



MAKE POOLING WORK TO END PANDEMICS

A QUALITATIVE ANALYSIS OF
THE COVID-19 TECHNOLOGY ACCESS POOL

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Make pooling work to end pandemics: A qualitative analysis of the Covid-19 Technology Access Pool

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MAKE POOLING WORK TO END PANDEMICS: IN A NUTSHELL

A global mechanism to **share intellectual property (IP), know-how and technology** for the production of essential medical innovations can play a key role in responding equitably and effectively to a pandemic. It can **help maximize global production** of and access to these products and increase **self-sufficiency** of low- and middle-income countries.

For this reason, the World Health Organization (WHO) set up the Covid-19 Technology Access Pool (C-TAP) at the beginning of the Covid-19 pandemic. Unfortunately, C-TAP has **not reached its full potential** as only a limited amount of research institutes and not a single private pharmaceutical company have shared their knowledge around Covid-19 technologies through this mechanism.

As outlined in this report, the lack of success of C-TAP till now has several **remediable causes**, such as a significant **lack of funding, human resources and political support**, and **unwillingness** of private pharmaceutical companies. To reach the full potential of global pooling of IP, know-how and technology, the WHO and its Member States can take **concrete steps**.

As substantiated in this report, the WHO, the EU and national governments should **sufficiently fund and resource** C-TAP and/or its equivalent for pandemic prevention, preparedness and response as **part of the Pandemic Accord**. Moreover, governments should **create incentives** for pharmaceutical institutes and companies to share IP, know-how and technology. Lastly, governments should attach **conditions to public investments** in medical innovations to ensure access for all.

Read all the findings and recommendations on the functioning of C-TAP in this qualitative analysis report. For this research, representatives of the WHO and Member States, funders of C-TAP, civil society organisations and the private pharmaceutical industry were interviewed.

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ABBREVIATIONS & ACRONYMS

| | |
|--------------------------------------|---|
| ACT-A | ACCESS TO COVID-19 TOOLS (ACT) ACCELERATOR |
| BMGF | BILL & MELINDA GATES FOUNDATION |
| CEPI | COALITION FOR EPIDEMIC PREPAREDNESS INNOVATIONS |
| CIFA | COVID-19 INNOVATIONS FOR ALL CONSORTIUM |
| COVID-19 | CORONAVIRUS DISEASE 2019 |
| C-TAP | COVID-19 TECHNOLOGY ACCESS POOL |
| COVAX | COVID-19 VACCINES GLOBAL ACCESS |
| CSIC | SPANISH NATIONAL RESEARCH COUNCIL (<i>CONSEJO SUPERIOR DE INVESTIGACIONES CIENTÍFICAS</i>) |
| EU | EUROPEAN UNION |
| HICS | HIGH-INCOME COUNTRIES |
| IP | INTELLECTUAL PROPERTY |
| IPR | INTELLECTUAL PROPERTY RIGHTS |
| IPRH | INTELLECTUAL PROPERTY RIGHTS HOLDERS |
| K&TT | KNOWLEDGE AND TECHNOLOGY TRANSFER |
| LMICS | LOW- AND MIDDLE-INCOME COUNTRIES |
| MRNA | MESSENGER RIBONUCLEIC ACID |
| MPP | MEDICINES PATENT POOL |
| NIH | USA NATIONAL INSTITUTES OF HEALTH |
| PVA | PEOPLE'S VACCINE ALLIANCE |
| PPRA | (WHO) PANDEMIC PREPAREDNESS AND RESPONSE ACCORD |
| PPE | PERSONAL PROTECTIVE EQUIPMENT |
| R&D | RESEARCH AND DEVELOPMENT |
| SC2A | SOLIDARITY CALL TO ACTION |
| TECH TRANSFER | TECHNOLOGY TRANSFER |
| TECHNOLOGY TRANSFER MECHANISM | TECHNOLOGY TRANSFER AND IP POOLING MECHANISM |

| | |
|--------------|---|
| TRIPS | TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS |
| WHO | WORLD HEALTH ORGANIZATION |
| WTO | WORLD TRADE ORGANIZATION |

EXECUTIVE SUMMARY

PURPOSE OF THE REPORT

In May 2020, C-TAP was created to respond to the global Covid-19 pandemic. Its aim is to provide a platform for IP pooling and facilitation of technology transfer that is required for the production of essential Covid-19 countermeasures. Following the model of the Medicines Patent Pool (MPP) with the added mandate of vaccines, C-TAP has since secured two licences with public research organisations in Spain and the United States. Creating a global technology transfer mechanism housed under the WHO has the potential to reduce the dependency of low- and middle-income countries on high-income countries and on the private sector. It can diversify and increase manufacturing capacity and thereby increase the availability of important countermeasures required in a pandemic.

The unequal access to available life-saving countermeasures during the Covid-19 pandemic has illustrated that functional structures and approaches are needed to ensure rapid and equitable access to countermeasures during future pandemics. WHO Member States therefore decided to supplement the existing International Health Regulations with the Pandemic Prevention, Preparedness and Response Accord, aimed at strengthening pandemic preparedness, prevention and response. Throughout 2022, the International Negotiation Body has convened talks with WHO Member States. The outlines of the accord clearly underline the importance of technology transfer and IP sharing for more equitable access to pandemic countermeasures and to the knowledge needed to produce them.

Against this background, a qualitative analysis of the functioning of C-TAP was undertaken to generate and document knowledge in relation to the functioning and impact of C-TAP, to investigate if and how a similar mechanism could function (better) and to make policy recommendations for a future technology sharing mechanism as part of the Pandemic Accord.

METHODOLOGY

The research took place between August and October 2022. The qualitative research was conducted through a document review and semi-structured interviews with 21 stakeholders. The stakeholder groups were WHO staff and members of the technical advisory group, the private pharmaceutical industry, civil society organisations, funding organisations, and an external WHO consultant. The research data was captured using basic coding.

KEY FINDINGS

- Respondents helped determine the indicators of success, which involved qualitative assessment of the licences concluded, quantitative elements related to the number of licences and products, and normative elements like the creation of a new global technology transfer mechanism. Reflecting on these indicators, respondents generally deemed C-TAP to be a promising mechanism which has not yet reached its full potential.

- Efforts by C-TAP to contact IP rights holders and Member States were recognized but deemed insufficient given the urgency of action required during the pandemic. All respondents agreed that within the C-TAP initiative, insufficient funding, human resources and political support have been key factors hindering C-TAP's potential impact.
- The role of Member States in ensuring interaction with C-TAP and public research institutions has been shown to have a positive effect. However, stronger action is required by the Member States to incentivize public research institutions to license to C-TAP. This can be done by attaching conditions to public funding.
- Furthermore, C-TAP being housed within the WHO brings advantages and disadvantages. The WHO has the competence to set global norms in public health and has vast expertise in the area of global health and houses vast expertise. It thereby provides legitimacy to the initiative. On the other hand, an initiative like C-TAP must function within the bureaucratic environment and political dynamics inherent to a member state body such as the WHO, and this impacts its operations.

In the following section, policy recommendations to the WHO, Member States and policy-makers and for the inclusion of technology transfer mechanisms within the Pandemic Accord have been formulated.

POLICY RECOMMENDATIONS

RECOMMENDATIONS FOR THE FUNCTIONING OF C-TAP

RECOMMENDATIONS FOR NATIONAL GOVERNMENTS AND THE EU

Policy recommendation: Attach access conditions to funding of R&D and procurement contracts, as early as possible

For R&D funders to use the full scale of leverage that they have over a product, they should include access provisions in funding and procurement contracts of health products at their earliest stage of research. Once the product exists and has received approval, forcing access conditions is more difficult, so such conditions should be included at the earliest stage of negotiations between funding governments, the publicly funded research institutions and/or pharmaceutical companies developing the product. Funding should require approaches which increase access to the products, such as non-exclusive licences with reasonable royalties, or licensing to global technology transfer mechanisms¹ such as C-TAP.

Policy recommendation: Provide resources for technology transfer mechanisms

Governments and policy-makers who publicly support mechanisms such as C-TAP should also provide resources to these mechanisms to the best of their capacity. Resources required that Member States can provide are: funding, political engagement and advocacy activities. Support can also be given by entering into discussions with fellow Member States and international organisations, and by national actions directed at IP rights holders.

Policy recommendation: Seek opportunities for technology buy-outs

Where there is limited interest from IP rights holders to share with C-TAP, governments could consider pooling their funds collectively and buying out certain IP rights and technologies, and in turn, licensing these to C-TAP. Monopolies could be avoided by offering cash payments to technology and IP rights holders to give these up. This would not impair the current incentives of gaining financial profit by commercialising the invention (e.g. through royalties and exclusive licences) but offer a solution for overcoming the obstacles of monopolies rendering innovations expensive and with limited availability. This option could be adopted in the Pandemic Accord.

¹ The terms “technology sharing mechanism” and “mechanism” will be used throughout the report to refer to a “technology transfer and IP pooling mechanism” such as C-TAP or a future mechanism of this sort. The abbreviated form is used for readability but does not intend to limit the scope of the mechanism in question.

Policy recommendation: Increase interest of generic manufacturers

Member States should increase the interest of generic manufacturers to become out-licensees of C-TAP and similar mechanisms. They should create demand on the side of manufacturers to increase the amount of products manufactured through such a mechanism.

Policy recommendation: Implement incentives for sharing with technology transfer mechanisms

Member States should furthermore create a system of incentives proposed to IP rights holders to make sharing with a technology transfer mechanism more advantageous. Incentives could be attached to the research and product licences through technology transfer mechanisms. However, these incentives should not come at the cost of quality and safety of the research and products. Incentives could include:

- Priority status in regulatory approval procedures and IP recognition;
- Simplified procedures and administrative requirements for approval and clinical trials of the technologies licensed;
- Funding of clinical trial costs;
- Tax incentives such as benefits and exemptions for income linked to licensed products;
- Financial incentives such as cash payments linked to sharing with technology transfer mechanisms.

RECOMMENDATIONS FOR THE WHO, NATIONAL GOVERNMENTS AND THE EU

Policy recommendation: Be proactive in finding relevant research and products

The technology transfer mechanism should actively seek out IP rights holders of relevant research and products. These rights holders should be approached and pursued actively with information about C-TAP, sparking their interest in licensing through the technology transfer mechanism. It should not be left up to IP rights holders to approach the technology transfer mechanism.

Policy recommendation: Focus on governmental research institutes and those receiving significant public funding

The first years of C-TAP have shown that Member States can significantly influence public research institutes to license to C-TAP on a voluntary basis. This was not the case for the private industry. It would be best if Member States simultaneously encouraged these institutes to collaborate with C-TAP. C-TAP should therefore focus its advocacy efforts on Member States, encouraging them to support their publicly funded institutions to interact and share with C-TAP.

Policy recommendation: Create more concrete information material about C-TAP

C-TAP should be promoted more intensely at the WHO and Member State levels, including amongst national funders, research institutes and private industry. The C-TAP initiative should therefore create more information material that can be used to inform research institutes and other stakeholders. Such material should clearly explain its structure, its benefits, the standard procedures and requirements for licensing a product (sharing of IP, R&D data and clinical trials, transparency requirements) and the steps required. The material can take the shape of a video, a user guide and manual, as well as more documentation on C-TAP's webpages on the WHO website. Ideally, a handbook would be created that can be shared digitally with and by various stakeholders.

RECOMMENDATIONS FOR THE WHO

Policy recommendation: Accept products which do not yet have regulatory approval

Technology transfer mechanisms should not restrict themselves by focusing only on certain types of products or only accepting products which have obtained regulatory approval. In practice, convincing an IP rights holder to license to the technology transfer mechanism will be easier in the early stages of research, prior to the research entering the market as an approved product. It is important to incentivise open science by licensing research that may become useful in the future or could potentially contribute to the development of another product. C-TAP should therefore actively seek out and license products pending regulatory approval or research that could become useful.

Policy recommendation: Ensure a flexible and transparent governance structure

The technology transfer mechanism should not have an overly bureaucratic internal governance structure. Leadership and delegation of tasks must be clear with strong accountability and transparency requirements and processes. Working groups should remain adaptable and flexible to deal with emergency situations. Collaboration with external organisations like the MPP must be promoted but not create confusion for third parties about the governance structure.

