



UNITAID

**UPDATE OF THE MID-TERM EVALUATION OF THE HIV/HCV DRUG
AFFORDABILITY PROJECT**

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Final Report

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ACRONYMS AND ABBREVIATIONS

Acronym	Full description
ALCS	Association de Lutte Contre le Sida
CPLUS	Coalition PLUS
CEPA	Cambridge Economic Policy Associates
CoNE	Community Network for Empowerment
CSO	Civil society organisation
DAA	Direct acting antiviral
DNP+	The Delhi Network for Positive People
HCV	Hepatitis C virus
HCW	Healthcare workers
LED	Ledipasvir
Logframe	Logical framework
MAC	Malaysian AIDS Council
M&E	Monitoring & evaluation
MoH	Ministry of health
MPP	Medicines Patent Pool
MTAAG+	Positive Malaysian Treatment Access and Advocacy Group
NSP	National Strategic Plan
PLHIV	People living with HIV
PLHCV	People living with HCV
SOP	Standard Operating Procedure
TWN	Third World Network
PWID	People who inject drugs
ToR	Terms of reference
TTAG	Thai Treatment Action Group
UHC	Universal Health Coverage
VEL	Velpatasvir
VL	Voluntary licence
WHO	World Health Organization

1. INTRODUCTION

This report provides an update to CEPA's June 2018 mid-term evaluation of the "HIV-HCV Drug Affordability project", being implemented by Coalition Plus (CPLUS), to provide an assessment of country-level progress made since the mid-term evaluation. The objective is to inform the Unitaid Secretariat's review of a follow-on proposal to be submitted by CPLUS for a next phase of the project between January 2019 to December 2020.

This is a short and focused evaluation based on a rapid review of select documentation for context (Annex A provides a list of references) and telephone interviews which form the main basis for the assessment (Annex B provides a list of consultees and the interview guide). Interviews have been conducted with project implementing partners (CPLUS and country CSOs) and approximately two additional country-based stakeholders (Ministry of Health (MoH), others) in four of seven project countries (India, Malaysia, Morocco and Thailand).¹

An important limitation is that we have not engaged directly with country-based stakeholders through field visits which would be important to fully understand the extent and nature of the impact, especially given the advocacy and policy-based nature of this project. Also, the review does not aim to be exhaustive of all country-level activities; rather, it focuses on the main areas of feedback provided by stakeholders.

The following section summarises the feedback and assessment for each of the four focus countries in turn (Section 2), followed by a high-level review of the approach to impact measurement adopted by the project (Section 3), and finally, overall conclusions and recommendations (Section 4).

2. COUNTRY PROGRESS

We provide a brief overview of project activities, followed by an assessment of the progress and impact achieved (including a table discussing achievements in relation to the project plan²) as well as remaining challenges and gaps by country. With regards to impact, we note the ways in which the project has helped to address the key access barriers of "demand and adoption" as well as "affordability", as defined in Unitaid's Strategy 2017-21.

¹ The other project countries are Brazil, Colombia and Indonesia.

² Progress in relation to the plans outlined in Section 5 of the project plan for the extension have been commented upon. However, the planned progress has been presented at both the "activity" and "results" level and at times the plan is not fully clear to us or not directly linked with the objective. As such, progress is reported upon as feasible with some key "general progress" aspects noted where particularly relevant. We recommend the main sections on progress and impact achieved are focused upon.

2.1. India

2.1.1. Overview of activities and country context

In India, two organisations have been supported through the project: (i) the Community Network for Empowerment (CoNE based in Manipur); and (ii) The Delhi Network of Positive People (DNP+ based in Delhi).

The funding has provided CoNE with the means to undertake the following key activities (primarily in Manipur state): (i) conducting meetings to help formalise the Hepatitis C virus (HCV) task force as well as conducting training for health care workers (HCW); (ii) developing a standard operating procedure (SOP) for Manipur state with the objective of bringing uniformity to HCV treatment and more simple and straightforward diagnosis; (iii) reaching more people who inject drugs (PWID) through increased testing and treatment; (iv) developing a free HCV treatment programme particularly for prisoners and indigent people which was launched in September 2017; and (v) undertaking awareness campaigns.

The project has enabled DNP+ to undertake the following whilst working in Delhi: (i) increase their work and undertake more advocacy activities at higher government levels; (ii) work together with other HCV coalitions, and assist the government with the design and rollout of the programme; (iii) advise HCWs in one public hospital in Delhi that provides free treatment – in particular for PLHIV.

The Indian government announced a National Action Plan for Hepatitis C over a three year period, starting in 2018 and with an allocated budget of US\$95m.³ However, the national programme has not yet been implemented.

2.1.2. Progress and impact achieved

The main contribution of the project CSOs in India has been to support the development of the National Action Plan, reflecting the community voice as well as encouraging the inclusion of the provisions for vulnerable populations.

The progress and impact of the project work was reported by our consultees as follows:

- **Policy and guidelines development:**
 - As emphasised by an external stakeholder, both CoNE and DNP+ (alongside other organisations) have assisted with the development and finalisation of the National Action Plan. They have provided a strong community voice, advocating for the plan to be agreed to, and putting pressure for the plan to be launched by the Government. This has been a key contribution of both project CSOs.

³ At end of 2017 exchange rates.

