

Supporting the use of TRIPS Flexibilities: Joint Portfolio End-of- Project Evaluation

Unitaid

9 December 2022

Executive Summary



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ACRONYMS AND ABBREVIATIONS

| Acronym | Full description |
|-----------|-----------------------------------------------------------------------------------|
| ABIA | Associação Brasileira Interdisciplinar de AIDS |
| ACAME | Association Africaines des Centrales d'Achats de Médicaments Essentiels |
| AfCFTA | African Continental Free Trade Area |
| Afl | Area for Intervention |
| APN+ | Asia-Pacific Network of People living with HIV/AIDS |
| ARVs | Antiretrovirals |
| BDQ | Bedaquiline |
| CBO | Community-based organisation |
| CL | Compulsory License |
| CSO | Civil Society Organisation |
| C-TAP | Covid Technology Access Pool |
| DNP+ | Delhi Network of Positive People |
| DTG | Dolutegravir |
| EPHA | European Public Health Alliance |
| EPO | European Patent Office |
| EU | European Union |
| FGEP | Fundación Grupo Efecto Positivo |
| FTA | Free Trade Agreement |
| FTC | Emtricitabine |
| GFATM | Global Fund |
| GIZ | Deutsche Gesellschaft für Internationale Zusammenarbeit GmbH |
| GTPI | Grupo de Trabalho sobre Propriedade Intelectual |
| HCV | Hepatitis C Virus |
| IAC | Indonesia AIDS Coalition |
| IGJ | Indonesia for Global Justice |
| IP | Intellectual Property |
| ITPC | International Treatment Preparedness Coalition |
| ITPC-MENA | International Treatment Preparedness Coalition- Middle East and North Africa |
| ITPCru | International Treatment Preparedness Coalition- Russia (became ITPC EECA in 2022) |
| ITPC EECA | International Treatment Preparedness Coalition- Eastern Europe and Central Asia |
| LATCA | Latin America and Caribbean |
| LDC | Least developed countries |
| LIC | Low-income country |
| LMIC | Lower-middle-income Country |
| M&E | Monitoring and evaluation |
| MENA | Middle East and North Africa |
| MIC | Middle-income country |

| Acronym | Full description |
|----------|---------------------------------------------------------------------|
| MSF | Médecins sans Frontières |
| MTAAG+ | Positive Malaysian Treatment Access and Advocacy Group |
| MoH | Ministry of Health |
| MMA | Make Medicines Affordable |
| MPP | Medicines Patent Pool |
| NCE | No-cost extension |
| OSF | Open Society Foundations |
| PAHO | Pan-American Health Organisation |
| PEPFAR | President's Emergency Plan for AIDS Relief |
| PLHIV | People Living with HIV |
| PO | Patent Opposition |
| POA | Patent Opposition Academy |
| PrEP | Pre-exposure prophylaxis |
| PSM | Procurement and supply management |
| R&D | Research and development |
| SC | South Centre |
| SOF | Sofosbuvir |
| SPC | Supplementary protection certificate |
| TDF | Tenofovir disoproxil fumarate |
| TNP+ | Thai Network of People living with HIV/AIDS |
| TOC | Theory of Change |
| TOR | Terms of Reference |
| TPO | Third Party Observation |
| TRIPS | Trade Related Aspects of Intellectual Property Rights |
| TWN | Third World Network |
| UMIC | Upper middle-income country |
| UNAIDS | Joint United Nations Programme on HIV/AIDS |
| UNCTAD | United Nations Conference on Trade and Development |
| UNDP | United Nations Development Programme |
| VL | Voluntary License |
| WHO | World Health Organisation |
| WIPO | World Intellectual Property Organisation |
| WIPO-PCT | World Intellectual Property Organisation- Patent Cooperation Treaty |
| WTO | World Trade Organisation |
| 3HP | Isoniazid/ rifapentine fixed-dose regime |

EXECUTIVE SUMMARY

Cambridge Economic Policy Associates (CEPA) was appointed by Unitaïd to conduct a joint portfolio end-of project evaluation of its investments on “Supporting access to medicines through innovative use of TRIPS flexibilities”.