Policy recommendation: Ensure sufficient resources and encourage this through high-level advocacy

A technology transfer mechanism housed under the WHO should be adequately staffed and funded. Diverse staff competencies are required, from managerial and negotiation skills to contracting and communication. More high-level advocacy by the WHO and UN towards Member States is needed, backed up by detailed funding proposals and operational strategies. To this effect, we recommend a high-level ambassador be appointed to conduct advocacy activities and regularly meet with the Member States, industry and delegations.

Policy recommendation: Advocate for more active engagement by SC2A signatory Member States to promote C-TAP

The WHO C-TAP initiative should advocate for more concrete steps and actions to be taken by the Member States who signed the [Solidarity Call to Action \(SC2A\)](#). These actions could take the form of Member States actively approaching publicly funded research centres and facilitating the contact and communication with the C-TAP initiative. Governance structures should be created which facilitate interaction between C-TAP, IP rights holders and the MPP. An idea would be to set up national points of contact and to delegate this responsibility to a specific person to ensure longevity of contact and overview.

Policy recommendation: Provide a model agreement and written overview of the costs of technology transfer

The technology transfer mechanism should have a model licensing agreement available on its website. This agreement needs to provide an overview of relevant clauses, royalty conditions and exemptions, as well as which party is intended to bear the costs of technology transfer, such as for the experts, equipment and travel. Moreover, the various terms under which a licence can be agreed on, such as global licensing, non-exclusive licensing and more, along with the possibility for IP rights holders to benefit from royalties through the mechanism, must be clarified.

RECOMMENDATIONS FOR THE INCLUSION OF A TECHNOLOGY TRANSFER MECHANISM IN THE PANDEMIC ACCORD

RECOMMENDATIONS FOR THE PARTIES NEGOTIATING THE PANDEMIC ACCORD

Policy recommendation: Mandate the use and support of a global technology transfer mechanism

The Pandemic Accord should include clauses which create a legal obligation for Member States to enable national systems that support a global technology transfer mechanism. This includes interaction between various ministries involved in the pandemic response, such as ministries of health, science, and economic affairs, and appointing contact persons to whom the WHO and interested IP rights holders can reach out to in instances where IP pooling and technology transfer could be beneficial.

Policy recommendation: Ensure sufficient resources for the mechanism

The Pandemic Accord should contain a binding commitment for Member States to support the establishment of a global technology transfer mechanism for sharing technology, know-how and IP for all medical products related to pandemics. Member States should provide support for such a technology transfer mechanism to the maximum of their available resources. Such support can include political engagement and advocacy activities. Support can also be given by

entering into discussions with fellow Member States and international organisations, and by national actions directed at IP rights holders. Moreover, the WHO must also encourage participation with and support for the mechanism and ensure high-level advocacy activities are taking place. It must also make sure that sufficient financial and human resources are made available for the optimal functioning of the mechanism.

Policy recommendation: Ensure affordable pricing in out-licensing agreements

The Pandemic Accord should ensure that the technology-sharing mechanism encourages reasonable pricing and cost transparency of products manufactured through its out-licences. This can be done by including clauses in the out-licences which require the manufacturer to be transparent.

Policy recommendation: Ensure transparency in the process and timelines

The Pandemic Accord should create accountability and transparency requirements for the mechanism. Technology transfer selection criteria, procedures and timelines should be clear and transparent. Expected turnaround times and the maximum time delay for answers between the mechanism and IP rights holders should be established. The mechanism should provide regular updates on its progress through briefings to the interested IP rights holders and the Member States' community.

Policy recommendation: Ensure access provisions in funding and procurement agreements

The Pandemic Accord should create obligations for Member States to include access provisions in funding contracts for R&D of relevant countermeasures and within procurement contracts of relevant countermeasures. Countermeasures should be shared with the mechanism.

Policy recommendation: Enable an ecosystem which creates demand from generic manufacturers

The Pandemic Accord should encourage Member States to create a national ecosystem which increases the interest and demand on the side of generic manufacturers to become out-licensees of the technology transfer mechanism. National policies should increase the number and quality of manufacturing companies and the affordability of the manufactured products. This step is crucial for pandemic preparedness and a speedy response. The creation of such an ecosystem requires political commitment and funding.

CONSIDERATIONS FOR THE WHO

CONSIDERATION 1: MAKE C-TAP INDEPENDENT FROM THE WHO OR NOT

Option to have C-TAP absorbed by the MPP

The MPP is an independent organisation with a strong international reputation and network. It is currently also the organisation that negotiates and signs the licensing agreements between IP rights holder and C-TAP. We envisage a scenario in which C-TAP is taken out of the WHO and absorbed by the MPP. It would thereby become an additional branch of the MPP that focuses on vaccines and provides more extensive support for technology transfer and the sharing of know-how required for the manufacture of safe, high-quality vaccines. This could overcome internal obstacles currently identified within the WHO such as lengthy bureaucratic processes.

Option to keep C-TAP within the WHO system

In this scenario, C-TAP would remain housed under the WHO in its current form. However, in this case sufficient funding, staffing and the support of high-level WHO leadership and Member States are required. Recommendations as mentioned above for the improvement of C-TAP would therefore be applicable and should be taken into account.

CONSIDERATION 2: FOCUS ON GLOBAL NON-EXCLUSIVE LICENCES OR MORE FLEXIBILITY IN THE LICENSING TERMS

Option to aim for licences with a broad scope, such as global non-exclusive licences with reasonable royalties

In the case of C-TAP remaining a voluntary mechanism, it will face difficulties to receive licences and technology transfer support from the private sector. It is therefore important to focus on maximising reach of the licences secured. The aim is for licences to be global, non-exclusive and with reasonable royalties for low- and middle-income countries, following the example of the CSIC and NIH licences. This might limit the number of licences from the private sector but will amplify the effect of licences secured by increasing the amount of products manufactured and made available at an affordable price through the mechanism.

Option to allow for negotiation and strong flexibility of the licensing terms

An alternative option would be to allow various degrees of pooling and sharing within the mechanism. It would thereby not be required for licences to be global or non-exclusive and royalties could differ depending on whether the out-licensee is in a high-income country or lower-income country. This would create more interest in licensing from parties who are currently wary of global licensing and would like to gain profit from high royalty fees from manufacturers in high-income countries. The relationship between royalties and global licensing would thereby be addressed in a way that royalties can be increased when sharing with high-income countries.

1. INTRODUCTION

The Covid-19 pandemic, declared on 11 March 2020 by the WHO (WHO Director-General's Opening Remarks at the Media Briefing on Covid-19, 11 March 2020, 2020), has amplified the worldwide inequalities of access to medicines further and brought these to a new level of global attention. In order to combat the crisis of inequitable health product distribution, the Solidarity Call to Action (SC2A) was launched by the government of Costa Rica and the WHO in May 2020 (Love, 2020). SC2A, which now comprises 43 signatory Member States, seeks to “realize equitable global access to Covid-19 health technologies through the pooling of knowledge, intellectual property and data”. To achieve this, it created the Covid-19 Technology Access Pool (hereafter C-TAP) in May 2020, which aims to ensure that Covid-19 countermeasures become global, public and affordable goods by facilitating technology transfer and the sharing of intellectual property (IP) of such countermeasures.

C-TAP is a voluntary platform through which IP rights holders can out-license IP related to their products, including patents, know-how, research data, and material such as cell lines, and facilitate technology transfer with a network of manufacturers. Licences are aimed to be global, non-exclusive and transparent, but this is negotiable.²

Since its foundation, C-TAP has concluded two non-exclusive, global licencing agreements: the first with the Spanish National Research Council (CSIC) in November 2021 for their serological Covid-19 antibody test (CSIC Licence to C-TAP, 2021), and the second with the USA National Institutes of Health (NIH) for 11 Covid-19 technologies and related research (US NIH Licenses to C-TAP, 2022).

However, to date, no private company has engaged with C-TAP to license its products, which limits the number of products within the pool. Some private sector stakeholders have expressed doubt about the effectiveness of such a global transfer mechanism and argued that the added value is not always clear (IFPMA Statement on the Solidarity Call to Action 2020a). The People's Vaccine Alliance, on the other hand, has called upon governments and the private sector to endorse and support C-TAP as one of its 5 key asks (People's Vaccine, 2022).

In summary, while there have been some successes, C-TAP has not reached its full potential. Given the continued need for pandemic preparedness and response, and the role of sharing of IP, know-how and technology in the Pandemic Accord currently being negotiated, it is important to understand and reflect on the factors that have influenced the functioning of C-TAP, the good practices, challenges, and lessons learned for the future.

The objective of this study is to document the functioning and impact of C-TAP, to investigate if and how a similar mechanism could function (better) in the Pandemic Accord and to make policy recommendations.

² Non-exclusive licencing refers to the IP rights holder providing the licence to manufacture and sell to multiple out-licensees simultaneously. There is, therefore, no exclusivity on the production of the product. Global licencing refers to the practice that manufacturers worldwide can receive an out-licence under the conditions set out in the initial agreement of the IP rights holder and the pooling mechanism. This means that licensees can produce, use and sell the products worldwide and that the licensor can sub-licence to multiple manufacturers at once. This increases generic competition and the capacity to manufacture certain health products around the world, which in turn often leads to lower prices.

2. BACKGROUND

The Covid-19 pandemic has made it clear that international efforts are necessary to effectively combat a pandemic and reverse the trend of inequitable access to health products worldwide. This is especially necessary as we saw government actions such as vaccine nationalism and hoarding, export restrictions, limited manufacturing capacity and supply chain limitations further amplify inequalities and affecting LMICs disproportionately. Covid-19 attributed mortality was higher in these countries than in HICs (Wang et al., 2022), where the provision of antiretrovirals, PPE equipment, diagnostics and vaccines was non-existent or heavily disrupted and expensive (Akande-Sholabi & Adebisi, 2020). Covid-19 has claimed around 14.4 million lives (World Health Statistics, n.d.) around the world, has reversed the progress made on the Social Development Goals, including on gender and education, and has severely stunted economic growth (Ashraf & Goodell, 2022) (Goal 3: Ensure Healthy Lives and Promote Well-being for All at All Ages, n.d.).

To counter these effects, international efforts have been made to create systems and structures that could distribute manufacturing power and products more evenly around the globe. The international community set up mechanisms to facilitate production through technology transfer and IP pooling, pooled procurement and donation of vaccines, such as the ACT-A initiative with its four pillars: COVAX, Diagnostics, Therapeutics, and Health Systems strengthening (The Access to Covid-19 Tools (ACT) Accelerator, 2022). Furthermore, the mRNA hubs were launched to create training hubs for mRNA vaccine manufacturing in LMICs, but as no company participated in tech transfer, the initiative now focuses on reverse engineering mRNA vaccines, such as the Moderna vaccine (Johnson, 2022) (Cullinan, 2022). Wemos has mapped the various global Covid-19 initiatives and reviewed them according to their governance and funding structures and their strengths and weaknesses (Review of Initiatives for Access to Covid-19 Innovations, n.d.-b).

In addition to ACT-A, COVAX and the mRNA hubs, distinct proposals were made for compulsory and voluntary methods for the sharing of IP, know-how and technology. In May 2020, C-TAP was launched, and in October 2020 India and South Africa proposed a waiver under the TRIPS agreement, asking for intellectual property rights to be lifted for Covid-19 countermeasures. The intention of the proposal was to receive the rights to manufacture, sell and distribute products necessary to combat the Covid-19 pandemic, waiving the monopoly rights attached to the new vaccines (Medecins Sans Frontieres, 2020). However, the final TRIPS compromise agreement does not extend as far as the original proposal. It therefore remains to be seen how the agreement can be used to incentivise companies to share their IP and know-how in different ways (Medicines Law & Policy, 2022). The production of (mRNA) vaccines requires more know-how and technology transfer than the information found in the patent dossier and further collaboration will be required for the manufacturing of vaccines (World Trade Organization, 2022).