- DNP+ has organised national meetings on an annual basis in support of the National Action Plan. These meetings provided information on the plan, budget and guidelines and included key stakeholders such as WHO country and regional offices, UNAIDS, FIND, MSF, etc. These organisations developed a joint response to provide input on the National Action Plan. Following this submission, the government made a number of changes, particularly with regards to inclusion of vulnerable communities whom the government had not previously adequately considered.
- CoNE indicated that the streamlined SOP developed for Manipur state on HCV diagnosis and treatment is soon to be adopted by the government. External stakeholders confirmed that this work has been key for the expected roll out of the programme in Manipur one of the key changes taken forward is that people diagnosed with HCV will be put on treatment straight away.
- **Treatment access:** CoNE indicated that their work has helped diagnose high HCV prevalence among PWID in Manipur and have been able to identify issues with their access to treatment. External stakeholders commented that CoNE's work has been instrumental in demonstrating how prison treatment can be rolled out and CoNE has repeatedly been asked to present their experiences, including to the WHO regional office. Further, DNP+ linked PWID and HIV+ people with regards to access to treatment.
- **Information generation:** DNP+ have been monitoring how the national programme can be implemented and related implementation challenges. For example, DNP+ is monitoring stock-outs which are a crucial bottleneck, as highlighted by one of the external stakeholders consulted.
- **Training:** DNP+ and CoNE have trained HCWs who now have increased information regarding appropriate treatment for HCV, including for PLHIV.
- **Awareness building:** External stakeholders noted that the project work has helped raise community awareness especially through awareness campaigns and this has resulted in increased testing for HCV.

As such, the feedback indicates that the work of the project CSOs has supported progress against the **demand and adoption barrier**, importantly through supporting policy and guidelines development, but also through information generation, awareness building and training of HCWs. The project has also **supported treatment access** for key and vulnerable populations.

More generally, consultees provided feedback that strongly reflected the **added value** of the project work – for example:

- Both organisations were noted to be much valued by the external stakeholder community – e.g. the government has turned to DNP+ and CoNE for the experience

they bring and advice for policy level. They are able to share insight into the gaps and challenges, especially with regards to reaching vulnerable populations.

- DNP+ and CoNE have worked closely with other organisations and provided information such as on state budgets which has been useful. It was noted that because of this project, MSF has been able to have strong partners in India and the work of the project partners and MSF has been well complemented. This has aided their efforts, and emphasised the catalytic impact of the project funding – as a respondent stated, “if we did not have these partners we wouldn’t have made the progress that we have” and “a little money has gone a long way”.
- CoNE is working where no other organisations are currently working (e.g. in prisons). In addition, external stakeholders noted the key gap that DNP+ and CoNE fill with regards to linking vulnerable groups with the health system.
- While CoNE’s work is at the state/ regional level, it is expected to influence national policy (as communicated by external stakeholders).

Table 2.1 provides a summary of the progress/ achievements in relation to the expected outcomes in the project plan.

Table 2.1: Progress/ achievements against projected outcomes in project plan - India

Outcome	Progress/achievements
P1: National guidelines including DAAs	CoNE confirms that this activity has progressed and the guidelines are soon to be adopted by the State of Manipur.
P2: NSP for HCV addressing KPs	The policy dialogue has been supported and NSP is launched. There is reference to legal actions within this activity/ indicator, for which progress was not intimated to CEPA. Stakeholders confirmed that the work of CoNE and DNP+ assisted the development and finalisation of the National Action Plan, particularly the inclusion of vulnerable communities.
P3: Adoption/ expansion of national treatment programme with DAAs	Policy dialogue has been conducted at the state and federal levels for the launch of treatment programmes. The National Programme has been launched at the federal level. The project CSO confirmed engagement with the health Secretary on HCV mandate for the National AIDS Control Organisation.
P4: Increased investments (or decisions to invest) in HCV programmes	Policy dialogue in this regard was supported by the project CSOs.
P5: Increased HCV awareness	Project CSOs confirmed that awareness building activities were conducted, although the planned survey to assess increased awareness has not yet been issued by CoNE.

2.1.3. Challenges and remaining gaps

The following main challenges were noted for the Indian context:

- Although there is a national programme, it is up to individual states to implement the programme (given India’s federal structure) and political commitment is lacking across states. This includes Manipur state where there is still no confirmed plan to implement the programme, although it is expected that the SOP will aid the implementation.
- There are multiple challenges along the cascade of care, including challenges at the start with regards to lack of availability of diagnostic testing.

Further work was noted to be required for the following aspects in India – where ongoing support from Unitaid could add value:

- Implementation of the national programme:
 - There is a need for CSOs to play a catalytic role to expedite the process for rolling out the national programme.^{4,5}
 - CSOs will need to provide ongoing accountability to ensure political commitment is maintained, and encouragement to implement the national programme. Monitoring will be required at a community level, alongside a “watchdog role” to ensure political commitment is maintained.
 - CSOs need to be engaged, especially regarding aspects such as simplification of the treatment algorithm and to bring the programme to the communities, alongside providing technical advice to the government.
- Awareness raising amongst people living with HCV and others to reduce stigma and discrimination.
- Development of a strong evidence base on the benefits of the HCV programme which can be used as advocacy tools to garner support for scale up.

