INNOVARTE ONG
PROPIEDAD INTELECTUAL Y COMPETENCIA

Research on awareness and incentives in Latin American countries to participate in WHO's C-TAP.

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Intellectual Property and Competition for Development

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INTRODUCTION

In 2022 and 2023, NGO INNOVARTE conducted a qualitative study through interviews and focus groups with research and innovation institutions in different Latin American countries in order to measure the level of participation and awareness of the COVID-19 Technology Access Pool (C-TAP), an initiative of the World Health Organization (WHO). The analysis also focused on identifying how technology transfer processes and licensing agreements are undertaken within the institutions, as well as their potential willingness to participate in collaborative technology platforms such as C-TAP. The institutions surveyed include research centers in Chile, Uruguay, and Peru.

These interviews are part of the work on access to health and medicines that the organization has been engaged in since its inception, which since the 2020 pandemic has focused on strengthening mechanisms for technological collaboration to fight inequity.

In this sense, NGO INNOVARTE addresses this problem with the understanding that an innovation and development model based on collaboration between researchers, developers and producers is necessary to accelerate innovation processes and provide equitable access to key medical technologies through non-exclusive global licensing and technology transfer.

I. WHO's C-TAP BACKGROUND

On March 23, 2020, the President of Costa Rica, Carlos Alvarado Quesada, and his Minister of Health, Dr. Daniel Salas Peraza, sent a letter to Dr. Tedros Adhanom Ghebreyesus, WHO Director-General, to foster collaboration between research centers. The letter proposed the creation of a repository to facilitate access to and use of intellectual property that protects technologies to detect, prevent, control and respond to the COVID-19 pandemic. The idea was to establish a voluntary agreement whereby holders of intellectual property rights (IPR) and other forms of know-how related to the development and manufacture of diagnostics, devices, drugs or vaccines would contribute them to a common repository.

In response to this initiative, on May 29, 2020, WHO and its partners launched the COVID-19 Technology Access Pool (C-TAP) to promote solidarity and facilitate timely, equitable and affordable access to COVID-19 health products[1]. The COVID-19 Technology Access Pool (C-TAP) is currently supported by 43 countries, as well as the Office of the United Nations High Commissioner for Human Rights (OHCHR), the Joint United Nations Programme on HIV/AIDS (UNAIDS), the United Nations Development Programme (UNDP), the United Nations Educational, Scientific and Cultural Organization (UNESCO), Unitaid, the United Nations Technology Bank, and several other non-governmental organizations and private entities.[2]

C-TAP is designed to accelerate the development of products needed to address the pandemic, promote widespread production, and remove barriers to entry so

[1] World Health Organization. Response to the COVID-19 pandemic. WHA73.1. May 19th, 2020. https://apps.who.int/gb/ebwha/pdf_files/WHA73/A73_R1-sp.pdf

[2] World Health Organization. Endorsements of the Solidarity Call to Action. https://www.who.int/initiatives/covid-19-technology-access-pool/endorsements-of-the-solidarity-call-to-action

that products can be available worldwide. In other words, C-TAP has the following objectives:

1. Foster open scientific development to accelerate product development by sharing intellectual property, know-how and clinical data to facilitate regulatory approval.

2. Accelerate the large-scale production of needed products and facilitate equitable access to these new technologies through transparent, non-exclusive licenses with public health and technology transfer provisions.

3. Promote relationships between key stakeholders such as funders, research institutions and governments to facilitate the transfer of these technologies and thereby maximize access to them.

The current model for innovation, development and distribution of health technologies, based on exclusive rights and non-transparent licensing, has proven ineffective in the face of a global pandemic. This approach has created extreme inequity and inequality in access to these technologies around the world. An example of this is the global immunization target set by the WHO in 2021, which calls for 70% of the world's population to be immunized by mid-2022. However, as of June 2022, only 58 of WHO's 194 member states have reached this goal. Moreover, only 37% of health workers in low-income countries had received a full course of primary immunization.[3]

As an alternative to this exclusivity-based model, the WHO's C-TAP initiative is based on collaboration between researchers, developers and manufacturers to accelerate innovation and facilitate equitable access to key medical products through non-exclusive global licensing and technology transfer. In particular, this alternative model would make it easier for middle- and low-income countries to

[3] World Health Organization, Vaccine Equity. Available in: https://www.who.int/campaigns/vaccine-equity

reproduce the health technologies included in C-TAP, giving them greater autonomy in access. This approach could also help to reduce the price of health technologies, which would help to increase their accessibility.