Background/ context and evaluation objectives

Unitaid is a global health agency engaged in finding innovative solutions to prevent, diagnose and treat diseases more quickly, cheaply and effectively in low- and middle-income countries. One of the challenges to access to medicines is the existence of intellectual property rights (IPR) and patents that are enforceable across countries. Unitaid has been one of the key global health organisations at the forefront of working through this challenge, notably through its “game-changing” support for the creation and expansion of the Medicines Patent Pool (MPP). However, often MPP licenses do not include key middle-income countries, and as such in these countries the use of the TRIPS flexibilities is the only remaining option. There are also instances where voluntary licenses have not been made available by originators, for example with the newer TB-regimens (delamanid; bedaquiline), vaccines or biologics; as such the promotion and implementation of TRIPS flexibilities remains a critical policy tool for addressing IP-related access barriers. Unitaid therefore developed an Area for Intervention (Afi) on supporting access to medicines through innovative use of TRIPS flexibilities which was approved by the Board in December 2016. Following a call for proposals in 2017, three grants for a total of US\$ 22 million were awarded in 2018 which form the TRIPS flexibility portfolio for review under the current evaluation, namely:

- Expanding the use of TRIPS flexibilities to promote affordable access to medicines implemented by South Centre (SC) – July 2018 to June 2022, US\$ 6.9 million.
- Use of TRIPS flexibilities to increase affordability of treatment for HIV, TB and hepatitis C virus in middle-income countries, implemented by International Treatment Preparedness Coalition (ITPC) – September 2018 to August 2022, US\$ 10 million.
- Health for all: Increasing access to HIV, TB and Hepatitis C treatment through effective use of TRIPS flexibilities, implemented by Third World Network (TWN) – July 2018 to December 2022, US\$ 4.9 million.

The scope of the grants was expanded in April 2020 to include work on COVID-19 and all three grants received a no cost Extension (NCE) due to COVID-related disruption (reflected in the project dates above). A costed extension of all three grants to December 2023 was approved by the Unitaid Executive Board in May 2022.