In terms of aspects relating to sustainability, from a project perspective, CoNE, and particularly DNP+, are very reliant on CPLUS support. There was some concern that the project CSOs should focus their efforts on key influential stakeholders such as academics, senior medical doctors, etc. in order to ensure efforts are sustainable. However, other feedback suggested that key policy makers have already been targeted.

2.2. Malaysia

2.2.1. Overview of activities and country context

Malaysia has made strong gains since the start of the project. At the end of 2017, DAAs were included in national guidelines and the national hepatitis programme was introduced in 2018.

⁴ Feedback indicated that accountability measures from CSOs should ideally remain in place for five years once the national programme implementation has started.

⁵ From the HCV programme perspective, a number of aspects will be required in order for the roll-out of the programme including greater capacity amongst HCWs, consistent access to diagnostics, roll out of programme at state levels is needed.

The programme has been launched in 19 government hospitals and so far 1,500 people have been treated. However there are barriers to implementation of the programme with regards to the treatment pathway, as well as insufficient awareness from the demand side.

There are three project CSOs in Malaysia – Malaysian AIDS Council (MAC), Positive Malaysian Treatment Access and Advocacy Group (MTAAG+) and Third World Network (TWN). With regards to MAC’s activities, the funding from the CPLUS project enabled them to start their HCV work, in addition to their previous HIV work. They have conducted an awareness workshop with HCWs across Malaysia and are developing a toolkit for CSOs to help communities better understand HCV. MTAAG+ have done some research on the different drugs, specifically on patent states, price, registration, and affordability. They have also assisted with capacity building and training for key populations and promoted testing in communities. TWN has also been involved in the clinical trial for Ravidasvir with the MoH and DNDi which is aiming to provide access to another DAA.

2.2.2. Progress and impact achieved

The main contribution of the project CSOs in Malaysia has been to provide much needed technical expertise and guidance alongside engaged advocacy to the government. While there has been strong political will in the country, the project CSOs have helped speed up the process of policy development, including supporting the inclusion of decentralised treatment.

The impact of the work of the project CSOs is reported as below.

With regards to the **affordability barrier**:

- **Market access:** As verified by external stakeholders:
 - TWN provided technical expertise (including examples from other countries) and built up capacity within the government to expand access to HCV care.

With regards to the **demand and adoption barrier**:

- **Guideline and policy development:**
 - As agreed by external stakeholders, the pressure and technical support from project CSOs was key to speeding up the process of guideline and policy development (especially regarding inclusion of DAAs in national guidelines and introduction of the national programme), even though the will of the MoH was already there.
 - The CPLUS organisations have raised awareness on the need to decentralise treatment to the primary health care level. This has aided discussions with the MoH about the decentralisation of care and there have been changes made to

the strategy. However, it was also noted that it was a missed opportunity that the CSOs did not advocate more for the simplification of the treatment algorithm at the time of the national strategic plan (NSP) drafting, instead of afterwards.

- **Training:** The project has helped to scale up training of HCW, which is considered to be key as the country moves to decentralise treatment.
- **Awareness building:** External stakeholders agree that:
 - There is increased awareness regarding HCV, as well as improved coordination and mobilisation of stakeholders, including civil society. However, some stakeholders noted that some of this awareness raising has been focused on other CSOs and should have been extended further to other key stakeholders.
 - MAC has been a key stakeholder involved in advocacy, especially providing a much-needed link between the work of CSOs and government based on MAC’s work in HIV. This is expected to be useful with regards to reaching vulnerable communities.
- **Information generation:** External stakeholders noted that:
 - MTAAG produced a report which provided evidence of global issues on HCV and how this related to Malaysia, serving as a useful advocacy tool.
 - Through MTAAG’s screening work, especially with PWID, needed evidence has been provided regarding HCV prevalence. The work of the CSOs has enabled prisoners to have access to treatment.

Table 2.2 provides a summary of the progress/ achievements in relation to the projected outcomes in the project plan.

Table 2.2: Progress/ achievements against projected outcomes in project plan - Malaysia

Outcome	Progress/achievements
P1: National guidelines including DAAs	Malaysia’s national guidelines for HCV include DAAs.
P2: NSP for HCV addressing KPs	The national plan is in place and there is a move to address KPs. Policy dialogue has been supported on inclusion of key populations in the strategic plan –guidelines have not been made public yet, but the expectation is that key populations will be included.
P3: Adoption/ expansion of national treatment programme with DAAs	Policy dialogue was conducted and treatment programme was launched. There is ongoing work on registration of generic companies but this has not been achieved yet. There is ongoing advocacy on other patents as well.
P4: Increased investments (or decisions to invest) in HCV programmes	Policy dialogue is ongoing and the budget is yet to be finalised. The budget for 2018 was increased to launch the program and although the budget is yet to be finalised for

Outcome	Progress/achievements
	2019, the government announced publicly that it would be increased.
P5: Increased HCV awareness	Awareness activities have been conducted, in particular to combat stigma regarding HCV and HCV treatment.

2.2.3. Challenges and remaining gaps

The following main advocacy-related challenges and gaps, as well as associated areas of further work were noted in Malaysia:

- The longer term national programme budget beyond 2018 is still being finalised, therefore there is a need to develop an investment case for HCV elimination, with the aim of leading to an increase in number of HCV patients treated under the national programme budget allocation.
- Gaps remain within the treatment algorithm, especially with regards to reaching high risk groups – these gaps need to be addressed.