Although the number of countries committed to the C-TAP initiative is high, the efforts made so far have not been sufficient for this tool to be used by entities holding IPR. While governments are responsible for enforcing public policies, regulating and financing development and innovation in their countries, they have failed to encourage collective efforts and facilitate exchange.

Currently, there is only weak commitment on the part of Member States to promote the C-TAP mechanism and no concrete measures have been defined in this regard.

In this scenario, it is necessary for Member States (MS) to implement lines of action that actively seek out publicly funded research centres to establish contact and communication with the C-TAP initiative. It is also important that governance structures are put in place to facilitate interaction between C-TAP, IPR holders and the Medicines Patent Pool (MPP), through, for example, the establishment of national focal points.

Governments have a key role in the promotion of mechanisms such as C-TAP. They could create incentives for right-holders to participate in and benefit from mechanisms such as C-TAP in their countries. These incentives could be administrative in nature, simplifying the burocratic procedures for obtaining and maintaining intellectual property rights, such as exemption from government fees, annotation of licenses or other documents related to technologies licensed through C-TAP before the proper national authorities. In addition, incentives could be related to rights, procedures and import tariffs. For example, governments could simplify and streamline import procedures and formalities, including reducing or suspending tariffs for the importation of medical technology products licensed through C-TAP.

To date, C-TAP's greatest impact has been reflected in commitments from Spain and the United States. On November 23, 2021, C-TAP and the Medicines Patent Pool (MPP) entered into a license agreement with the Spanish National Research Council (Consejo Superior de Investigaciones Científicas, CSIC) for an antibody serology method against COVID-19. This test is capable of effectively detecting the presence of anti-SARS CoV-2 antibodies that are synthesized in response to COVID-19 or a vaccine[4]. The license agreement will enable more widespread and affordable production and distribution of this technology, thereby increasing access to effective diagnostic tests for COVID-19.

During the second Global Covid-19 Summit, held on May 12, 2022, and co-sponsored by the United States, Belize, Germany, Indonesia and Senegal; the U.S. government announced the licensing agreement between C-TAP, the Medicines Patent Pool and the U.S. National Institute of Health (NIH) for the development of several innovative therapies, early-stage vaccines and diagnostic tools for COVID-19 [5].

In June 2022, through the MPP, C-TAP signed its first sublicense agreement with BioTech Africa, allowing this company to manufacture and commercialize the serological tests provided by the Spanish CSIC.[6]

[4] "WHO and MPP announce the first transparent, global, non-exclusive licence for a COVID-19 technology." https://www.who.int/es/news/item/23-11-2021-who-and-mpp-announce-the-first-transparent-global-non-exclusive-licence-for-a-covid-19-technology

[5] WHO and MPP announce agreement with NIH for COVID-19 health technologies. https://medicinespatentpool-org.translate.goog/news-publications-post/who-and-mpp-announce-agreement-with-nih-for-covid-19-health-technologies?_x_tr_sl=auto&_x_tr_tl=es&_x_tr_hl=auto

[6] Medicines Patent Pool. "New agreement under C-TAP aims to improve global access to COVID-19 testing technologies" (June 16, 2022). Available in: https://medicinespatentpool.org/news-publications-post/new-agreement-under-c-tap-aims-to-improve-global-access-to-covid-19-testing- technologies[last consultation on September 26, 2022].

These licenses are transparent, global and non-exclusive, allowing manufacturers around the world to work with MPP and C-TAP to make these technologies available in low- and middle-income countries.

II. SURVEYS ANALYSIS

The surveys of the research centers focused on four thematic axes:

(i) Previous technology transfer experience of the centers or researchers;
(ii) Awareness of the C-TAP initiative;
(iii) Suggestions and proposals for improving technology transfer through C-TAP;
(iv) Other proposals for technology transfer using other mechanisms.

i) Technology transfer experience from centers or researchers

The aim of this thematic axis was to understand the experience and capacity of the centers to carry out technology transfer, not only through the C-TAP platform, but also through other mechanisms. Answers varied by research center surveyed.

For example, Interviewee 1 (AG[7]) stated that he do not currently participate in C-TAP but expressed interest in exploring this option in the future.

Interviewee 2 (INS[8]) stated that his center carries out knowledge transfer from the public health laboratory and has transferred procedures to the healthcare system. They also explained that the policy defining technology transfer at the National Institute of Health (INS, by its initials in Spanish) is currently being approved and is in line with the OECD, the Frascati and Oslo manuals. They also pointed out that the transfer of knowledge is an integral part of it and that the transfer of technology is something more specific that makes the processes easier.