This is where C-TAP as a voluntary technology transfer mechanism comes into play. Covid-19 has shown that next to lack of solidarity, international logistics structures come under increased pressure during a pandemic. A voluntary technology transfer mechanism such as C-TAP can overcome these obstacles. Through C-TAP, IP rights holders of health products can give out-licences and support the transfer of required expertise and know-how as well as data to ensure that manufacturers across the globe have the tools and information necessary to

recreate the product with identical quality. This could solve a multitude of the issues the world has faced during the pandemic.

Firstly, production capacity would be expanded, as there would be more qualified manufacturing sites with expertise. Furthermore, the effects of supply-chain disruptions would not be as far-reaching, as supply chains would be shorter and vaccines would be produced from scratch worldwide. There would be less dependence on supply from other regions affected by scarcity and export restrictions. Moreover, non-exclusive, global licences could decrease prices as they generate competition and break up the worldwide monopolies. Affordability and (geographical) access can thereby be increased and accelerated worldwide, particularly in LMICs. Lastly, by facilitating the technology transfer process with quality-assured manufacturers and close cooperation and assistance from the original IP rights holder, the quality of the products would be the same as through the current model run by the private pharmaceutical industry.

C-TAP is operating under the WHO Access to Medicines Division and is currently funded by two Member States – Spain and Belgium – and UNITAID. With the support of the implementing partner organisations, particularly the MPP, C-TAP was able to secure the two licences with CSIC and NIH and one out-licence of CSIC’s diagnostic test. There is hope for more manufacturing partners to come on board. Moreover, the NIH has entered into an agreement with Afrigen Biologics based in South Africa for the exchange of scientific expertise that may be used to make mRNA vaccines (Johnson, 2022).

The MPP negotiates and concludes the licences on behalf of C-TAP and other organisations present in its steering committees such as UNITAID, UNAIDS, UNDP and the Open COVID Pledge, which also provide their expertise and guidance on which products to take on board. However, C-TAP has faced external and internal hurdles to securing more licences and political support from Member States. No private pharmaceutical companies have shown interest in engaging with C-TAP so far. Another frequent point of feedback is that the progress of C-TAP has been too slow to achieve its aim for the Covid-19 pandemic, which requires fast action.

This research, therefore, aims to uncover these hurdles and analyse how they have impacted the evolution of C-TAP over the last two years. Furthermore, the qualitative analysis conducted will provide an overview of lessons learned and recommendations for technology transfer mechanisms in order to improve global pandemic preparedness and cooperation.

“When [...] a country is throwing away vaccines at the same time another country desperately needs them, that is not sustainable and [...] cannot continue to happen.”

Roman Macaya, former executive president of the Costa Rican Social Security Fund

3. METHODOLOGY

The overall objective of this analysis is to generate and document knowledge in relation to the functioning and impact of C-TAP, to investigate if and how a similar mechanism could function (better) and to make policy recommendations for a future technology-sharing mechanism as part of the Pandemic Accord. This research took into account the internal organisation and operational plan of C-TAP and key successes and setbacks within its timeline. Moreover, the internal and external limitations of C-TAP and the impact of the current licences of the CSIC and NIH on the functioning and the public perception of the C-TAP were determined.

The research objectives for this review are as follows:

- To document the internal features of C-TAP: its mandate, operational structure, governance structure, operational plans and budgets, human resources etc.
- To document the journey (timeline) of C-TAP: the key moments since its inception.
- To document the successes of C-TAP in relation to its mandate and the external and/or internal factors contributing to these successes.
- To document setbacks and or missed opportunities of C-TAP in relation to its mandate and the contributing external and/or internal factors.
- To formulate lessons learned on what has and has not worked, and to make recommendations for a future technology transfer mechanisms part of a global pandemic preparedness and response.

The main research questions are:

- Which internal and external factors have facilitated and/or hindered C-TAP in achieving its objectives?
- What recommendations can be made for the optimal performance of a technology transfer mechanism in the context of pandemic preparedness and response?

A qualitative design was applied including document analysis and semi-structured interviews with key informants. The research was conducted using two different data collection methods, namely document review and semi-structured interviews. Content analysis was applied through basic coding.

The document review consisted of a review of policy briefs and publications of key international stakeholders on the subject of patent and know-how pooling in health, as well as documents of the WHO International Negotiation Body for the Pandemic Preparedness Accord.

The semi-structured interviews were conducted online and interviewees were selected based on their past and present interaction with, and current expertise of the C-TAP and technology transfer and pooling mechanisms. Key informants included representatives of the WHO, members of C-TAP governance structures, representatives of national governments, IP rights holders and civil society representatives.

The timeline for this research was from the beginning of August until the end of October 2022. The document review and interviews were conducted in August and September 2022, followed by the writing of the report. Findings and recommendations have been presented to the CIFA consortium³ and the People's Vaccine Alliance and feedback has been incorporated.

DOCUMENT REVIEW

The document review was aimed mainly at finding more information concerning the internal organisation of C-TAP within the WHO apparatus, creating a timeline of significant published successes, and gathering a basis of knowledge and expertise related to technology transfer, the WHO Pandemic Accord negotiations, the role technology transfer can play, as well as information which interviewed stakeholders could complement with their own expertise.

The search strategy applied for the document analysis involved searching the WHO website and C-TAP webpages for relevant documents and briefings. Academic journals and online repositories were also searched for “technology transfer”, “Covid-19 initiatives”, “patent pooling”, “pandemic preparedness” and “Covid-19 Technology Access Pool”. The document review included policy briefs and articles in accredited journals by international experts on pooling of pharmaceutical patents and know-how. Documents shared by the WHO International Negotiation Body for the Pandemic Accord were also studied. Interviewees shared further documents during the research process which were also taken into account.

The following documents were reviewed:

- C-TAP Concept Paper from 23 March 2021⁴
- C-TAP Briefing Document (undated)⁵
- Briefing Presentation of C-TAP to Member States from June 2022⁶
- Briefing and Updated Presentation of C-TAP at the World Intellectual Property Organization (WIPO) in August 2021.⁷
- The webinar held by the C-TAP Secretariat for the 2nd Anniversary of C-TAP on 16 June 2022.⁸

³ The Covid Innovations for All (CIFA) consortium consists of Corporación Innovarte, Health Action International, Knowledge Ecology International (KEI), Medicines Law & Policy, Pharmaceutical Accountability Foundation and Wemos.

⁴ The C-TAP Concept Paper is available here: <https://www.who.int/publications/m/item/c-tap-a-concept-paper>

⁵ The C-TAP Briefing Document is available here: https://www.who.int/docs/default-source/coronaviruse/who-c-tap-briefing-doc_formatted.pdf

⁶ The C-TAP briefing presentation to Member States is available here: https://apps.who.int/gb/COVID-19/pdf_files/2022/09_06/Item2.pdf

⁷ The C-TAP Secretariat presentation at WIPO 2022 is available here: https://www.wipo.int/edocs/mdocs/scp/en/scp_34/scp_34_b_health.pptx

⁸ Information including speakers on the C-TAP 2nd Anniversary Webinar of 16 June 2022 is available here: <https://www.who.int/news-room/events/detail/2022/06/16/default-calendar/webinar--realizing-equitable-global-access-to-covid-19-health-technologies.-who-c-tap-s-progress--challenges-and-opportunities>. The

The following documents were searched and/or asked for, but were unavailable or did not exist:

- Funding overview and strategy
- Budgetary plans
- Operational plan
- Strategy for contacting Member State and IP rights holders

SEMI-STRUCTURED INTERVIEWS

Next to the document review, interviews with key experts and stakeholders were conducted. These interviewees were asked about which factors they believe facilitated or hindered C-TAP in achieving its objectives, about C-TAP's internal features, to provide an overview of key moments within C-TAP's evolution, and for their suggestions for policy recommendations.

The aim of the interviews was to receive further information about C-TAP which was not available publicly and thereby complement the findings of the document review. The interviews also played an important role in determining how experts identify certain key moments, obstacles and successes within the timeline of C-TAP and gather their concerns and recommendations for improvement. A semi-structured interview was prepared, based on topics deemed important by the research team, whilst maintaining room for flexibility and probing as well as for unexpected topics that may have come up.

SELECTION OF STUDY POPULATION

The interview population was selected on the basis of their current and previous interaction with C-TAP, as well as their level of expertise in the field of global access to medicines policy and technology transfer. Special attention was paid to interviewing people from four diverse stakeholder groups: experts working in civil society and advocacy organisations, experts working on C-TAP internally, pharmaceutical industry companies and larger funding organisations. Other interviewees were added using the snowball strategy, based on the frequency that these respondents or organisations were mentioned by other interviewees or on the basis of interviewees' recommendations.

DATA COLLECTION, PREPARATION AND CONDUCTING OF INTERVIEWS

Interview guides were developed on the basis of each stakeholder group, and personalised to the specific respondent, based on their background and organisation affiliation. A few respondents received the questions in advance upon their request, although this was the

recording of the event can be viewed here: <https://www.who.int/multi-media/details/access-to-covid-19-health-technologies--who-c-tap-s-progress>

exception. All interview guides contained questions relating to the perceived indicators of the evolution and success of C-TAP, external and internal limiting and enabling factors for its evolution, and the role of stakeholders in the evolution of C-TAP. Interviewees were also asked more general questions in relation to technology transfer and pooling mechanisms and the WHO Pandemic Accord negotiations. These respondents were also interviewed about their perception of the current and potential role of IPRH in technology transfer mechanisms. Pharmaceutical industry respondents were asked to elaborate on their access strategies not involving C-TAP and their recommendations. Interview guides were sometimes adjusted for stakeholders based on documents and information shared by other respondents, to reflect on current developments and seek out further information.

All respondents received an informed consent form before the interview and were walked through the main points again before consenting to their interview being recorded for internal purposes. The interviews were individual, aside from three group interviews held online via Zoom or MS Teams, and lasted between 30 and 60 minutes. The respondents were aware that the information would remain confidential, and they were later contacted in line with the requirements mandated by the consent form, to receive their explicit consent for direct quotes and to ask in which way they would like any quotes to be (or not to be) attributed to them. The confidentiality of the setting may have contributed to the openness and honesty of the answers of respondents. Participants had the right to refuse to answer any particular question and to withdraw from the study at any time.

The coding guide of the interviews was designed based on information from the document review, and slightly adjusted per stakeholder group. In total, there were 19 respondents and 15 interviews, as three interviews were with two or more respondents. In total, the respondents represented 14 different organisations. Overall, first contacts and interview invitations were sent to 38 people. The difference between the number of contacted people and respondents is due to not having received responses from a variety of stakeholders.

Despite these missing responses, the study cohort provided sufficient elaborate and diverse findings and perspectives for the research objectives to be achieved.

The limitations of this research are missing perspectives from other Member States and research organisations. This is due to the fact that contacted stakeholders did not find the time to participate in the research. Moreover, because of time restraints on the side of contacted representatives of the Global South, not as many respondents as initially aimed for contributed to this research. Potential bias is therefore possible due to the proportional underrepresentation of Global South voices and IP rights holders from public research institutions. Having said that, further insights of Global South members were included through the feedback and review process of the report.

4. RESULTS

THE INTERNAL FEATURES OF C-TAP

C-TAP'S MANDATE

C-TAP operates under the Access to Medicines and Health Products Division, chaired by the Assistant Director-General Dr Mariângela Simão.⁹ This division is further split into health product policy and standards, and regulation and prequalification.

C-TAP describes itself as a technology transfer mechanism providing a single platform that can increase the global supply of Covid-19 health products to qualified manufacturers through its licences. It does so by transmitting legal rights to manufacturing, technology and know-how required for the development of products and access to clinical trial data for regulatory approval.¹⁰ As other initiatives such as ACT-A, COVAX and the mRNA hubs seek to increase production in the long term, C-TAP can facilitate manufacturing in LMICs in parallel to other initiatives,¹¹ making it a complementary mechanism to ACT-A.¹²

It positions itself as a mechanism promoting open science and accelerated product development and innovation by facilitating technology transfer, pooling of intellectual property rights and distributed manufacturing licences. C-TAP seeks to establish a new, global, public system of facilitating technology transfer and IP pooling, based on the concept of open science and equitable and affordable access. The current knowledge sharing and transfer system remains mostly in the control of private IP rights holders and the pharmaceutical industry. C-TAP proposes an alternative system of sharing and transferring of expertise, aiming to conclude licences with intellectual property right holders of various health products and countermeasures. Licences are in turn intended to provide legal rights and technical know-how required for the lawful and high-quality manufacture of the products.