The following aspects were noted to be important from a sustainability perspective:

- From a CSO perspective, feedback indicated that the CSOs need to maintain strong strategic vision and ensure that their work was well aligned with the current advocacy needs, especially given the leadership change in MAC.

2.3. Morocco

2.3.1. Overview of activities and country context

In 2017, project partners, Association de Lutte Contre le Sida (ALCS) and ITPC Mena contributed to developing NSP which is now in place. However the NSP has not been launched as progress was stalled due political instability. There is also a significant challenge with regards to financing the NSP.

Project CSOs previously included ALCS and ITPC Mena but now just include ALCS. Whilst ALCS has undertaken a number of activities, the main activities conducted recently are noted below.

- Firstly an external consultant was commissioned to undertake a benchmarking study regarding on prices and availability of diagnostic tests. This showed that in Morocco, the cost of treatment and diagnosis was relatively expensive in comparison to other low- and middle-income countries and as such has been used to advocate to parliament, civil society, doctors, etc. for lower pricing.
- Secondly, the project supported the development of an investment case by Pharos Global Health advisors and was presented to the MoH in September 2017. This clearly showed the cost effectiveness of the proposed plans in the NSP, and for example, that

it is less expensive to treat now, and then avoid cancer and the associated costs in 10-20 years' time.

- Thirdly, in anticipation of the launch of the NSP, ALCS has: (i) trained doctors; (ii) engaged with pharmaceutical companies to reduce their DAA costs; (iii) simplified and reduced the cost of the diagnosis stage with regards to the number of viral load tests. With regards to (iii), ALCS has been advocating to suppress genotyping as this is expensive (and the cost of this testing is born by patients) and not necessary as the country DAAs treat the majority of the HCV genotypes (are able to treat types 1-6) and decrease viral load testing, in line with the “treat all” guidance issued recently by WHO.

2.3.2. Progress and impact achieved

Although there are key constraints in Morocco, the fundamental contribution of the project has been viewed as the investment case, which has been disseminated amongst the government health programmes. Government confirmed that progress towards HCV policy development would have been slower without the support of ALCS.

The project has facilitated several aspects of progress in support of addressing the **demand and adoption barrier**, as follows:

- **Policy development:** ALCS have helped to obtain political support for the NSP from the King and the executive government. The government representative interviewed indicated that the advocacy work of ALCS was very helpful and supported the development of the NSP as well as motivated the government to adopt it. However the acceptance of the legislative side of parliament is still needed.
- **Financing:** The benchmark study and investment case have provided an evidence base for decision makers and provided the basis for discussions on HCV financing that otherwise would not have happened. The work was well disseminated and was viewed to have been developed through a clear and sound methodology. The MoH now needs to convince the new Ministry of Finance (MoF) and an MoU to be sent to the MoF will include the investment case and benchmarking study results.
- **Awareness raising:** ALCS indicated that civil society groups have been more focused on HCV through the advocacy work of the project. There was a need to ensure that HCV was a priority amongst the many diseases that CSOs focus on, and at the start of the project, HCV was less of a focus. The government did not emphasise this impact, although did view the overall advocacy work of ALCS in awareness raising on HCV as useful.

Other areas of progress include the following:

- **Efficiency in the testing algorithm:** A reduction in number of viral load tests (from four to two) and genotyping tests was achieved through the advocacy work of ALCS in their role as participatory members of national committees. This is expected to reduce costs to the patient, and improve loss to follow up within the cascade of care.
- **Access to treatment:** Through the work of ALCS with the delegation of prisoners, support was obtained to provide HCV care (although in theory only, as this is dependent on NSP implementation and decrease in prices). Previously the delegation of prisoners had only focused on TB.

In summary, good progress has been made although important challenges and further work remains. The added value of the work of the project is reflected in the fact that government indicated that, without ALCS, all of this progress would have happened much more slowly.

Table 2.3 provides a summary of the progress/ achievements in relation to the projected outcomes in the project plan.

Table 2.3: Progress/ achievements against projected outcomes in project plan - Morocco

Outcome	Progress/achievements
P1: National guidelines including DAAs	The project CSO have proved input through engagement in the expert committee, although the NSP has not been launched yet.
P2: NSP for HCV addressing KPs	ALCS has engaged in the development of the plan, but it has not been launched yet.
P3: Adoption/ expansion of national treatment programme with DAAs	The NSP has not yet been launched. The seroprevalence study was noted as one of the areas of support once the treatment programme is launched.
P4: Increased investments (or decisions to invest) in HCV programmes	Policy dialogue on funding has been supported by the project CSO, especially through the use of the investment case.
P5: Increased HCV awareness	Awareness raising has been part of the work of the project CSOs, including focussing on raising awareness amongst CSOs.

2.3.3. Challenges and remaining gaps

The following aspects have been noted as key areas further work:

- The project is needed in order to continue to streamline advocacy and launch the NSP. Also, there is a need for a watchdog role from the CSO community to ensure that progress, alongside implementation support for the NSP activities.
- A further priority is to advocate and work with the Ministry to procure DAAs (ideally at lower price than what is currently available). The government indicated that going forward, ALCS should continue its advocacy role, especially focusing on advocating for price reductions, and making available and affordable screening for patients

- There is also a need to undertake a seroprevalence study to better understand HCV prevalence and the populations affected.