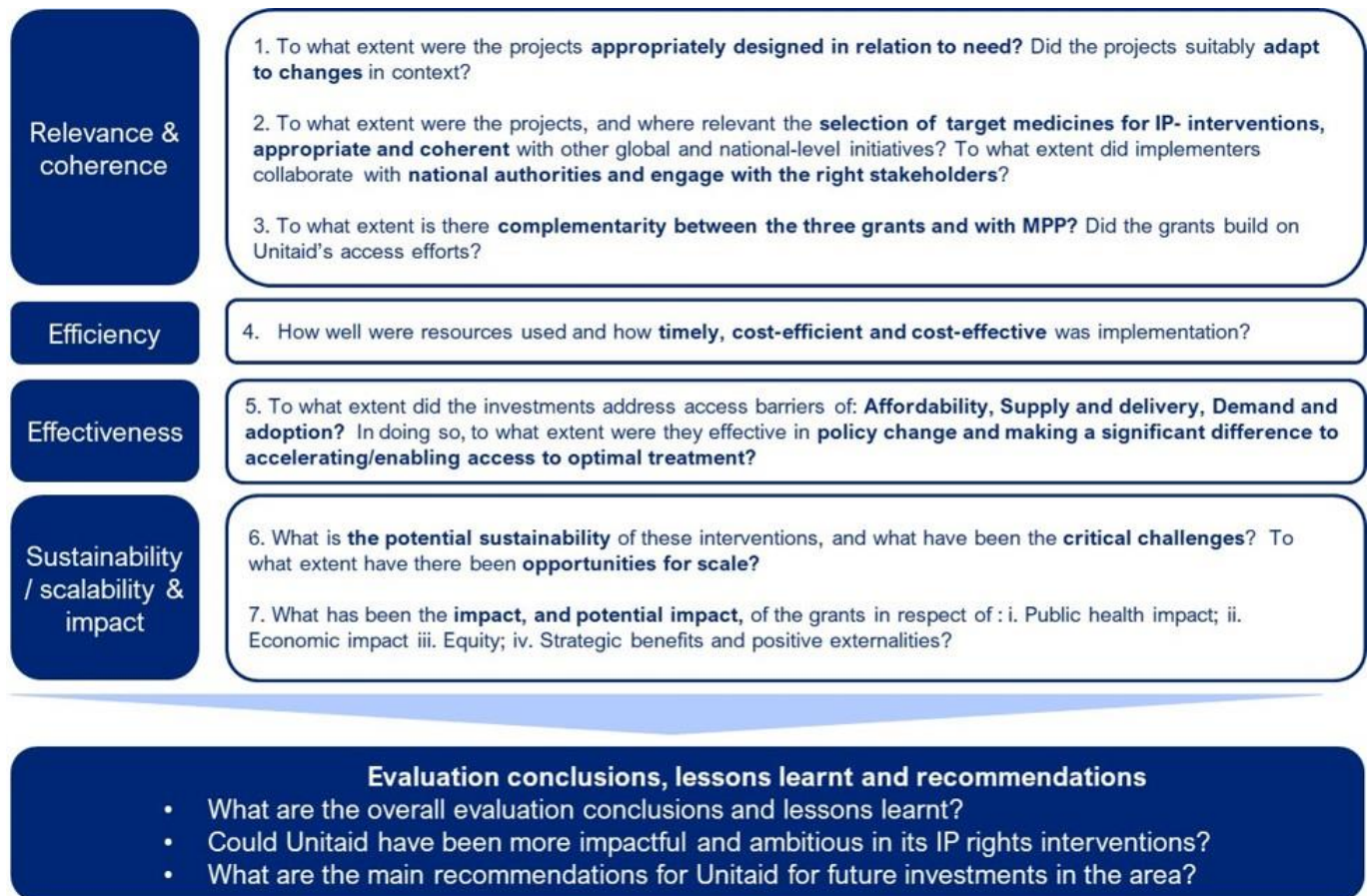
The objectives of the evaluation were as follows:

- To assess the relevance, coherence, efficiency, effectiveness, impact, sustainability and lessons learned for the portfolio, as captured by the activities performed and outputs and outcomes achieved.
- To assess the overall impact of the portfolio on increasing equitable access to affordable and appropriately formulated medicines.

The timeframe for the evaluation included activities and progress made from 2018 up to and including the semi-annual project reports for 2022 as well as costed extensions for the portfolio approved in May 2022.

The evaluation is presented by the OECD DAC evaluation criteria and the evaluation framework is shown below (Figure E.1).

Figure E.1: Evaluation framework



The evaluation adopted a theory-based approach, which means that it is grounded on a theory of what the different grant activities of Unitaids investments in supporting TRIPS flexibilities were seeking to achieve, considering the pathways to impact represented through a portfolio-level Theory of Change (ToC) that was developed for this evaluation. The evaluation used mixed-methods within the approach, including: (i) review and analysis of documentation and data; (ii) semi-structured interviews with key stakeholders at global, regional and country-level; (iii) quantitative funding and programmatic data analysis; and (iv) quantification of the ranges of impact from select grantee activities using pre-existing models developed for Unitaids and MPP and analyses in the public literature.

Key findings

Table E.1. over page includes the key findings of this evaluation, presented by the evaluation criteria and review question.