Unlike the MPP, C-TAP also seeks to licence vaccines, which requires more technology transfer that is often not needed for small molecules. Along with IP rights, data, regulatory dossiers and specifications for manufacturing processes are shared with manufacturers. C-TAP aims to support technology transfer to boost local production of relevant products in LMICs through the MPP and the Technology Access Partnership.

Unlike COVAX, C-TAP is not a donation tool. It allows for royalties to be distributed too, thereby generating income for the licensor. By providing manufacturing licences to multiple actors, prices will be lower due to competition than they would be in situations of market monopolies.

⁹ Dr Simão will soon go into retirement. Her successor ADG will then take over charge of the division including the C-TAP initiative.

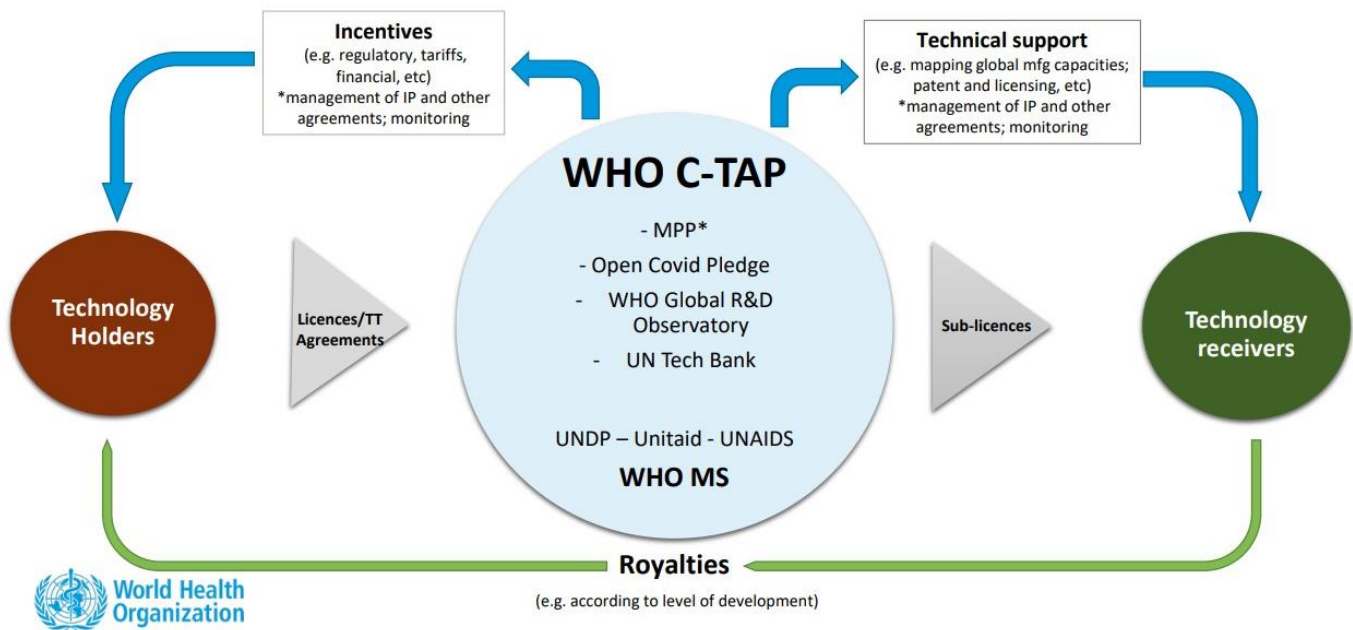
¹⁰ C-TAP Briefing Document page 1.

¹¹ C-TAP Briefing Document page 2.

¹² C-TAP Concept Paper page 4.

Figure 1 demonstrates how C-TAP seeks to perform its licences and technology transfer agreements.

Figure 1: How C-TAP works to facilitate technology transfer and IP pooling¹³



¹³ Graphic found on page 5 of the Briefing Presentation to Member States; a similar graph is also found on slide 11 of the presentation to WIPO.

C-TAP'S GOVERNANCE AND OPERATIONAL STRUCTURE

All the key informants interviewed perceived a lack of transparency of the operational, governance and funding structure of C-TAP. Documents published by C-TAP concerning operationalization plans dated back to 2020 and updated versions have not been found. Moreover, the documents which were found were not all directly available on the webpages of C-TAP but were found on general WHO media platforms and through specific Google searches. C-TAP is structured into a steering committee, a secretariat, a technical advisory group and a Member States working group. Moreover, five technical working groups have been formed to advise on different kinds of products.

The Secretariat is housed under the Access to Medicines and Health Products Division chaired by the Assistant Director-General Dr Mariângela Simão. It collaborates with other divisions of the WHO and further interacts with other WHO departments, such as the Science Division and the Global R&D Observatory. The secretariat is in charge of compiling the database, Member States' pledges under the SC2A and any shared products, knowledge, IP, data and licences to the C-TAP. The secretariat plans and monitors the activities of C-TAP, coordinates day-to-day tasks such as agenda setting and communicates with implementing partners. It develops communication materials and supervises all activities for and within C-TAP. It currently consists of three WHO staff and around 10 external consultants. The WHO staff working on C-TAP also occupy other positions within the WHO. The three staff, therefore, do not work full-time on C-TAP. The external consultants are active in areas of vaccine expertise, in-vitro diagnostics and medical devices, the database and as external researchers for access provision in public funding.

The C-TAP **steering committee** provides advice on the overall direction of C-TAP. It consists of representatives of the implementing partners UNDP, UNITAID, UNAIDS, MPP, and the Open COVID Pledge. Costa Rica and the chair of the Technical Advisory Group (TAG) also attend the meetings. The steering committee provides support for advocacy and policy objectives, guidance on operationalization and collaboration with other initiatives. The MPP is an especially important member as it is in close contact with the C-TAP Secretariat and interested IP rights holders. It negotiates and signs the licences with the interested parties on behalf of C-TAP. MPP is experienced in IP pooling licences and contributes crucial expertise and advice on non-exclusive public health-oriented licensing of medicines in LMICs. MPP is intensively involved in providing guidance on which products to license and licensing criteria. Furthermore, it negotiates the agreements with the IP rights holders and is also a signatory to the licensing agreements and a party to the contract.

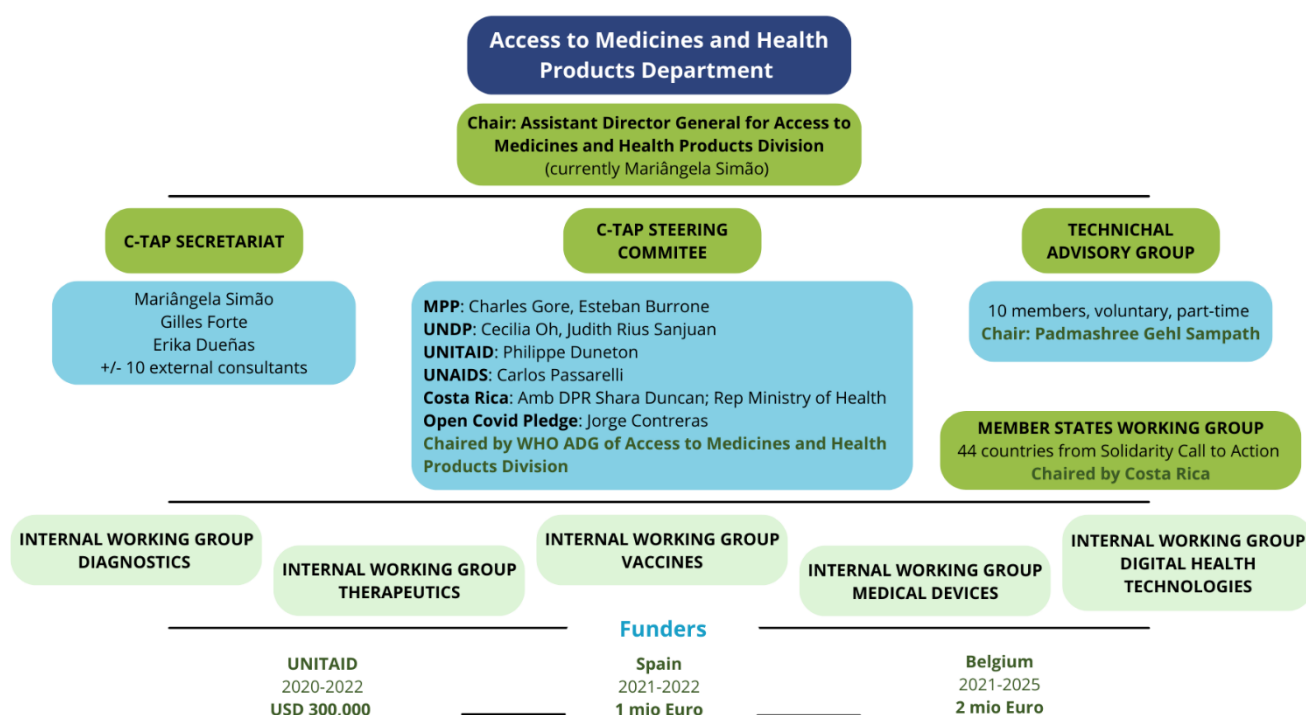
The **Technical Advisory Group** (TAG) is a group of 10 experts that advises the steering committee on which products to accept or decline and which products to seek out and prioritise. The TAG published its opinion on the NIH licences prior to the publication of this deal (C-TAP WHO Technical Advisory Group, 2022).

Finally, the **Member States working group** is chaired by representatives of the government of Costa Rica. It represents C-TAP to the Member States and carries out advocacy on behalf of C-TAP. Further research and interview responses have indicated that there are also **internal working groups**. The five internal working groups – on diagnostics, vaccines, therapeutics, medical devices, and digital health technologies – are run by WHO staff experts in these fields and provide further resources and expertise to C-TAP in relevant areas of health products. The staff working in these groups do not work on the C-TAP portfolio full-time.

C-TAP'S BUDGETARY AND FUNDING PLANS AND STRATEGIES

The document review did not provide any data on the **funding of C-TAP**. However, interview respondents were able to provide this information. The results, which can be seen in Figure 2 below, show that C-TAP operates on a small budget. It received 300,000 US dollars in funding from UNITAID from 2021 until the end of 2022. Spain and Belgium also joined as funders from 2021 onwards, supporting C-TAP with 1 million and 2 million euros, respectively. This is less than the funding provided to ACT-A initiatives like COVAX or the mRNA hubs. It therefore seems difficult to increase the capacity of human resources of the C-TAP initiative. For example, ACT-A provides a tracker of their funding on their webpages (World Health Organization, 2022a). According to this tracker, from 2020 until 2021, ACT-A received USD 17.766 million, and another USD 5.900 million from 2021-2022. This type of funding tracker and transparency is not available for C-TAP.