ALCS appears to be crucial to fighting HCV in Morocco and therefore will require ongoing funding, especially as their work is not currently maximising its sustainable impact given that the NSP has not been launched. However, given that they were already working in Morocco before this funding, they may be able to receive funding from other sources.

2.4. Thailand

2.4.1. Overview of activities and country context

A number of gains have been made in Thailand, including the launch of an NSP at the end of 2016 (although some significant gaps have been noted in implementation of the plan as discussed below). In addition, civil society and community representatives have been included in the national viral hepatitis sub-committee.

However, there are a number of obstacles with regards to the introduction of the national programme. These include lack of access to diagnostics, inefficient service delivery, lack of awareness among general and key populations and HCWs, and inadequate access to drugs. For example, drugs for HCV are on the special drug list and therefore need have a ‘TI Doctor’ (specially qualified doctors that have been practicing for at least five years) to prescribe treatment. There are also treatment criteria that create barriers, these include people living with HCV needing to be at certain stage of disease to receive treatment, special criteria for PWID, etc. Furthermore, whilst there have been gains made regarding the inclusion of SOF/LED and SOF/Velpatasvir (VEL) in the Essential Medicines List, there is a need for access to more DAAs, such as Daclatasvir especially as a large proportion of people living with HCV in Thailand have Genotype-3.

The project CSOs include Thai Treatment Action Group (TTAG, focusing primarily on PWID)⁶ and Treat Asia (focusing primarily on access to treatment, drug prices, etc but also training of HCWs). Their work has included the following:

- In 2017 most of the actions focused on reviewing, identifying and addressing major gaps in the NSP. The gaps noted included: little mention of treatment, or strategies or pathways for accessing treatment; absence of specific plans to scale-up access to DAAs; no mention of PWIDs; no inclusion of civil society and of peers in recruiting and supporting PLHCV.
- CSOs are also working with the Medicines Patent Pool (MPP) to extend the VL to Daclatasvir and this work is ongoing, primarily by Treat Asia but also with TTAG’s input. TTAG has been providing data on the Genotype-3 prevalence.

⁶ Ozone Foundation is also included in the project as an associate partner of TTAG.

In addition, Treat Asia's work has also included: holding a two-day training in December 2017, in collaboration with the WHO WPRO and SEARO offices for 36 physicians from nine Asian countries.

TTAG have been the primary organisation working on advocacy and are a member of the national sub-committee on HCV and have been representing PWIDs in this committee. In the past year they submitted policy briefs on: (i) situation on Hepatitis C; (ii) hepatitis C testing barriers; (iii) need for DAAs. TTAG have also been assisting people to get tested (e.g. PWID and those who do not have ID numbers). TTAG has been undertaking a watchdog role with regards to encouraging the government to have more DAAs. TTAG has been advocating for HCV drugs to be on the 'regular' drug list rather than the 'special' drug list as the 'regular' drug list has a lot less criteria.

2.4.2. Progress and impact achieved

The HCV policy landscape in Thailand faces some key challenges and there is a suggestion that presently the government has a degree of complacency following the issuance of the Voluntary License. However, the work of project CSOs has supported "a number of smaller but key wins" such as improving the treatment access criteria. More generally the work of Treat Asia has been pivotal across the region.

Regarding the **demand and adoption barrier**, progress has been made in support of **policy and guidelines development** as follows:

- In 2016 there was limited leadership in the country regarding hepatitis but after the project CSOs advocated for an HCV bureau to be set up, this was done, and a forum has been created for decision-making regarding HCV.
- The policy briefs from TTAG have been shared in the National Hepatitis C sub-committee meeting and government have since been reviewing their national policy, with the NSP launched at the end of 2016. As confirmed by an external stakeholder, the policy briefs had an impact to inform organisations, the MoH and the health financing office to include DAAs in the Universal Health Coverage (UHC) system.
- TTAG and Treat Asia have been focusing on improving access to medicines, especially through guiding the government regarding improving the treatment criteria. The efforts have been noted but uptake will be dependent on the National Hepatitis C sub-committee decision.
- Inclusion of different treatments (SOF/LED and SOF/VEL) in the Essential Medicines List was viewed by the project CSO as being due to their participation in the HCV sub-committee.

There have also been several areas of contribution from the project towards enhancing **treatment access** as follows:

- **Financing for diagnosis:** As reported by an external stakeholder, TTAG's advocacy and guidance has encouraged the government to now separate the budget between diagnostic tests and treatment, and people are being referred a lot more for diagnostic tests, therefore addressing one of the barriers to accessing treatment. This is a key attribution to the work of the TTAG.
- **PWID access:** As confirmed by external stakeholders, through their inclusion in the UHC system, there is an increasing willingness from government and HCWs to reach PWID and this has resulted in an increased number of PWID who are being treated for HCV. This inclusion was attributed to the work of TTAG. As intimated by an external stakeholder, although the government does provide testing and treatment, the government has difficulty in reaching key populations, especially PWID. TTAG have therefore enabled more key populations to have access to testing and treatment.
- **Training:** As confirmed by external stakeholders, the training by Treat Asia, in collaboration with WHO WPRO and SEARO has built capacity with regards to knowledge of WHO guidance (especially as there is not a standard approach at this stage), and increased physicians' confidence to treat HCV in their respective countries. This training has been complementary to WHO/SEARO work as they do not conduct training on the guidelines. The training is to be undertaken this year again and there are plans to publish the training material into modules. However, this was noted to only be at a relatively small scale, and some of the impact of this work will only be fully realised once national programmes are fully implemented.
- **Awareness building:** External stakeholder agree that due to TTAG's work with PWID, PWID now have increased knowledge and awareness of HCV.
- **Information sharing:** The guidelines for HCV testing and treatment are reportedly frequently changing so TTAG has provided support to PWID to know what options are available to them.