The INS has not transferred technology for two reasons: a) it is necessary to identify the institution receiving the technology to initiate the process and b) because the system itself does not allow it, since there are no production centers in Peru. For example, if one wanted to transfer technologies for the production of vaccines, it

[7] Andrés Abin, Scientific Director. ATGen, Uruguay.
[8] Cristian Palomino, Head of the General Office of Research and Technology Transfer of the National Institute of Health (INS, by its initials in Spanish), Ministry of Health, Peru.

would not be possible because there are no factories in Peru that can produce them, and the INS is the only one that has a public vaccine production center. In addition, there are no medical device or pharmaceutical manufacturers in the country engaged in these processes. However, there have always been processes of cooperation with other countries, and technologies can be transferred when appropriate.

Interviewee 4 (PUCP[9]) explained that all technology developed in the pandemic is open source and hosted on an open platform for anyone to download. This is because the goal was to meet a public health need and, as a university, to help foster the technological developing industry.

The Pontifical Catholic University of Peru has a laboratory where different projects are developed and there is a manufacturing area where DIGEMID's sanitary authorization is already being processed to officially manufacture some technologies. The primary goal is not to gain commercial advantage but to break down barriers so that other developers can obtain the necessary certifications and manufacture these technologies.

The goal is to make its laboratory available for the production of technologies from other countries and then to allow the holder of the intellectual property rights to commercialize them. The interest is not in marketing but in production.

ii) Awareness of the C-TAP initiative

None of the centers surveyed were previously aware of the C-TAP initiative. While most expressed support for collaboration in science, none were aware of the platform or how it works.

iii) Suggestions and proposals for improving technology transfer through C-TAP

[9] Dra. Sandra Pérez, Pontifical Catholic University of Peru.

Interviewee 1 (AG) suggested that it would be important to expand the platform beyond the COVID-19 pandemic to address, for example, endemic diseases in third world countries. This would make possible a more effective response to the needs of the Latin American healthcare ecosystem and achieve greater equity in access to healthcare.

In addition, he points out that a tax incentive could be beneficial for companies participating in this initiative, since currently in Uruguay there is a similar tool that allows for tax deductions, reductions or eliminations for R&D investments, but its application is bureaucratic and complex. In this sense, they suggest that C-TAP membership could serve as a kind of certification to facilitate local procedures to obtain this tax rebate for R&D in their technologies would be ideal. However, in their view, there is no need for a tax incentive in addition to what is already available in their country. The goal is easier processing, and C-TAP may be a way to do that.

Regarding regulatory issues, the interviewee points out that the requirement of FDA or EMA approval for the commercialization or offering of technologies targeted at the Latin American market can be disproportionate and unjustified, which hinders the scalability of the market. The interviewee does not propose to lower the necessary safety, quality and efficiency standards in the industry, but rather a proportionate and balanced approach to the requirements, adapted to local conditions. For example, the need for FDA approval makes it very difficult for local innovation by small companies in countries like Uruguay to compete in tenders. Therefore, tender conditions should be adapted to local conditions. The C-TAP endorsement could act as a validation standard to support the offering of these technologies in bidding processes, allowing bids to flourish more effectively and not be bogged down by this regulatory aspect.

Regarding intellectual property and patents in particular, the respondent highlights the complexity for companies of its size to perform patentability analyses and comprehensive Freedom to Operate (FTO) reports for each innovation developed.

However, they do so with the projects that are the most viable. In the case of technologies that are plausible for C-TAP, the incentive to comply with third party rights is viewed positively.. This is because there is a risk of bona fide infringement of intellectual property rights in connection with the potential exposure of its products to other markets.

It also considers it extremely important to have fast-track mechanisms for import clearance and tax exemption for COVID-19 related supplies. This was very useful at the beginning of the pandemic, as even in Uruguay it was possible for customs to operate at extraordinary hours to expedite import procedures.

Finally, Interviewee 1 (AG) underlines the importance of the incentive of networks and networking, as it allows to connect with other experts in the field and to foster the necessary confidence to undertake and improve open innovation projects such as the one that had to be done in the face of the pandemic. This incentive would complement the value of the C-TAP bet.

Interviewee 2 (INS) suggests that the first step would be to know the supporting processes to identify the minimum requirements and make sure that everyone understands them. This is critical when adopting any technology. Interviewee 2 (INS) adds that it is important to standardize approaches, to identify the minimum conditions for adopting the technology, especially if the technology is developed in Europe or the USA, where the level of technology transfer differs in terms of the preconditions for the process. Therefore, it is essential to identify the minimum fence to adopt the technology and to plan its implementation in an adequate manner that will allow to take full advantage of the technologies shared in the C-TAP. He also points out that one can get methods, processes, and do the filtering to know how far one can go.