Figure 2: Organogram C-TAP initiative and funding.¹⁴

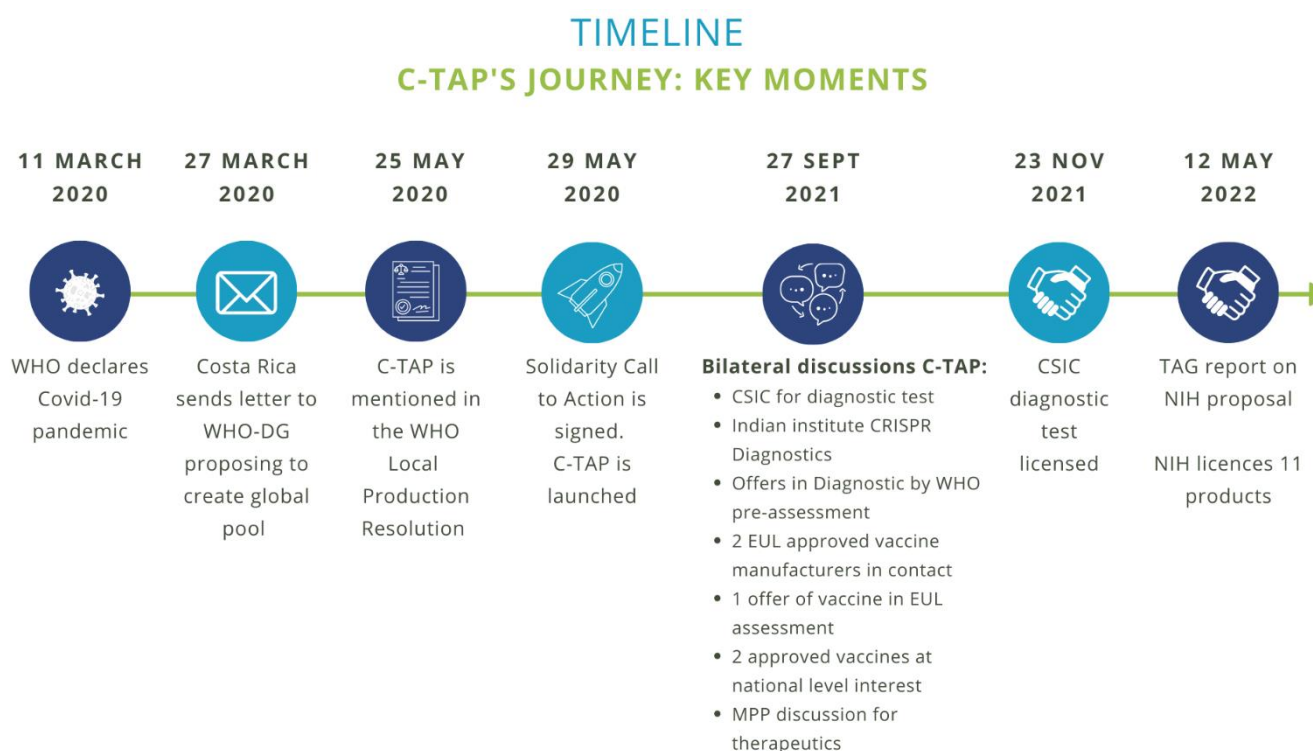


¹⁴ The information in this graph was completed and confirmed by the WHO C-TAP Secretariat.

EVOLUTION OF C-TAP

The following section provides an overview of the evolution and timeline of C-TAP from its inception to the present.

Figure 3: Timeline of C-TAP's key moments:¹⁵



Since its inception in May 2020, C-TAP has gathered political support from 43 signatory states and funding from two Member States. In its month of establishment, C-TAP was included in the World Local Production resolution under point PP11, for Member States to support technology transfer mechanisms such as C-TAP to increase manufacturing capacity. In 2021, discussions amongst the C-TAP Secretariat and several interested parties took place. Interview respondents complemented this information with the fact that these discussions were conducted with the Texas Children's Hospital and Baylor College of Medicine for the Covid-19 Vaccine CORBEVAX.

Since then, C-TAP has concluded two licences. The first one is with the **Spanish National Research Council (CSIC)** for their ELISA antibody technology serological test for Covid-19. This agreement covers all related patents and biological materials necessary for manufacturing the test. The global, non-exclusive licence is given on a royalty-free premise to LMICs, and is valid until the expiration of the patent (CSIC-MPP licence 2021, article 3 page 4). This licence has now

¹⁵ Information found on slide 13 of the C-TAP Secretariat presentation to WIPO.

also been out-licensed to the manufacturing company Biotech Africa, the very first out-licence agreement of C-TAP. The licencing agreements between MPP and CSIC, and MPP and Biotech Africa are available on the C-TAP website. Moreover, the relationship between CSIC and C-TAP is strong, as evidenced by the contribution of CSIC staff during the webinar on C-TAP's second anniversary (Access to Covid-19 Health Technologies: WHO C-TAP's Progress, 16 June 2022). The CSIC has said that it intends to maintain this relationship and provide further licences when deemed relevant.

The second agreement is with the **USA National Institutes of Health (NIH)** spread over two licences for a total of 11 technologies for therapeutics, early-stage vaccines and diagnostic tools for Covid-19. The licences are global, non-exclusive and royalty-free for production and sale within the least developed countries (NIH-MPP licensing agreement 2022, Annex C, Page 22).

List of licenced technologies of NIH to MPP/C-TAP:

1. Prefusion spike proteins (Vaccine Development)
2. Structure-Based Design of Spike Immunogens (Research Tool for Vaccine Development)
3. Pseudotyping Plasmid (Research Tool for Vaccine Development)
4. ACE2 Dimer construct (Research Tool for Drug Development)
5. Synthetic humanized llama nanobody library and related use (Research Tool for Drug and Diagnostic Development)
6. Newcastle Disease Virus-Like Particles Displaying Prefusion-Stabilized Spikes (Vaccine Candidate)
7. Parainfluenza virus 3 based vaccine (Vaccine Candidate)
8. A VSV-EBOV-Based Vaccine (Vaccine Candidate)
9. RNASEH-Assisted Detection Assay for RNA (Diagnostic)
10. Detection of SARS-CoV-2 and other RNA Viruses (Diagnostic)
11. High-Throughput Diagnostic Test (Diagnostic)

C-TAP'S SUCCESSES AND THEIR CONTRIBUTING EXTERNAL AND INTERNAL FACTORS

In this section we describe the successes of C-TAP in relation to its mandate and the contributing external and/or internal factors to these successes. The responses of interviewees relating to these factors can be categorized into quantitative indicators, qualitative indicators, and normative indicators of success.

INDICATORS OF SUCCESS IDENTIFIED BY RESPONDENTS

The majority of respondents agreed that the **quantitative** number of licences is a relevant measurement for C-TAP's success. This includes the number of in-licences and out-licences, but also the amount of products held within the pool. In this instance, there are four licences in total: one with CISC, two with NIH, and one out-licence with Biotech Africa. As a result, there

are in total 12 products and technologies in the pool (one CSIC, 11 NIH). Interviewees also emphasized that C-TAP initially wanted to cater to the demand for Covid-19 vaccines, as so far the MPP itself has not provided licences for vaccines. Another measurement is therefore the number of vaccines licenced. Five respondents mentioned that it is relevant to look at the amount of products actually produced as a result of these licences, and how many products are delivered to people. The majority opinion showed that the number of licences was important, but that the actual content of the licences and the number of products produced was closer to the goal of C-TAP to increase the manufacture of and affordable access to Covid-19 countermeasures.

When using the **qualitative indicators** as a measure of success, it was found that the products had to meet a certain health need, focusing on their usefulness and applicability. Other qualitative factors mentioned were the growth of C-TAP's network, such as partnerships with governmental research institutes which have the potential to provide important technology. Moreover, four respondents also noted the importance of the potential that products could have in the future, which is relevant for products which do not yet have regulatory approval or are not yet finished. Lastly, geographical access to the manufactured products was mentioned as a factor. It can be said that qualitative indicators place strong importance on the impact created by the licences and products, rather than the (amount of) products per se.

Lastly, **normative indicators** also play an important role in the definition of the success of C-TAP as a technology transfer mechanism. Whether as the main goal or a by-product of its activity, the systemic change initiated by such a mechanism is an important factor to consider. C-TAP aims to create new infrastructure for R&D, technology transfer and manufacturing which is not controlled by the usual actors. Moreover, respondents mentioned that an important factor to consider when assessing the success of C-TAP is the involvement of WHO Member States and the support of public research institutions and centres. Furthermore, it was mentioned that support from key players like the MPP, the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) and UNITAID could also be considered an important endorsement of C-TAP and therefore a factor of success. Lastly, the systemic change which mechanisms such as C-TAP seek to launch is a guiding element of the normative indicators.

“A licence is a piece of paper. [...] What we want is not pieces of paper, but medicines, vaccines or diagnostic tests reaching people. So, you could say that the real success comes after the out-licence, when a medicine is actually reaching people that didn't have access before.”

Anonymous interviewee

SUCCESSSES OF C-TAP IN RELATION TO ITS MANDATE

The analysis shows that within the last two years C-TAP has delivered on some aspects of its mandate. Firstly, respondents recognised the difficulty of creating a new global mechanism in the wake of a global pandemic. The fact that C-TAP has become operational as a new technology

transfer mechanism is therefore considered a success by all respondents. Furthermore, respondents mentioned the structure of C-TAP and the successful recruitment of the members of the technical advisory group and the internal working group as important. C-TAP thereby succeeded in increasing the technical expertise required for the assessments of the health products proposed.

Moreover, C-TAP has secured some political support from Member States. C-TAP and SC2A have gathered signatures from 43 WHO Member States, Belgium and Spain provide funding for C-TAP, and the public research institutions CSIC (in Spain) and the NIH (in the US) have provided licences. Support is also seen in the fact that C-TAP is mentioned in the World Local Production Resolution (WHO Resolution A74/A/CONF./1 2021, PP11) as a voluntary technology transfer and IP pooling tool to be used to increase access to health technologies.

Furthermore, C-TAP is supported by implementing partner organisations such as UNAIDS, UNITAID, the MPP and the Open COVID Pledge, alongside Costa Rica. The implementing partners provide guidance on the operationalization of C-TAP, collaborate with other initiatives and promote policy and advocacy dialogues on C-TAP objectives. The MPP is closely involved with C-TAP and provides its expertise for negotiating licences and IP pooling and technology transfer. The MPP's mandate was extended to Covid-19 health products, increasing its expertise for this disease as well. The MPP is intensively involved in the negotiation of licencing agreements and a party to the contracts. Interviewees considered the strong collaboration between the MPP and C-TAP to be a sign of successful endorsement and a key driver for successful licences for C-TAP.

Lastly, C-TAP's mandate revolves around securing IP licences and facilitating technology transfer for global manufacturing of Covid-19 countermeasures. The licence with CSIC for their diagnostic test is considered a strong start for C-TAP. It is perceived as a powerful endorsement of C-TAP by CSIC, which has also assured further collaboration in the future. Technology transfer of the licence is currently being implemented. The South African manufacturing company Biotech Africa is the first company to receive an out-licence and thereby the rights to produce, sell and obtain the necessary knowledge to reproduce the tests on a large scale. Another successful element of this licence is that it is granted on a royalty-free basis for sales and production in LMICs (CSIC-MPP licensing agreement 2021, article 3 page 4).

The licences of the NIH are also considered a strong endorsement of C-TAP by the US. The 11 products encompassed by the licences are a mixture of finished and as-yet-unfinished products that can be useful for developing and producing further countermeasures. The NIH licence includes three vaccine candidates and three research tools for vaccine development, as well as four products related to diagnostics. Not all products are relevant for Covid-19 infections but the research behind them could be. The NIH licences comprising unfinished health products and vaccine components was considered by four respondents to be a first step in the right direction for C-TAP. The NIH licences are global licences, meaning products can be produced and sold worldwide. They are also royalty-free for sale and production within the least developed countries (NIH-MPP licensing agreement 2022, Annex C, Page 22).

The licences themselves represent milestones for C-TAP. All are global non-exclusive licences, and therefore correspond to the main aim of C-TAP, which is to conclude global transparent licences and show that it is possible.

Lastly, interview respondents also shared that further negotiations and discussions with IP rights holders are in the pipeline and we can expect further licences to come.

EXTERNAL AND INTERNAL FACTORS CONTRIBUTING TO THE SUCCESSES

Different factors have contributed to the successes of C-TAP. The **external factors** will be discussed first, followed by internal factors.

An overarching factor, identified to be key for all milestones mentioned above, is the political will of Member States. The Costa Rican initiative and the signatories of the SC2A are the basis for the creation of C-TAP. Member State support was also a strong driving factor behind the CSIC and NIH licences. The licences being given by public research institutes were made possible by the strong political will of the governments of Spain and the USA to authorise and follow through with the licences to C-TAP. Especially in the case of the NIH licence, there was a strong will on the side of the government to support C-TAP specifically and therefore license to it, as was announced by President Biden during the second global Covid-19 pandemic summit (Biden Jr. & The White House, 12 May 2022). WHO Member States also showed support for C-TAP when integrating it into the World Local Production Resolution (WHO Resolution A74/A/CONF./1 2021 PP11).