With regards to the **affordability barrier**, project work has contributed to improved **market access**:

- updates on prices of DAAs paid by select other countries provided by project partners have informed country policy, and have been used in the context of price negotiations.
- the fact that the MPP and BMS are in discussion to include Daclatasvir in licence is a result of the project.

More broadly, across the countries that Treat Asia have been working in, there have been a number of aspects noted with regards to their information sharing on DAAs: cost reductions, additional approvals, improvements in regulation as well as policy briefs on topics such as simplified treatment algorithms. External stakeholders noted that Treat Asia's work has been very influential in this area with the policy briefs being used in workshops and to inform

technical guidelines in SEARO region countries. In addition, their work regarding transparency and the prediction of drug prices has helped policy makers to obtain this knowledge.

Table 2.4 provides a summary of the progress/ achievements in relation to the projected outcomes in the project plan.

Table 2.4: Progress/ achievements against projected outcomes in project plan - Thailand

Outcome	Progress/achievements
P1: National guidelines including DAAs	Project CSOs have been involved in policy dialogue aiming at removal of interferon as treatment mainstay and have been advocating for Daclatasvir instead. General progress: guidelines were launched in 2018 and do refer to KPs. PWID have been included in the UHC system and project CSOs have been advocating for better treatment access.
P2: NSP for HCV addressing KPs	General progress: NSP was launched at the end of 2016, although some significant gaps have been noted in implementation of the plan.
P3: Adoption/ expansion of national treatment programme with DAAs	Policy dialogue has been ongoing with the National Hepatitis C sub-committee. General progress: A programme was launched in February 2018.
P4: Increased investments (or decisions to invest) in HCV programmes	The HCV bureau has been set up and CSO advocacy and policy dialogue work is ongoing. General progress: The MoH announced the budget raise for the year 2018.
P5: Increased HCV awareness	Awareness raising has been part of the work of the project CSO, especially amongst PWID.

2.4.3. Challenges and remaining gaps

The following main advocacy-related challenges and gaps were noted in Thailand:

- A systematic approach is required from policy makers regarding the best means to diagnose and treat PLHCV and reach national targets.
- There is still only a single supplier of drugs and more DAAs are needed. Daclatasvir is not available on the national drug list (and this is needed to treat a high proportion of people living with genotype 3 HCV). It would be helpful to have access to one drug for all genotypes.
- Gains need to be made with regards to getting SOF and LED off the ‘special’ drug list and onto the ‘regular list’.

The following areas of work were noted to be priorities:

- There is a need for a clear plan for additional DAAs to be registered.

- Guidance is required in order to decentralise treatment. Further advocacy is required in order for this to change to a community level.
- There is a need to focus on key populations beyond PWID.
- Additional awareness is required to ensure there is sufficient demand and to decrease stigma and discrimination around treatment.

The following aspects were noted to be important from a sustainability perspective:

- Regarding Thailand’s HCV response, a positive step from a sustainability perspective is that DAAs have been included in UHC – something that cannot be undone. However, there are still aspects outstanding that pose risks to the sustainability of the programme including: (i) existing drugs being on the ‘non-special’ drug list; (ii) additional drugs need to be put on the list; (iii) changes to the guidelines to reduce barriers along the treatment cascade are required.
- From a CSO perspective, reportedly no organisation will be able to continue the scale of work that is currently being conducted once funding is withdrawn which poses a sustainability challenge. Reportedly Treat Asia have formulated a global strategy that is having a strong impact, but there is room for improvement with regards to TTAG’s work and how to best focus their efforts for maximum impact.

3. ASSESSMENT OF IMPACT MEASUREMENT

In this section, we firstly provide a high-level assessment of the logframe and secondly, we consider the likelihood of countries reaching the project goal.

3.1. Review of logframe

Following CEPA’s mid-term evaluation, CPLUS made changes to the logframe to better show impact of the multi-faceted strategy (targeting policymakers, empowering communities and building knowledge).⁷ We note that the theory of change underpinning this change to the logframe is coherent and rational. In addition, the project goal linking to global HCV goals makes it appropriate, as it places the project results in the context of global goals. The inclusion of qualitative assessment of certain aspects of progress is also useful e.g. it is an improvement to be able to measure various outcome level indicators (such as number of project countries with increased investments, or decisions to invest, in HCV programmes) through official government statements, reports, statistics, press releases etc rather than the percentage of policy makers who were in agreement as per the previous logframe.

⁷ Project plan

3.2. Likelihood to reach project goal

The project goal has two key indicators: (G1) projected number of HCV patients cured (2018-2023)⁸ and (G2) Projected savings in the cost of HIV/HCV co-infection treatment.⁹ We consider the likelihood of these goals being achieved in turn, based on stakeholder feedback.