Table E.1: Key findings from the evaluation

| Evaluation Criteria | Review Question | Key findings |
|---------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><i>Relevance and Coherence</i></p> | <ol style="list-style-type: none"> 1. <i>To what extent were the projects appropriately designed in relation to need? Did the projects suitably adapt to changes in context?</i> 2. <i>To what extent were the projects, and specifically the selection of target medicines for IP-interventions, appropriate and coherent with other global and national-level initiatives? To what extent did implementers collaborate with national authorities and engage with the right stakeholders?</i> 3. <i>To what extent is there complementarity between the three grants and with MPP? Did the grants build on Unitaids access efforts?</i> | <ul style="list-style-type: none"> • <i>Unitaid's portfolio has been highly relevant and responsive to country needs for addressing access gaps in HIV, TB, HCV and COVID-19 drugs, where IP-barriers have created inequitable access and unaffordable market prices.</i> • <i>Unitaid's funding of this very challenging and politically sensitive area of TRIPS flexibilities is viewed as highly relevant, further amplified by the limited number of funders in the space and complementing its funding of the MPP.</i> • <i>This portfolio is well crafted in delivering a balanced and coherent intervention mix, though with some areas not adequately covered and would benefit from attention going forward including competition law, expansion/safeguarding of generics manufacturing, policy coherence, regional/international IP fora, access requirements in R&D, and public campaigning.</i> • <i>The focus on the disease areas of HIV, TB and HCV, as well as the expansion to COVID-19 was appropriate for the LIC/MIC context, though did not address some of the most significant IP-challenges faced by countries such as cancer treatments and the use of biologics. Grantees, however, also focused on systemic change (e.g., preventing TRIPS-plus provisions) which has a spillover effect to other diseases.</i> • <i>Grantee selection was well done and supported the success of the portfolio – grantees are highly regarded technical experts, experienced and networked in their respective areas and in countries.</i> • <i>The portfolio adapted to changes in context over the duration of the grant, most notably in response to COVID-19. Further adaptation is warranted in relation to the evolving context of IP barriers and use of TRIPS flexibilities, including trends in more generic manufacturers (esp. in India) collaborating with originators under voluntary licenses and less likely to challenge patents.</i> • <i>There has been strong coherence with country stakeholders and other global access stakeholders in regard to the prioritisation of medicines and key messages. There were several instances of collaboration with UN partners at country/regional level, with more limited global level engagement at the portfolio level. High complementary between grantees – ITPC, TWN and South Centre - and with MPP, where grantee actions have also supported MPP goals to expand access through voluntary licenses.</i> • <i>The TRIPS flexibilities portfolio provides an IP-focused solution to the Unitaids access barriers, particularly in support of MICs. However, given the crosscutting nature of IP, as also recognised in the new Unitaids Strategy, the grants could have been better integrated with the Unitaids portfolio rather than being structured as individual grants.</i> |