Furthermore, civil society and advocacy organisations have played a big role in the successes. Knowledge Ecology International and Medicines Law & Policy supported Costa Rica in its letter to the WHO and proposed multiple products for consideration to the C-TAP Secretariat and MPP. Respondents shared that civil society organisations in Spain have also conducted advocacy efforts over the last few years to inform the Spanish government and CISC of the possibility to license to C-TAP and the related benefits. A similar process took place behind the scenes in the USA, leading to the NIH licences. Lastly, many advocacy groups reported on the evolution of C-TAP throughout the last two years and provided additional information and resources to the Member States to incentivize further support of C-TAP. The decision of Spain and Belgium to provide funding for C-TAP is also based on political will and civil society advocacy efforts.

Formal and informal support by renowned organisations like MPP, UNITAID and UNAIDS have been important as they provided staff expertise in business development for the operationalization of C-TAP.

Furthermore, the fact that there are multiple organisations and companies researching and developing Covid-19 therapeutics, diagnostics and vaccines is considered to strengthen the potential pressure the WHO and C-TAP can exert, as they have the freedom to choose which IP rights holders to license with or not, depending on their interest.

Internal factors that contributed to these milestones are varied. Two-thirds of the respondents mentioned that C-TAP being housed under the WHO was a key contributing factor to its development in line with its mandate. This was attributed to the WHO being an organisation trusted by Member States worldwide with the capacity and mandate to take global decisions. The accountability system and transparency requirements of the WHO were also mentioned by respondents as inherent elements which make C-TAP a trustworthy tool for governments and public research organisations to license to. The WHO houses a vast amount of expertise on various fields relevant to C-TAP and is therefore considered a crucial resource. Consequently, the WHO is considered a positive brand label for C-TAP.

Moreover, a contributing factor identified was the funding C-TAP received from UNITAID, Spain and Belgium. The funding ensures the continuity of C-TAP's activities as it funds the external consultants hired for the database, the research on incentives and access

conditions in funding agreements, and expert advice on medical devices, in vitro diagnostic medical devices (IVDs) and vaccines within the working groups.

SETBACKS AND MISSED OPPORTUNITIES OF C-TAP IN RELATION TO ITS MANDATE

Alongside the successes, the research identified multiple setbacks and missed opportunities within the evolution of C-TAP.

All respondents agreed that the progress of C-TAP can generally be qualified as slow. The licences with NIH and CSIC and Biotech Africa were concluded from the end of 2021 up until May 2022, after the large peaks of Covid-19 infections worldwide. A large part of the global population still remains unvaccinated today. Respondents expressed that they had hoped for quicker activity and more licensing agreements, particularly for finished vaccine products, as this was considered the unique selling point of C-TAP. In comparison to the MPP, ACT-A initiatives seem to work faster.

“The issue was not mRNA factories laying fallow somewhere and we only needed IP to be shared with them for them to be used. The issues were beyond manufacturing in the value chain. For C-TAP to be viable in response to pandemics, it requires much more of the downstream ecosystem to be built out to be viable. [...] Without doing this broader ecosystem building, we risk introducing more chaos into underprepared environments during an already maximally chaotic moment.”

Senior Officer Global Health at the Bill & Melinda Gates Foundation
(BMGF)

Furthermore, it was found that C-TAP had engaged in discussions with interested parties that did not lead to licensing agreements. Respondents shared the instance of the CORBEVAX Covid-19 vaccine developed by the Texas Children’s Hospital and Baylor College of Medicine. Despite discussions with the C-TAP Secretariat, this did not lead to a licence (Baylor College of Medicine, Coronavirus Vaccines, n.d.). A similar situation occurred with the Sobrena02 vaccine produced by the Cuban epidemiological research body, the Finlay Institute (Taylor, 2022). At the time, neither vaccine had regulatory approval from the WHO. Another vaccine candidate also showed interest in C-TAP but lost interest once it received regulatory approval.

Moreover, C-TAP did not manage to gain support from the private sector pharmaceutical industry. The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) issued press releases at the beginning of the pandemic stating that IP was

not the issue and that the current IP system should be protected. It did not see the need for C-TAP as an additional technology transfer and IP pooling mechanism for increasing manufacturing capacity worldwide (IFPMA Statement on the Solidarity Call to Action 2020a). Whilst C-TAP staff did enter into contact with some companies, the discussions were not fruitful and did not spark interest from the industry side. The pharmaceutical industry maintains that IP rights are not the root cause of inequalities of access and that a technology transfer mechanism like C-TAP does not have a clear added value, as in their view the companies conduct their own technology transfer for vaccines, which they deemed successful. This was also reiterated by IFPMA representatives in the Webinar of C-TAP's 2nd anniversary (Access to Covid-19 Health Technologies: WHO C-TAP's Progress, 16 June 2022).

“Some of the premises behind C-TAP are not compatible with the way the world of biopharmaceutical innovation works now.”

Representative from Pfizer Inc.

A further missed opportunity was that C-TAP did not advocate with Member States at the time when funding and procurement agreements were concluded for vaccines with the pharmaceutical industry. This was a missed opportunity as access conditions could have been included to initiate licensing with C-TAP on vaccines and other countermeasures. This is compounded by the further setback that HICs and the European Union collectively did not show strong support for C-TAP. Whilst the two licences with C-TAP from Spain and USA are a step in the right direction, discussions in other nations about supporting C-TAP were limited or did not take place. Member State support, particularly of HICs, is limited. This is also evidenced by the fact that of the 194 WHO Member States, 43 support the SC2A, of which only 6 are European countries (WHO Endorsements of the Solidarity Call to Action, n.d.). The interest of HICs is thus very limited.

C-TAP has also received less attention within the WHO and the media than other Covid-19 initiatives like ACT-A, the mRNA hubs and pharmaceutical partnerships with other institutes.

“You get this vicious cycle. You don't have people to do the work, so the work doesn't get done and there are no results. And because there are no results, people think this is a useless thing and you don't get money [...] I think it's also the challenge that every start-up organisation is facing: you have to prove yourself, but you don't have the means to prove yourself.”

Anonymous interviewee

EXTERNAL AND INTERNAL FACTORS CONTRIBUTING TO SETBACKS AND MISSED OPPORTUNITIES

Multiple factors were identified that contributed to the slow progress, limited support of HICs and the pharmaceutical industry, and unsuccessful licence negotiations. **External contributing factors** to the slow progress were the following:

C-TAP was established at the beginning of the pandemic when the WHO had multiple projects, issues and shortcomings to tackle. As a new mechanism with ambitious goals, C-TAP needed a strong advocacy platform and high-level support within and outside of the WHO, which was not always forthcoming. Covid-19 initiatives of the WHO were found to be competing for media and high-level attention and external funding and expertise. C-TAP was not supported as much as ACT-A initiatives and did not receive funding from CEPI, the Bill & Melinda Gates Foundation and the EU like the other initiatives did. There was little high-level endorsement for C-TAP in national governments, and respondents further shared that within UNITAID and other large UN-based organisations C-TAP was not mentioned as much as they expected.

C-TAP is a voluntary mechanism which means it operates on the basis of voluntary participation to secure licences. The lack of cooperation of pharmaceutical companies to license to C-TAP and missed opportunities of HICs to include access conditions in their funding and procurement contracts contributed to the difficulties of C-TAP in receiving licences.

“A weakness of C-TAP is of course its voluntary nature. If companies that hold the IP do not want to come to the table, there is little C-TAP can do. This is why it’s so important that governments condition public financing of research and development of pandemic countermeasures with the requirement that such technologies will be shared with C-TAP or other, similar initiatives. Countries should agree to condition government-funded innovations in the Pandemic Accord negotiations.”

Dr Ellen 't Hoen, Director of Medicines Law & Policy

Respondents identified multiple **internal factors** that contributed to slow progress, missing high-level support and interested parties not licensing with C-TAP.

The C-TAP Secretariat has various tasks but operates with many external consultants and few WHO staff. The C-TAP initiative is operating with few human resources and many of them are working on a part-time or short-term basis. In addition, C-TAP operates on little funding, receiving 3 million from Member States over the course of five years and the initial seed funding of UNITAID of 300,000 US dollars over two years. With little funding, not many human resources can be employed to complete outstanding tasks, leading to slow progress. The document review and interviews confirmed that there is no business development strategy nor a strategy to contact and persuade IP rights holders and Member States of C-TAP to secure

licences. The C-TAP initiative worked on an ad-hoc basis in the beginning and the division of tasks and responsibilities was not always clear. Additionally, the lack of transparency in operational strategy and budget made some Member States hesitant to support C-TAP as there was uncertainty around whether the funding would be used in an effective and efficient way.

Internal factors were also the cause of interested parties not licensing with C-TAP. Response rates are considered slow and the C-TAP initiative has been hesitant to accept products that did not yet have regulatory approval. This is due to the fact that C-TAP was placed under the WHO's Access to Medicines Division that deals with IP and regulatory affairs, which places a strong focus on products with regulatory approval. As a result, C-TAP has been careful not to endorse unapproved products by licensing them. Regulatory approval is certainly important to assure the safety of products but could be disregarded in the interest of maximising the chances of licensing potentially useful countermeasures and furthering innovation. Another reason to licence unapproved products and research is to safeguard interest in an early stage of development, as the interest of the IP rights holder may fade once approval is gained. This happened to C-TAP on two occasions: the C-TAP initiative hesitated to grant licences to products awaiting regulatory approval, but once they received regulatory approval they had other developers and manufacturers show interest. Respondents identified this as an internal bureaucratic hurdle leading to missed opportunities for potential licences.

Lastly, the interviews revealed that the reason for missing HIC and IP rights holder support was also due to the way C-TAP is perceived. The first two licences are royalty-free for LMICs, global and non-exclusive, making them great examples of the ideal licences C-TAP aims for. Global licensing and the absence of royalties however scare away the private sector, as they believe there is only little possibility for them to make a profit from licensing to C-TAP, especially in HICs. However, C-TAP's licensing requirements are in fact much more flexible than perceived. C-TAP aims for global licences but will also accept other conditions. Interviews have evidenced that C-TAP is willing to negotiate the conditions with the IP rights holders. Product licence proposals will therefore not be rejected based solely on geographical limitations and royalty requirements.

“Should we wait every time for millions to die to get to pharmaceutical companies to do a voluntary action? They made obscene profit from a pandemic. If you don't use a mechanism for sharing technology, know-how and IP during a pandemic, then when?”

Dr. Mohga Kamal-Yanni, Senior Health Policy Advisor to UNAIDS and the
People's Vaccine Alliance

5. DISCUSSION

This chapter serves to provide interpretation of the research results and link them to the context of pandemic preparedness and response.

C-TAP is an instrument born out of the pandemic. It intends to facilitate and promote technology transfer and an IP pooling platform to facilitate upscaling and diversification of manufacturing capacity in LMICs, and also to promote and accelerate innovation of Covid-19 countermeasures. It has recently been most successful with research data and diagnostic tests of public research institutes. C-TAP is a new approach, complementing the existing MPP model by also accepting vaccine licences and providing arrangements for enhanced technology transfer. In the context of pandemic preparedness and response this is important, as it increases the number and location of manufacturing sites, and thereby the number of countermeasures available worldwide. This study identified multiple external and internal obstacles for C-TAP to fully achieve its mandate.

RESOURCES, SPEED AND QUANTITY OF PRODUCTS AND LICENCES

Overall, the research results have shown that the main pitfalls of C-TAP's evolution thus far are related to it being severely underfunded and understaffed. During an already busy time for the WHO, the many tasks to be completed for C-TAP to become operational and secure licences had to be done by just a few members of staff, who were not working on the initiative full time. As C-TAP is not the only priority of any full-time WHO staff member, many of the operational plans and strategies have been done on an ad-hoc basis. No business development plan was found in this research. Strategies for funding, approaching Member States and IP rights holders and broader high-level advocacy were also not found. This makes it hard to follow C-TAP's evolution and compare its current successes and setbacks to set goals. It seems critical that a mechanism housed at the WHO is transparent and deliberate in sharing crucial information such as funding, budget plans and operational structures, especially since this could significantly contribute to public perception, awareness and support of such a mechanism.