Indicator G1

With regards to countries reaching the reaching G1 indicator goal, we note the following:

India – India is planning to treat 100,000 each year against a viremic population of 6.2 million. The project targets 132,300 people by 2019 as per the logframe. Stakeholders have commented that, to date, the implementation of the national programme has been slow, raising questions about the ability to meet these targets, as well as the 2030 elimination targets.

Thailand – Around 7,500 people have been treated since 2012, against the project target of 4,816 by 2019. This is also far from the current country target to treat around 20,000 people per year against a viremic population of 463,000. Stakeholders think that Thailand is unlikely to make 2030 elimination goal, partly due to the specific challenges with diagnosis highlighted previously.

Malaysia – From 2018 to date, only 2,000 people have been treated (in contrast to project target of 4,650 in 2019 and an estimated 382,000 viremic population). Stakeholder feedback indicated that Malaysia may reach the target by 2030 but this will require a lot of effort and advocacy to ensure the government prioritises HCV.

Morocco – Morocco has an estimated 465,000 PLHCV and a project goal of 4,650 to be treated by 2019. While stakeholders think that the goal elimination goal could be reached if the NSP is launched, that is a large barrier at present, as emphasised above.

Across countries – We note that reaching the global goals is strongly reliant upon addressing key gaps in implementation and scale-up even once national programmes have been launched, thus posing risks to the achievement of the 2030 global goal.

Indicator G2

Table 3.1. provides an indication regarding the likelihood of the projected savings goal being reached based on the expected reduction in drug prices, as communicated during our stakeholder consultations.

⁸ Key assumptions regarding: Number of PLHCV in target countries, percentage of Co-infected patients, patients reached by 2023, course completers and cure rate

⁹ Key assumptions based on future WHO DAAs pricing report

Table 3.1: Indicator G2 likelihood of goal being reached

Country ¹⁰	Target DAA price per treatment (post reduction price from 2018 price)	Likelihood of being reached
Malaysia	US\$300 (from US\$12,000)	Likely to be achieved as drugs are currently costing US\$300.
Morocco	US\$902 (from US\$1,113)	Current cost is US\$1,315-US\$1,560. Expectation that DAA cost could be reduced by 50% if NSP launched but if NSP not launched, will not reach target. Government optimistic on price reduction feasibility.
Thailand	US\$300 (from US\$9,000)	Current cost is around US\$1,000. Expectation is that price will not reach US\$300 without additional DAAs being registered.

Overall, whilst we note that the project impact measurements have been sensibly developed in terms of methodology, these may not be achieved due to ongoing challenges on HCV policy and market, and level of progress achieved to date. Malaysia however may be an exception.

We suggest that it may be helpful to present the impact of the project through a range of different scenarios (rather than one impact number only), to show the range of outcomes that may be possible.

4. CONCLUSIONS, LESSONS LEARNED AND RECOMMENDATIONS

Overall the CPLUS project has had a positive impact in countries, with most of the planned activities and results being achieved, and good progress being made in all countries, although more so in some than others.

- In Malaysia the project CSOs have played a key role, and the work of TWN has had a particularly large impact with regards to expanding access to HCV care.
- In India, the national programme is being launched and the project CSOs played a large role in advocating for this, and their input has been recognised at the national policy level.
- The work of the project CSOs has had an impact in Thailand, although this has been less so because there are many CSOs, and more broadly, there has been some complacency at a government level since the VL was introduced. Several HCV treatment related implementation challenges remain.
- In Morocco, the project activities have been appropriate, but progress has stalled due the NSP not being launched.

¹⁰ India is not included in the calculation with regards to price.

There have been reports of benefits of the work of the project extending to other countries too, especially through the work of Treat Asia, whose work is particularly appreciated by stakeholders in a number of countries and they have filled an important role providing advice regarding drug pricing, registration and advocacy.

Although significant gains have been made in a number of countries, such as obtaining a CL or VL, and having NSP/ national action plans in place, there are a number of remaining challenges, especially around implementation. In particular, project CSOs are well placed to assist with some key aspects such as (i) undertaking a watchdog role to support government to provide budgets and implement programmes; (ii) advocating for more to be done such as more generics being registered, simplification of treatment algorithms, and improving and access to diagnostics and treatment and (iii) reaching vulnerable communities, which governments are generally not well placed to do.

Therefore, there remains a need for CSOs to continue the work that has been conducted within this project to date and a project extension from Unitaaid would be useful. The investment case approach in particular has served as a strong advocacy tool, and would be useful to expand, even in countries where the national plans have been launched, as implementation is still slow. Another priority would be in terms of advocating for registration of DAAs to support competition and decrease prices.

However, it will be very important to consider sustainability over the next extension period. There are two aspects to this: (i) capacity building support for CSOs to ensure that they have the capacity to apply for and acquire funding from other donors; and (ii) promoting linkages with in-country funding networks to more effectively absorb available funding in line with national strategic priorities. On (ii) for example, we understand that Treat Asia has been working with the Global Fund Country Coordinating Mechanism (CCM) in India to influence inclusion of HCV in the concept note, which would serve as an opportunity for supporting the future work of the organisation. Further, Unitaaid should also look to leverage its position in the global architecture with other donors.

ANNEX A LIST OF REFERENCES

Coalition Plus

Coalition Plus (2017) HIV/HCV Drug Affordability Project, Annex 1.b: Extension Period Project Plan

Coalition Plus (2017) Extension Period Logical Framework CPLUS – Excel Sheet

Coalition Plus (n.d.) Achievement Countries 2018 – Excel Sheet

Coalition Plus (2018) Mind the Gap: HCV policies vs. community experiences.