| Evaluation Criteria | Review Question | Key findings |
|---------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Efficiency | 4. <i>How well were resources used and how timely, cost-efficient and cost-effective was implementation?</i> | <ul style="list-style-type: none"> • <i>Grantees have valued Unitaids’s flexibility and portfolio management approach. Key issues however have been in terms of the three year limited timeframe for advocacy-focused grants as well as an over emphasis on log frames rather than on measuring systemic change. Further, there was undue focus on attainment of treatment price reductions which is often a longer-term result of the grantee activities and not directly controllable by their actions.</i> • <i>Grantees adapted well to the COVID-19 pandemic, which had a knock-on effect on project priorities and project delivery.</i> |
| Effectiveness | 5. <i>To what extent did the investments address access barriers of Affordability, Supply and delivery, Demand and adoption? In doing so, to what extent were they effective in making a significant difference to accelerating/enabling access to optimal treatment?</i> | <ul style="list-style-type: none"> • <i>Overall, the portfolio has made a substantial contribution to demand and adoption and affordability for some discreet drugs/ countries, but less so on supply and delivery.</i> <p><i>Demand and Adoption</i></p> <ul style="list-style-type: none"> • <i>Almost a fourth of patent oppositions filed have been successful to date, resulting in the withdrawal or rejection of the patent, and several having important economic and public health impact. The level of contribution of grantees varies. In approximately 75% of cases, a final decision is still pending, and whilst the removal of a patent barrier is significant, a pending decision is also of value because of the enabling environment this action creates for the patent applicant and patent review process to address public-health related concerns.</i> • <i>Amongst other civil society actors, grantees contributed to support of the proposal to the WTO for the COVID-19 TRIPS Waiver, with future expected results likely to be seen within a potential WHO pandemic treaty and other related pandemic preparedness discussions.</i> • <i>The novel approach of Third Party Observation (TPO) filings through the WIPO PCT system is a promising route to intervening early to curb ‘poor quality’ patent filings based on prior art – though it is too early to demonstrate effectiveness given the need for more evidence as to what extent national patent offices rely on TPO-notices.</i> • <i>Country-level consultations support the finding that the projects have contributed to an increase in knowledge/ capacity/ awareness across stakeholder groups, with some instances linked to improvements in the enabling environment for use of TRIPS flexibilities and patent oppositions.</i> • <i>The projects have made significant contributions to avoidance of TRIPS-plus provisions, which will support the ability of countries to exercise TRIPS flexibilities.</i> <p><i>Supply and Delivery</i></p> <ul style="list-style-type: none"> • <i>The portfolio has made some useful contributions to protecting future generic manufacturing in countries, which is important for domestic and global access e.g., holding the IP-policy space in India and</i> |

| Evaluation Criteria | Review Question | Key findings |
|-----------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | <p><i>Bangladesh and avoiding TRIPS-plus provisions in free trade agreements, but overall, this area could have been a greater focus within the portfolio (As noted under the relevance findings)</i></p> <p><i>Affordability</i></p> <ul style="list-style-type: none"> • <i>Grantees have contributed to price reductions for priority ARVs, DAAs, TB and COVID-19 therapeutics through different pathways, demonstrating the effectiveness of multiple strategies over a period of time. One approach has been to continue efforts to ensure subsequent price drops following removal of patent barriers, which can offer significant savings for UMICs with smaller economies transitioning from donor funds.</i> |
| Sustainability/ scalability | <p>6. <i>What is the potential sustainability of these interventions, and what have been the critical challenges? To what extent have there been opportunities for scale up?</i></p> | <ul style="list-style-type: none"> • <i>Several project activities have supported sustainability of results through building national ownership and capacities in LDCs and MICs to use TRIPS flexibilities, avoidance of TRIPS-plus provisions, and ‘pre-emptive’ capacity strengthening, including for countries benefitting from the LDC exemption</i> • <i>There is a risk that the momentum established by the projects on IP and access would be compromised, particularly for civil society, if viable funding did not continue given the shrinking number of funders in this space.</i> • <i>Unitaid funding has been better leveraged where grantees have secured complementary funding for other aspects of access work.</i> • <i>The longer-term continuity of Unitaid funding for ITPC, between the earlier ITPC-1 grant and the current ITPC-2 grant, was an important factor in the grantee’s achievements of the current project period.</i> • <i>ITPC’s Hub-and spoke model is an encouraging approach to scaling support to civil society on IP and access and the projects have developed replicable/scalable tools and approaches (e.g., e-learning) for use beyond project countries.</i> |
| Impact | <p>7. <i>What has been the impact, and potential impact, of the grants in respect of: i. public health impact; ii. economic impact; iii. equity; iv. strategic benefits and positive externalities?</i></p> | <ul style="list-style-type: none"> • <i>Existing approaches to quantifying impact from Unitaid’s TRIPS grants are inadequate.</i> • <i>It is clear that at least some of the patent barriers which grantees have helped to remove have made significant differences to health system costs, and likely also to health outcomes. The extent to which patent oppositions and observations filed by the grantees were responsible for those instances cannot be conclusively identified.</i> • <i>Oppositions pending on applications for cabotegravir, dolutegravir, and long-acting formulations of bedaquiline and various candidate drugs for long-acting ART/PrEP could all be potentially critical and thereby impactful in specific countries. Several high-potential oppositions for early-stage products are pending in India, which could strategically alter the future access landscape in other countries.</i> |