For C-TAP to be more successful in advocating for equitable and affordable access to health products worldwide, it needs more business development input, in order to become more strategically operational and tackle tasks such as funding requests, networking with IP rights holders and incentivizing Member States more systematically. To achieve this, it would be beneficial for the initiative to hire more experts with a business development background who can provide guidance on how to operationalize the mechanism in an efficient and strategic way. Especially in times of a global pandemic, technical expertise and time become scarce resources and the Covid-19 pandemic has shown us that a future technology transfer mechanism needs to operate more strategically and systematically than responding ad-hoc.

Human resource constraints have been further amplified by insufficient financial resources. With little progress to show and no clear operational and monitoring plan, it has been difficult for C-TAP to advocate among Member States for further support in financial form or by licensing products of public research institutes. Had there been more activity, we can assume that Member States would have been more interested and funding would have

followed, increasing the activities of C-TAP and securing more licences. Whether funding or Member State support would have needed to come first is a chicken-and-egg question.

With limited capacity to hire further expert staff to develop the initiative, progress has been slow. C-TAP missed the initial momentum and public and political interest in creating global public goods. The pandemic has shown that networking with Member States and IP rights holders should happen intensively in the beginning, before valuable products are patented and licensed on exclusive, royalty-bearing premises. Whilst C-TAP's achievement to secure two licences within two years of being operational is respectable, interviewed informants felt that the licences currently do not have a serious enough impact to effectively reduce the scale of the pandemic. The main missed opportunities are that HIC Member States and the EU have not attached access conditions to the funding and procurement contracts with vaccine developers. This could have been a chance to licence products to C-TAP. Particularly given the fact that vaccines were in large part developed with public funding (McCarthy, 2021), Member States should have used their leverage more.

Furthermore, C-TAP has struggled to overcome internal bureaucratic hurdles. The Access to Medicines Division's usual approach and task of ensuring regulatory approval of health products seems to have been projected onto C-TAP. Regulatory approval is of course a sign of safety and quality of the products. However, in the interest of getting products on board which are relevant for a pandemic response, another option would be to license research and products which could potentially become interesting and receive approval. This would increase the chances of potentially important countermeasures being licenced to C-TAP, and if they do not receive approval, then the option remains to simply leave the licence on the shelf.

In practice, it will most probably be easier to persuade an IP rights holder to license to the mechanism during the early stages of R&D, rather than later. Once a product is approved and on its way to market, the rights holder will likely not be as interested as the product holds more tangible value than before. This holds especially true in a pandemic, when it is not clear which product will be the first to succeed and be marketed.

Regulatory rigidity in this case also hindered the full scale of the momentum of success of the sealed licences, as other interested parties were not made part of the pool and long periods of silence towards the public made it seem like not much was happening. This led to a large amount of interest being deflected.

Moreover, funding seems to have not been distributed evenly amongst Covid-19 initiatives. This could widely be due to the fact that IP rights holders of innovative countermeasures were located in HICs with high funding capacity. However, HICs are protective of the current IP and the commercial interests of the pharmaceutical industry, as are large funding organisations like the Bill & Melinda Gates Foundation (Banco et al., 2022).

The voluntary nature of C-TAP poses obstacles to gaining more interaction with IP rights holders. Currently, no Member State or international regulation imposes receivers of R&D funding or procurement contracts to license their knowledge and products to C-TAP.¹⁶ The mechanism therefore heavily relies on the political will of Member States to cooperate and either include such access conditions in contracts, or have public research organisations license to C-TAP, like Spain and the USA have done. Unlike the MPP, C-TAP does not yet have a reputation and UN-like appeal. It therefore seems to take a lot more time and effort to

¹⁶ The World Local Production Resolution mentions C-TAP as an example of initiatives to support but does not attach legal obligations for Member States.

incentivize IP rights holders to participate in C-TAP. The lack of collaboration from the private industry in sharing know-how and technology during the peak of the pandemic has made this quest quite difficult. The driving argument of IFPMA and pharmaceutical industries participating in this research was that technology transfer is very intricate and takes enormous amounts of expertise to successfully complete. However, the fact that technology transfer, particularly for new mRNA technologies and products, is difficult does not in and of itself mean that C-TAP is not up to the task. It rather seems that the industry seeks to retain control of IP knowledge and the manufacture of said products. Because of the intricacies of the new technologies and vaccines generally, an IP rights waiver such as the TRIPS waiver would likely not suffice to reproduce items, but IP rights holders are currently uninterested in cooperating. The voluntary nature of C-TAP means it is at the mercy of political and commercial will to cooperate.

“C-TAP needs the WHO to throw the weight of the organisation behind it. And it needs governments to really support it, not only through financial donations, but also by forcing the industry to collaborate.”

Jaume Vidal, Senior Policy Advisor European Projects at Health Action
International

POWER, MEMBER STATE RESPONSE AND INDUSTRY INVOLVEMENT

This study has found that some Member States showed interest in finding a new approach for technology transfer and sharing by signing the SC2A. However, their support was not often evidenced by concrete actions such as financial support for the initiative, advocacy activities and encouraging research institutes and IP rights holders to interact with C-TAP. Another form of support could have been to encourage demand on the side of generic manufacturers, particularly in LMICs, to become out-licensees of the mechanism. Research by the C-TAP Secretariat on Member States' incentives showed that many types of incentives and access conditions have been employed to some degree, but so far none has had significant impact on licencing to C-TAP.

This also relates to another missed opportunity, which was not including more stringent access conditions in the R&D funding and procurement contracts of Member States and EU with the vaccine IP rights owners and producers. Had Member States been more thorough in their actions of aiming for global public goods and requiring Covid-19 countermeasures developed with public R&D funding to be licenced to C-TAP, this would have enabled greater availability and affordability of these products.¹⁷

¹⁷ See also the recommendations in this article Pehudoff, K., 't Hoen, E., Mara, K., Balasubramaniam, T., Abbott, F., Baker, B., Boulet, P., Kamal-Yanni, M., Martin, M., Munoz Tellez, V., Natsis, Y., Ortún-Rubio, V., Rathod, S., Torrent, M., Vawda, Y., Villarroel, L., & Love, J. (2022b). A pandemic treaty for equitable global

“If you want to make demands, you need to do that before you sign the cheque. Because once you’ve signed and they have your money, it will be very difficult to add anything to the contract later on. A number of governments have given quite significant support to companies to develop vaccines and they could have included conditions about equitable access, which they didn’t do. And I think that is quite a big mistake. One that I hope will not be repeated next time.”

Anonymous interviewee

Importantly, the research has shown that the private industry has been and will remain keen to retain its control over the market and product development. Many industry representatives have reiterated that IP rights and exclusive licences were not and are not obstacles to global access and that it is up to intergovernmental organisations and UN agencies to ensure access and last-mile health distribution in LMICs. They do not see IP as an issue and have assured that the technology transfer they provided was sufficient for the pandemic response, and for this reason C-TAP does not add value in their eyes. However, we know that a unique selling point of C-TAP is to diversify manufacturing capacity and increase manufacturing licences in LMICs, rendering the supply of countermeasures less fragile and dependent on imports from abroad, and thereby lowering prices.

It can be concluded that one cannot count on the voluntary participation of IP rights holders of products at the expense of making significant profits. Importantly, it is also not clear to what extent sharing of research data of products is required. Companies may fear that one would have to expose research and information relating to a product they want to licence which is also found in a potential blockbuster product that they were not intending on sharing with the pool.¹⁸ There is thus a sense of uncertainty around the extent and depth of sharing of materials required. Nevertheless, making the instrument voluntary from the start was also crucial. Creating compulsory licensing and pooling mechanisms in instances of pandemics could result in pharmaceutical companies being less interested in finding solutions and there may be a much slower, less effective R&D investment into a future pandemic response. This is something important to consider when thinking about ways to integrate Member States’

access to medical countermeasures: seven recommendations for sharing intellectual property, know-how and technology. *BMJ Global Health*, 7(7), e009709. <https://doi.org/10.1136/bmjgh-2022-009709>

¹⁸ This is also the reason why Moderna is suing BioNTech for alleged infringement of IP rights of their mRNA technology, as this technology will most likely be important for cancer, other viruses, and auto-immune diseases. More information can be found here: <https://www.science.org/content/article/scientists-question-moderna-invention-claim-covid-19-vaccine-dispute> (Cohen, 2022)

obligations to promote or force licensing and pooling of technology and IP in a Pandemic Preparedness Accord.

“Conditions always will help, of course. [...] The purchasing power of the European Commission or countries is important. So, if the European Commission, whilst purchasing, said we want you to make sure that your technology is also transferred to lower- and middle-income countries, then that has influence.”

Ad Antonisse, Director Market Access & External Affairs at AstraZeneca

LESSONS LEARNED

There are multiple lessons to be learned from this study.

Firstly, many states will face difficulties with downstream challenges, such as absorption of products, supply chain and logistics but also estimation of the need for therapeutics and vaccine hesitancy. These are not issues that could be solved through technology transfer mechanisms. However, with the right preparation and support, technology transfer mechanisms could very well provide quick and high-quality support to production, research sharing and innovation.

Moreover, it is important to consult and interact with a broad range of diverse stakeholders within the pandemic preparedness and global health ecosystem. C-TAP has never fully gained support from the private sector and HICs. C-TAP in turn positioned itself as a strong ideal, aiming for global and non-exclusive licences with reasonable royalties. The fact that conditions are flexible and negotiable is mainly discussed behind closed doors amongst the parties but should have been promoted more openly to all Member States and IP rights holders.

Furthermore, we have learned that Member States can have very strong power to leverage for global public goods of health countermeasures. Mechanisms housed under the WHO are heavily reliant on WHO and Member State leadership and support to gain access to the required resources and media attention and activities at the national level to incentivise licensing. Furthermore, access conditions should be attached when negotiating funding and procurement contracts, as it is much more difficult to impose these after contracts are signed and funding disbursed.

In addition, respondents agreed on elements that can determine the success of such a mechanism. These are the speed at which it creates ties with IP rights holders and Member States, the network it creates with manufacturers, and lastly the number of products and licences shared with the mechanism. C-TAP missed important licences by focusing on regulatory approval, whereas unapproved products could have made a big impact on the content and popularity of C-TAP.

Lastly, an important lesson learned is that a pandemic response is best prepared prior to and not during a pandemic. Intense discussions with all stakeholders and strategies to

maintain production capacities in times of health need to be conducted and created. Long-term pandemic response networks and mechanisms need to be kept operational to the extent necessary for them to be relaunched quickly for the next health emergencies. Once a pandemic begins, actors need to be able to move quickly.

“The NIH licence was also very important for C-TAP as a precedent of allowing not only final products in C-TAP but also early-stage technologies.”

Erika Dueñas, Head of the intellectual property unit at WHO’s Access to Medicines and Health Products Division and member of the C-TAP Secretariat

6. POLICY RECOMMENDATIONS

RECOMMENDATIONS FOR THE FUNCTIONING OF C-TAP

RECOMMENDATIONS FOR NATIONAL GOVERNMENTS AND THE EU

Policy recommendation: Attach access conditions to funding of R&D and procurement contracts, as early as possible

For R&D funders to use the full scale of leverage that they have over a product, they should include access provisions in funding and procurement contracts of health products at their earliest stage of research. Once the product exists and has received approval, forcing access conditions is more difficult, so such conditions should be included at the earliest stage of negotiations between funding governments, the publicly funded research institutions and/or pharmaceutical companies developing the product. Funding should require approaches which increase access to the products, such as non-exclusive licences with reasonable royalties, or licensing to global technology transfer mechanisms such as C-TAP.

Policy recommendation: Provide resources for technology transfer mechanisms

Governments and policy-makers who publicly support mechanisms such as C-TAP should also provide resources to these mechanisms to the best of their capacity. Resources required that Member States can provide are: funding, political engagement and advocacy activities. Support can also be given by entering into discussions with fellow Member States and international organisations, and by national actions directed at IP rights holders.