The working meetings between C-TAP and Public Research (IPIS, by its initials in Spanish) are important in this process to learn about the approaches, adoption conditions, transfer and verify if the products are aligned with our processes. These

meetings result in the prioritization of the agenda, remembering that we are a small economy, and we need to work together.

Interviewee 3 (AL[10]) also highlights C-TAP's support for progress on regulatory and internationalization issues. In particular, they mention the importance of obtaining FDA approval, a process that is currently cumbersome, time-consuming and very costly. The impact would be significant if the alliance with C-TAP could speed up and ease the process and the burden it places on entrepreneurs.

iv) Other proposals for technology transfer using other mechanisms.

Interviewee 1 (AG) suggests that the creation of a Latin American IP Office could help innovators like them in the field of biopharmaceuticals and biotechnology in general. This office would allow applicants to have a single point of contact and potentially achieve internationalization in the region much more easily and quickly. In addition, the establishment of the office is important to generate alliances with other business partners present in the US or Europe, where it would be interesting to cover the Latin American region as a whole.

Interviewee 3 (AL) believes that Uruguay's accession to the Patent Cooperation Treaty is necessary to support national innovators in the pharmaceutical and biotechnology industries, in order to expand the possibilities of internationalization. At present, under the Paris Convention, the decision in which countries to file a patent application within a period of only twelve months makes it very difficult to select with certainty the potential market of countries in which inventions could be protected.

[10] Laura Macció, Aravan Labs CEO, Uruguay.

III. FOCUS GROUP ANALYSIS

NGO Innovarte and RedGT organized an event in March 2023 to discuss the functioning of the World Health Organization's "COVID-19 Technology Access Pool (C-TAP)" and the incentives needed to boost the participation of Chilean research centers in this initiative.

The activity was attended by representatives of public entities and representatives of Technology Transfer Centers (hereinafter TTC) in Chile, such as Andrés Bello University; Los Andes University; Universidad Mayor; APTA Hub; Santo Tomás University; KnowHub.

SYSTEMATIZATION

After an introductory presentation on the WHO's C-TAP project, a roundtable discussion was invited to highlight the main doubts and concerns of TTCs about participating in the initiative:

- It has been observed that the interviewees have a number of relevant factors for an institution to decide on whether or not to transfer a technology. At first, they say, it does not seem advisable to be non-exclusive because they do not how long the WHO evaluation will take and how long the technology will be available in the pool. For example, if a drug passes the one-year evaluation period and an exclusive licensee for the technology comes along in the meantime, can it be removed from the WHO or the pool? In deciding whether to transfer technology, that is an issue that a university might consider.

  It is clarified that no license agreement has been signed during the technology transfer negotiations, and therefore there is no formal

commitment to the WHO. However, after signing a non-exclusive agreement, you could not sign an exclusive agreement. It is also important to consider the type of technology being offered to the WHO, as some may be more suitable for commercialization, while others may be more beneficial to the initiative. The length of time the technology is available to C-TAP depends on each holder, as these are individual negotiations. What C-TAP essentially requires is that it be non-exclusive and transparent.

- It should be noted that the reasons for participation are not only economic, but can also mean greater visibility and positioning at a global level, as well as the creation of international networks.
- For technologies that can no longer move forward, interviewees say it would be a good option.
- Interviewees agree that it is important to establish a partnership with the Chilean National Agency for Research and Development (ANID, by its initials in Spanish) and to study the results of projects funded by its public resources, such as the National Fund for Health Research and Development (FONIS, by its initials in Spanish).
- The interviewees also questioned the interest of a pharmaceutical company to invest in the missing development stage if it is granted a non-exclusive license. On the other hand, it is mentioned that the C-TAP could be a useful mechanism for green technologies in Chile.
- One possible incentive identified is for WHO to liaise with countries so that those who participate in C-TAP can receive greater facilities in health licensing procedures. In this context, it is asked whether some kind of fast-track for national sanitary approvals has been evaluated. For example, in Chile, coordination with the Public Health Institute (ISP, by its initials in Spanish) is proposed, so that the analysis and evaluation conducted by WHO for C-TAP entry is included in the ISP evaluation.