| Evaluation Criteria | Review Question | Key findings |
|---------------------|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | <ul style="list-style-type: none"> • <i>TWN's filing of TPOs through the WIPO PCT system is a promising route for intervening early to curb 'poor quality' patent filings, but it will likely be several years at least before their impact can be even tentatively assessed.</i> • <i>Many of the highest-potential impact claims made by grantees have involved advocacy rather than direct opposition to patents. The clearest impact examples demonstrate the value of combining credible threat of compulsory licences and / or patent rejection with a viable pathway for voluntary licensing.</i> • <i>Avoidance of TRIPS-plus provisions can achieve large-scale impact on a systemic, long-term basis. The degree to which grantee contributions to recent high-impact policy reforms cannot be conclusively identified.</i> • <i>The main beneficiaries of potential impact from grantee activities will likely be health systems of UMICs rather than LICs or LMICs. This result should be expected given the high commercial value of these markets to originators.</i> |

Conclusions and Lessons Learnt

Overall, this evaluation concludes that Unitaid's TRIPS flexibilities portfolio has been highly relevant in supporting countries to address IP barriers to access essential medicines for HIV, TB, HCV and COVID-19. In addition, the useful contributions of the projects to protect future generic manufacturing in some countries are strategically important to the overall access agenda, recognising local production was not a primary focus of the portfolio as a whole.

Funding of this portfolio since 2018 has been of particular significance, as during this period the funding landscape has rapidly shrunk. Alongside its support for the MPP, funding of the TRIPS flexibilities portfolio is seen as a bold move by Unitaid. The challenges faced by governments, patent officials and civil society to use TRIPS flexibilities and address IP barriers to access has been further highlighted by the COVID-19 pandemic.

In terms of effectiveness, there has been some good progress, with critical patent opposition wins or extensions to the VL agreements through MPP which has led to price reductions and increased access in some countries. Under this portfolio, the key oppositions filed to address patent barriers for priority ARVs, DAAs, TB, and COVID- therapeutics have had significant economic and health impacts. What is less quantifiable but still significant is the contribution of opposition filings more broadly to the enabling environment for lower prices and high-quality patents, by compelling originators to grant/expand licenses and indirectly through fostering more stringent patent examination. There have also been reported achievements seen in relation to improving the quality of patents granted and efforts to hold the policy space for the use of TRIPS-flexibilities through the avoidance of TRIPS-plus provisions in regional and bi-lateral free trade agreements.

In terms of whether Unitaid was impactful and ambitious enough with this portfolio, our assessment is yes – especially in terms of ambition, given the complexity behind supporting TRIPS flexibilities and the fact that Unitaid has managed to successfully fund this portfolio. It is recognised however, that this portfolio is a relatively small-sized portfolio for Unitaid, and atypical in terms of the types of grantees and activities funded, and in this sense is highly catalytic and impactful in terms of what it seeks to achieve and progress to date from available resources and approaches. Particularly given the scale of this portfolio also remains small in relation to the magnitude of other influences on access and IP-protection, including both political and commercial pressures. Some key aspects on where the portfolio has not done enough to date and merits consideration in the future include:

- **Limited approaches to supporting the growth and development of generics industry:** As a result of the COVID-19 pandemic, there is an increasing awareness of the need to reduce dependency on global procurement and imports, and to prioritise local or regional manufacturing capacity; notably this is now an aim within Unitaid's updated strategy. With a focus on local production, it is suggested that the interventions being developed and shared by grantees need to be shaped in line with procurement strategies, regional and local production/supply lines, and drive transparency on IP-issues.
- **Limited efforts directed at supporting policy coherence in countries:** It is suggested that the portfolio design could have had a greater focus on addressing access issues at the political level, such as better aligning the position of departments across governments to foster policy coherence.
- **Very limited exploitation of the nexus with competition law:** The portfolio has been designed with a narrow focus on the TRIPS flexibilities and to this extent limited the grantees approach in addressing IP-related access barriers. The WTO TRIPS framework also permits countries to address anti-competitive practices and abuse of intellectual property rights through competition law; and this could have been brought into the portfolio through closer partnership, even if it was not the core focus of the grantee's work.
- **Good examples of international and regional engagements to help facilitate country-level efforts, especially in relation to COVID, but this could have had an even greater emphasis across the portfolio as a whole.:** The international arena provides an opportunity to shape the global mechanisms on access and drive policy thinking on more sustainable solutions that are relevant at the country-level. The objectives of the portfolio were focused predominantly on the country level, but greater consideration should be given to also address advocacy targets at the international and regional levels e.g., WHO Pandemic Treaty.

- **A level of rebalancing required in terms of extent of public engagement and high-income countries:** The selection of grantees and the portfolio have been largely technical in nature, with only limited public engagement. Given the sensitivities of the issues, we recognise the complexities of being more vocal in the space, however it is suggested that greater public awareness including in high-income countries – is important factor for driving progress and has been missed out of the ToC.
- **Disease-based restrictions prevent leveraging of the potential of this work:** A broader IP-approach and scope would empower more translational work and support countries in addressing wider systemic barriers, such as research capacity, tech transfer and trade secrets.

Recommendations

Based on the main findings and conclusions from the review, we present recommendations for Unitaid to consider in any future funding for support of TRIPS flexibilities to facilitate access to medicines.

Recommendation 1: For the next RFP, Unitaid should consider an expanded scope and re-balanced focus for its portfolio on supporting TRIPS flexibilities, with additional suggestions on prioritisation and grantee selection detailed below.

- *Expansion:* key aspects that were flagged in this review for further expansion of the scope of the TRIPS flexibilities work supported by Unitaid include:
 - support for generic capacity development (e.g., through encouraging greater use of the research exemption, avoidance of data exclusivity, Bolar exception)
 - linkage with competition law
 - support for policy coherence across health trade and IP
 - exploit some very critical opportunities in terms of engaging with key global and regional initiatives setting the IP/access-agenda e.g., WHO pandemic treaty negotiations.
- *Re-balancing:* recognizing that the current Unitaid portfolio includes some of these activities, we recommend a re-balancing to further enhance efforts towards the following:
 - enhanced efforts at international WTO/ WIPO level
 - greater work on public engagement and community activism
 - more focus on high impact interventions in key countries (e.g., India, Bangladesh, Brazil, South Africa)

We recommend that all of the above be considered within the scope of the next RFP and approval of grants thereof. We see high priority in terms of supporting generic capacity development in particular, which is in line with the new Unitaid Strategy 2023-27. Equally, the range of existing interventions implemented by the grantees under the current portfolio have also been useful and should continue to be supported – particularly as grantees have emphasised the importance of having adequate flexibility in their approach to respond to emerging opportunities and this evaluation has also underscored the utility of the multi-pronged approach of this portfolio. Some of the areas of expansion suggested above would require different capacities to those currently held by the grantees which may shape selection of additional grantees and/or capacities under the new RFP.

Recommendation 2: Unitaid should reconsider the strategic positioning and structuring of this portfolio in a number of ways to enhance the portfolio utility and impact.

- *Within the portfolio, include a component that is structured as cross-cutting enabler/ support to the Unitaid-wide portfolio* and thereby positions the funding for this portfolio as envisaged in the Unitaid Strategy 2023-27 where IP is seen as a cross-cutting issue.

