Total expenditure to date	%
Output 3:	11601.02	11550.87	100	27647.26	11550.87	42

	Reporting period			Grant start to reporting period end		
	2022 budget	January to December 2022 expenditure	%	Cumulative budget	Total expenditure to date	%
Output 4:	9851.90	9758.61	99	16993.58	9758.61	57

	Reporting period			Grant start to reporting period end		
	2022 budget	January to December 2022 expenditure	%	Cumulative budget	Total expenditure to date	%
Output 5:	5739.75	5761.09	100	13439.75	5761.09	43