Policy recommendation: Seek opportunities for technology buy-outs

Where there is limited interest from IP rights holders to share with C-TAP, governments could consider pooling their funds collectively and buying out certain IP rights and technologies, and in turn, licensing these to C-TAP. Monopolies could be avoided by offering cash payments to technology and IP rights holders to give these up. This would not impair the current incentives of gaining financial profit by commercialising the invention (e.g. through royalties and exclusive licences) but offer a solution for overcoming the obstacles of monopolies rendering innovations expensive and with limited availability. This option could be adopted in the Pandemic Accord.

Policy recommendation: Increase interest of generic manufacturers

Member States should increase the interest of generic manufacturers to become out-licensees of C-TAP and similar mechanisms. They should create demand on the side of manufacturers to increase the amount of products manufactured through such a mechanism.

Policy recommendation: Implement incentives for sharing with technology transfer mechanisms

Member States should furthermore create a system of incentives proposed to IP rights holders to make sharing with a technology transfer mechanism more advantageous. Incentives could be attached to the research and product licences through technology transfer mechanisms. However, these incentives should not come at the cost of quality and safety of the research and products. Incentives could include:

- Priority status in regulatory approval procedures and IP recognition;
- Simplified procedures and administrative requirements for approval and clinical trials of the technologies licensed;
- Funding of clinical trial costs;
- Tax incentives such as benefits and exemptions for income linked to licensed products;
- Financial incentives such as cash payments linked to sharing with technology transfer mechanisms.

RECOMMENDATIONS FOR THE WHO, NATIONAL GOVERNMENTS AND THE EU

Policy recommendation: Be proactive in finding relevant research and products

The technology transfer mechanism should actively seek out IP rights holders of relevant research and products. These rights holders should be approached and pursued actively with information about C-TAP, sparking their interest in licensing through the mechanism. It should not be left up to IP rights holders to approach the mechanism.

Policy recommendation: Focus on governmental research institutes and those receiving significant public funding

The first years of C-TAP have shown that Member States can significantly influence public research institutes to license to C-TAP on a voluntary basis. This was not the case for the private industry. It would be best if Member States simultaneously encouraged these institutes to collaborate with C-TAP. C-TAP should therefore focus its advocacy efforts on Member States, encouraging them to support their publicly funded institutions to interact and share with C-TAP.

Policy recommendation: Create more concrete information material about C-TAP

C-TAP should be promoted more intensely at the WHO and Member State levels, including amongst national funders, research institutes and private industry. The C-TAP initiative should therefore create more information material that can be used to inform research institutes and other stakeholders. Such material should clearly explain its structure, its benefit, the standard procedures and requirements for licensing a product (sharing of IP, R&D data and clinical trials, transparency requirements) and the steps required. The material can take the shape of a video,

a user guide and manual, as well as more documentation on C-TAP's webpages on the WHO website. Ideally, a handbook would be created that can be shared digitally with and by various stakeholders.

RECOMMENDATIONS FOR THE WHO

Policy recommendation: Accept products which do not yet have regulatory approval

Technology transfer mechanisms should not restrict themselves by focusing only on certain types of products or only accepting products which have obtained regulatory approval. In practice, convincing an IP rights holder to license to the mechanism will be easier in the early stages of research, prior to the research entering the market as an approved product. It is important to incentivise open science by licensing research that may become useful in the future or could potentially contribute to the development of another product. C-TAP should therefore actively seek out and license products pending regulatory approval or research that could become useful.

Policy recommendation: Ensure a flexible and transparent governance structure

The technology transfer mechanism should not have an overly bureaucratic internal governance structure. Leadership and delegation of tasks must be clear with strong accountability and transparency requirements and processes. Working groups should remain adaptable and flexible to deal with emergency situations. Collaboration with external organisations like the MPP must be promoted but not create confusion for third parties about the governance structure.

Policy recommendation: Ensure sufficient resources and encourage this through high-level advocacy

A technology transfer mechanism housed under the WHO should be adequately staffed and funded. Diverse staff competencies are required, from managerial and negotiation skills to contracting and communication. More high-level advocacy by the WHO and UN towards Member States is needed, backed up by detailed funding proposals and operational strategies. To this effect, we recommend a high-level ambassador be appointed to conduct advocacy activities and regularly meet with the Member States, industry and delegations.

Policy recommendation: Advocate for more active engagement by SC2A signatory Member States to promote C-TAP

The WHO C-TAP initiative should advocate for more concrete steps and actions to be taken by the Member States who signed the Solidarity Call to Action (SC2A). These actions could take the form of Member States actively approaching publicly funded research centres and facilitating the contact and communication with the C-TAP initiative. Governance structures should be

created which facilitate interaction between C-TAP, IP rights holders and the MPP. An idea would be to set up national points of contact and to delegate this responsibility to a specific person to ensure longevity of contact and overview.

Policy recommendation: Provide a model agreement and written overview of the costs of technology transfer

The technology transfer mechanism should have a model licensing agreement available on its website. This agreement needs to provide an overview of relevant clauses, royalty conditions and exemptions, as well as which party is intended to bear the costs of technology transfer, such as for the experts, equipment and travel. Moreover, the various terms under which a licence can be agreed on, such as global licensing, non-exclusive licensing and more, along with the possibility for IP rights holders to benefit from royalties through the mechanism, must be clarified.

RECOMMENDATIONS FOR THE INCLUSION OF A TECHNOLOGY TRANSFER MECHANISM IN THE PANDEMIC ACCORD

RECOMMENDATIONS FOR THE PARTIES NEGOTIATING THE PANDEMIC ACCORD

Policy recommendation: Mandate the use and support of a global technology transfer mechanism

The Pandemic Accord should include clauses which create a legal obligation for Member States to enable national systems that support a global technology transfer mechanism. This includes interaction between various ministries involved in the pandemic response, such as ministries of health, science, and economic affairs, and appointing contact persons to whom the WHO and interested IP rights holders can reach out to in instances where IP pooling and technology transfer could be beneficial.

Policy recommendation: Ensure sufficient resources for the mechanism

The Pandemic Accord should contain a binding commitment for Member States to support the establishment of a global mechanism for sharing technology, know-how and IP for all medical products related to pandemics. Member States should provide support for such a technology transfer mechanism to the maximum of their available resources. Such support can include political engagement and advocacy activities. Support can also be given by entering into discussions with fellow Member States and international organisations, and by national actions directed at IP rights holders. Moreover, the WHO must also encourage participation with and support for the mechanism and ensure high-level advocacy activities are taking place. It must also make sure that sufficient financial and human resources are made available for the optimal functioning of the mechanism.

Policy recommendation: Ensure affordable pricing in out-licensing agreements

The Pandemic Accord should ensure that the technology-sharing mechanism encourages reasonable pricing and cost transparency of products manufactured through its out-licences. This can be done by including clauses in the out-licences which require the manufacturer to be transparent.

Policy recommendation: Ensure transparency in the process and timelines

The Pandemic Accord should create accountability and transparency requirements for the mechanism. Technology transfer selection criteria, procedures and timelines should be clear and transparent. Expected turnaround times and the maximum time delay for answers between the mechanism and IP rights holders should be established. The mechanism should provide regular updates on its progress through briefings to the interested IP rights holders and the Member States' community.

Policy recommendation: Ensure access provisions in funding and procurement agreements

The Pandemic Accord should create obligations for Member States to include access provisions in funding contracts for R&D of relevant countermeasures and within procurement contracts of relevant countermeasures. Countermeasures should be shared with the mechanism.

Policy recommendation: Enable an ecosystem which creates demand from generic manufacturers

The Pandemic Accord should encourage Member States to create a national ecosystem which increases the interest and demand on the side of generic manufacturers to become out-licensees of the technology transfer mechanism. National policies should increase the number and quality of manufacturing companies and the affordability of the manufactured products. This step is crucial for pandemic preparedness and a speedy response. The creation of such an ecosystem requires political commitment and funding.

CONSIDERATIONS FOR THE WHO

CONSIDERATION 1: MAKE C-TAP INDEPENDENT FROM THE WHO OR NOT

Option to have C-TAP absorbed by the MPP

The MPP is an independent organisation with a strong international reputation and network. It is currently also the organisation that negotiates and signs the licensing agreements between IP rights holder and C-TAP. We envisage a scenario in which C-TAP is taken out of the WHO and absorbed by the MPP. It would thereby become an additional branch of the MPP that focuses on vaccines and provides more extensive support for technology transfer and the sharing of know-how required for the manufacture of safe, high-quality vaccines. This could overcome internal obstacles currently identified within the WHO such as lengthy bureaucratic processes.

Option to keep C-TAP within the WHO system

In this scenario, C-TAP would remain housed under the WHO in its current form. However, in this case sufficient funding, staffing and the support of high-level WHO leadership and Member States are required. Recommendations as mentioned above for the improvement of C-TAP would therefore be applicable and should be taken into account.

CONSIDERATION 2: FOCUS ON GLOBAL NON-EXCLUSIVE LICENCES OR MORE FLEXIBILITY IN THE LICENSING TERMS

Option to aim for licences with a broad scope, such as global non-exclusive licences with reasonable royalties

In the case of C-TAP remaining a voluntary mechanism, it will face difficulties to receive licences and technology transfer support from the private sector. It is therefore important to focus on maximising reach of the licences secured. The aim is for licences to be global, non-exclusive and with reasonable royalties for low- and middle-income countries, following the example of the CSIC and NIH licences. This might limit the number of licences from the private sector but will amplify the effect of licences secured by increasing the amount of products manufactured and made available at an affordable price through the mechanism.

Option to allow for negotiation and strong flexibility of the licensing terms

An alternative option would be to allow various degrees of pooling and sharing within the mechanism. It would thereby not be required for licences to be global or non-exclusive and royalties could differ depending on whether the out-licensee is in a high-income country or lower-income country. This would create more interest in licensing from parties who are currently wary of global licensing and would like to gain profit from high royalty fees from manufacturers in high-income countries. The relationship between royalties and global licensing would thereby be addressed in a way that royalties can be increased when sharing with high-income countries.

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ANNEX

LIST OF INTERVIEWEES

PRIVATE INDUSTRY

- Pfizer Inc.
- Ad Antonisse, Director Market Access & External Affairs at AstraZeneca
- Renée de Vries, Manager Communications at AstraZeneca

WORLD HEALTH ORGANIZATION (WHO)

- Erika Dueñas, Head of the intellectual property unit at WHO's division for access to medicines and health products and member of the C-TAP Secretariat
- Jan Hendriks, member of Technical Advisory Group of the Covid-19 Technology Access Pool (C-TAP)
- Elena Villanueva, External Consultant at the WHO C-TAP Secretariat (2020-2021)

CIVIL SOCIETY ORGANISATIONS

- Ella Weggen, Senior Global Health Advocate at Wemos
- Dr Ellen 't Hoen, Director of Medicines Law & Policy
- James Love, Director of Knowledge Ecology International
- Jaume Vidal, Senior Policy Advisor European Projects at Health Action International
- Luis Villarroel Villalón, Director of Corporacion Innovarte, Chile
- Marianne Meijer, (former) Global Health Advocate at Wemos
- Dr Mohga Kamal-Yanni, Senior Health Policy Advisor to UNAIDS and the People's Vaccine Alliance
- Thirukumaran Balasubramaniam, Geneva Representative at Knowledge Ecology International and Managing Director at Knowledge Ecology International Europe
- Dr Wilbert Bannenberg, Chair of the Pharmaceutical Accountability Foundation (FtV)

MEMBER STATE REPRESENTATIVE

- Roman Macaya, former executive president of the Costa Rican Social Security Fund which provides all public health care services in Costa Rica (CAJA/CCSS)

UNITAID

- Karin Timmermans, Technical Manager in the Strategy Team at UNITAID

MEDICINES PATENT POOL (MPP)

- Esteban Burrone, Head of Policy of the MPP

BILL & MELINDA GATES FOUNDATION (BMGF)

- Senior Officer in Global Health at BMGF