- This could be akin to the Unitaid funding for the WHO enabler grants, where WHO supports the work of other grantees in the portfolio. However, an appropriate grantee would need to be selected by Unitaid that could function in a similar capacity.
 - This recommendation does not suggest that Unitaid support for TRIPS flexibilities gets rolled into other existing grants (we understand this was tried but not successful). Individual grants in this area should be well integrated with the wider Unitaid portfolio.
 - The suggestion is more that Unitaid’s approach to support access to medicines starts with the access barrier rather than the grant and/ or country, and better coordinates across grantees to address the barrier through multiple strategies, including imploring the use of TRIPS flexibilities.
- *Provide longer term funding to support the nature of grant activities to facilitate change.* Whilst recognizing that Unitaid is able to provide 3-year grants as per its Strategy and funding, given the nature of these grants (advocacy, awareness building, knowledge sharing) and the more complex and lengthy time taken to impact, Unitaid should explore options to support longer term grant funding such as providing the same grantees with repeat funding or including “in-principle agreements” with grantees to provide continuous funding subject to certain criteria being met. This would support a longer-term planning horizon for the grantees and provide them with the much-needed security of funding to step-up their work.
 - *Monitor “critical events” or “pathways to change” rather than discrete logframe indicators.* We would recommend Unitaid moving away from logframe based target setting and monitoring for these grants, and rather monitor the achievement of critical events or pathways to change that qualitatively explain important progress and its significance (e.g., key developments in FTAs or country legal frameworks that better support access through effective use of TRIPS flexibilities) in line with the grant/ portfolio theory of change. Unitaid should look to employ new/ different approaches to assessment such as prospective evaluation and/ or real-time monitoring of results to support grantee reporting and programme learning.

Recommendation 3: Adopt a more integrated approach that transcends specific diseases.

Greater opportunities and efficiencies can be leveraged by adopting a disease-agnostic approach to this portfolio of work. While recognising the limit of Unitaid’s scope of work, efforts should be made to partner with other funders/ organisations to ensure seamless working of the grantees in the area. There are several opportunities that would be afforded through this approach – importantly cross-fertilisation of work within the Unitaid Secretariat, but also greater support for CSO grantee sustainability with a wider disease focus.

Recommendation 4: Noting sensitivities, selectively raise Unitaid’s profile in the area to recognise contributions.

We see merit in Unitaid being more explicit in the achievements through this portfolio, albeit selectively, which would help garner more support for this area (noting the very dry funder space and limited number of organisations being active in the area). It would also help coordinate with partners on an expanded disease focus (e.g., on vaccines, non-communicable diseases, etc.).

Recommendation 5: Re-align the approach to impact assessment with the specific nature of this portfolio and ensure adequate emphasis is accorded to more relevant and robust impact measurement.

Unitaid should consider robust analytical approaches that carefully map the pathways to impact and potentially adopt impact measurement approaches as posited in this evaluation (where we have aimed to bring out the critical impact of the grants/ portfolio based on which aspects are going to make the biggest difference to access and based on the level of contribution of the grantees). Some key aspects to consider for more effective impact assessment given the nature of this portfolio include:

- Getting the “basics right” should be prioritised (e.g., recording activities in a systematic way to facilitate impact measurement)
- Grantees should not be expected to report a single headline impact number for the full portfolio, which would not be credible, or a good representation of what grantees do
- Grantees should be expected to understand and communicate which of their activities have the greatest chance of generating real impact, their approximate values, and key dependencies
- Assessing impact can be difficult. Reporting must be proportionate. Rough orders of magnitude are still valuable (e.g., high / low / nil). Greater effort can be invested in the most significant instances.
- Assessing potential impact of activities should be an intrinsic part of grantees’ internal planning to help target effort to the most significant barriers, drugs, diseases and countries.
- A portfolio-style monitoring approach should be embraced. Not all activities will generate impact.



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