Coalition Plus (2017) Impact Estimates: CPLUS 2018 – Excel Sheet

Coalition Plus (2018) Annual & End of Project Report: HIV/HCV Drug Affordability Project, Reporting Period: 2017

Unitaid

Unitaid (2017) Costed Extension of the HIV/HCV Drug Affordability project

Unitaid (2018) CPLUS Risk Register: Updated with review of 2017 annual report – Excel Sheet

Unitaid (2018) Grant Brief Overview: HIV/HCV Drug Affordability Project, January – December 2017 progress update.

Unitaid (2018) Grant Agreement Fact Sheet: Signed CPLUS Cost Extension

Academic Papers

Durier et al (2016) Chronic hepatitis C infection and liver disease in HIV-coinfected patients in Asia. *Journal of Viral Hepatitis*, pp: 1 – 10

Platt et al (2016) Prevalence and burden of HCV co-infection in people living with HIV: a global systematic review and meta-analysis. *The Lancet: Infectious Diseases*. Vol 16, pp: 797 – 808

Other

Multiple Organisations (2017), Submission to Indian government based on viral hepatitis consultation, titled 'Technical inputs to address viral hepatitis in vulnerable/key populations with reference to the National Viral Hepatitis Action Plan (2017–20)

Treat Asia (2018) Panel Discussion: Access and elimination of Hepatitis C. APACC 2018, June 2018

Treat Asia (2018) Current treatment standards, access to generic DAAs globally. VI Eastern Europe and Central Asia AIDS Conference, April 2018

ANNEX B CONSULTEE LIST AND INTERVIEW GUIDES

B.1. Consultee list

This annex provides the list of consultees interviewed as well as the interview guide.

Consultee lists

Table B.1: Global consultee list

Stakeholder	Name	Position
Unitaid	Kate Hencher	Programme Manager
	Romane Theoleyre	Programme Officer
	Karin Timmermans	Strategy Manager/IP Technical Manager
	Loveena Dookhony	Monitoring and Evaluation Officer, Results
	Tijana Dragicevic	Impact team
CPlus	Maria Donatelli	Senior Hepatitis Advocacy Manager
	Jean-Luc El Kaim	Hepatitis Country Partnerships Manager
	Valentina Lombardo	Country Partnership Manager
Other	Eric Fleutelot	Regional Counsellor in Global Health, Embassy of France in Thailand

Table B.2: Country stakeholder consultee list

Stakeholder	Organisation	Name	Position
India			
Project CSOs	CoNE	Kanta Rajkumar	President
	DNP+	Paul Lungdim	Program Manager
CSO	MSF	Leena Menghaney	MSF Access Campaign, India
MoH	Medical Directorate, Manipur	Dr Sasheekumar Mangang	Additional Director (public health)
Malaysia			
Project CSOs	Third World Network (TWN)	Yoke Ling Chee	Director of Programmes
	Positive Malaysian Treatment Access & Advocacy Group (MTAAG+)	Edward Low	Coordinator
	Malaysian Aids Council (MAC)	Tamayanty Kurusamy	Director of Programme

Stakeholder	Organisation	Name	Position
CSO/ Academia	My commitment to Cure – Hepatitis C	Pr Rosmawati MoHammed	Chairman
NGO	DNDi	Jean-Michel Piedagnel	Head of South-East Asia Office
Morocco			
Project CSO	ALCS	My Ahmed Douraidi	Advocacy Director
		Taha Brahni	Advocacy Project Manager
MoH		Ibtissam Khoudri	Head of Epidemiology Department (interim)
Thailand			
Project CSO	TTAG	Jirasak Sriparmong	Project Manager
	Treat Asia	Giten Khwairakpam	Project Manager
MoH	Department of Disease Control	Dr Suchada Jiamsiri	Division of Vaccine Preventable Disease
WHO	WHO South East Asia Regional office ¹¹	Dr Bharat Rewari	Point person for HIV/STI and hepatitis

B.2. Interview guides – consultees

A short introduction to the evaluation was provided to all consultees. The following questions were asked of consultees.

1. What has the project helped to achieve in the project country? This is in regards aspects such as (i) increased commitment of national public authorities to HCV care (including national guidelines, national strategic plans, adoption or expansion of national treatment programs, increased investments in HCV programmes); (ii) increased HCV awareness; (iii) increased knowledge building and coordination among national and international HCV stakeholders and (iv) reduction in HCV drug prices.
2. What results are likely to have been achieved in the absence of the projects activities? What might not have been possible without this project work?
3. With regards to increasing HCV testing and treatment, what are the remaining advocacy-related gaps and challenges?

¹¹ Although represents SEARO, the consultation was primarily around Thailand.

4. In order to support HCV testing and treatment goals over the next one to two years, what priority advocacy, policy development and awareness activities do you think should be considered for further funding, and why?
5. To what extent are project activities and intended results likely to be sustained after the project is completed? What factors would determine sustainability of intended project results?
6. Is your country on track to reach the Global 2030 HCV targets? What key indicators or measurement activities would be most useful to assess in-country progress towards Global 2030 HCV targets?¹²

¹² This question was only asked of the project implementer and project CSOs.