- In the same vein, another incentive would be for national intellectual property offices to implement a fast-track for patents on technologies contributed to C-TAP, promoting an exemption or subsidy.
- One of the key challenges is the timeliness of the assessment process for entry into C-TAP. According to one interviewee, researchers also have to meet their academic publication obligations, so the patent has to be filed quickly so that they can publish. However, they are often in the proof-of-concept phase when they enter the national phase. In addition, it would be too late to join the C-TAP, as some TTCs do not apply for protection in African countries, or even in Latin America. Another interviewee then points out that there is an exception, since it could do so if it enters the PCT earlier, and that there is an interesting budget for patenting in those countries.
- NGO Innovarte points out that it is not necessary to have a patent to license. It is also possible to license know-how.
- From the interviewees' comments, it appears that they do not have more information about the type of technologies accepted by C-TAP, whether they are only for COVID-19, or what type. They are also unaware of the existence of the Medicines Patent Pool (MPP).
- Another incentive is the creation of an exclusive public fund for the acceleration of C-TAP technologies. Maybe not just a fund but also public policies in innovation and health that are aligned in some way with global solidarity.

IV. Comparative Experiences of C-TAP Incentives

At the international level, the World Health Organization has addressed the issue of incentives and explored measures that could be implemented by Member States (MS) to encourage technology holders to pool technologies through C-TAP.

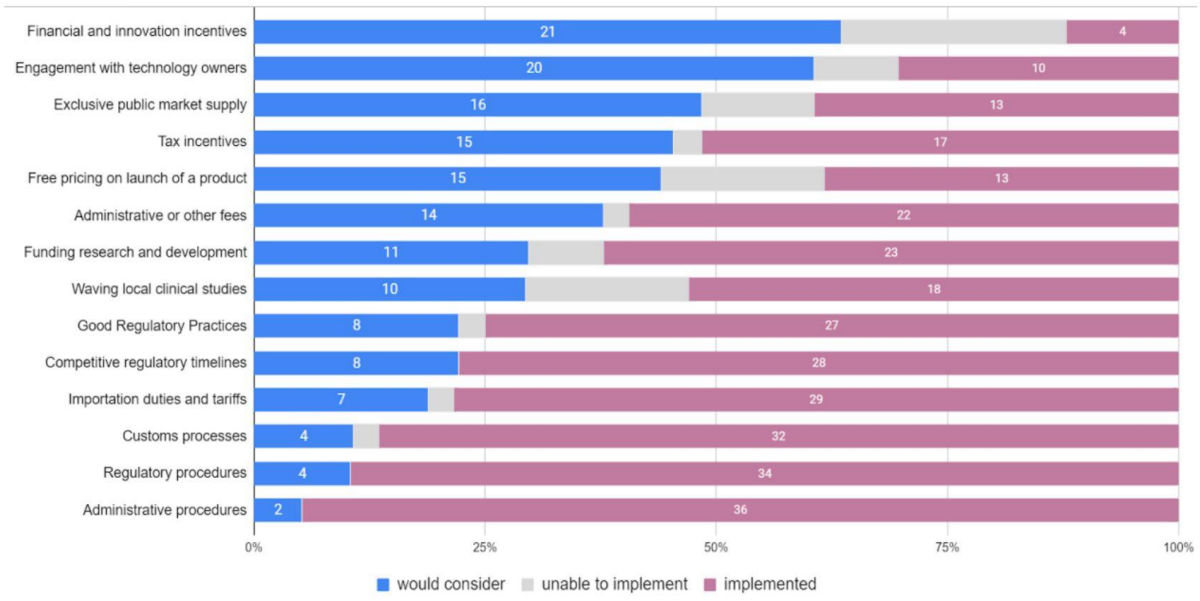
To do so, it designed a survey to analyze the incentives and their level of implementation in each country, and asked the states to respond if:

- Incentives were already implemented in their country or region; or

- Their country or region has not been able to implement them; or

- Incentives were not implemented, but they would consider introducing one.

The survey collected information from responses submitted by 38 Member States (MS) between August 2021 and October 2022. The graphical results are shown below.



Source: WHO[11]

As can be seen, the vast majority of Member States have implemented incentives in the areas of administrative procedures, regulatory procedures, customs formalities, import duties and taxes, competitive regulatory time limits, good regulatory practices, research and development funds, and incentives in other administrative fees.

On the other hand, it is possible to see that MS would consider as incentives to apply those related to financial and innovation, commitments with technology owners or exclusive supply of the public market.

[11] https://apps.who.int/gb/COVID-19/pdf_files/2022/09_06/Item2.pdf

V. CONCLUSIONS

This work, carried out through interviews and focus groups, is part of one of the many instances that NGO INNOVARTE has undertaken in its quest to strengthen the WHO's C-TAP mechanism. Thanks to this work, it has been possible to get to know the vision of the agents who would be directly involved in C-TAP and who coexist with the processes that innovation and development entail. In this way, it was possible to gain a deeper understanding of the needs and expectations of key stakeholders in order to improve the functioning and effectiveness of C-TAP.

Considering the results of the interviews and focus groups conducted, as well as the study recently published by the WEMOS organization entitled "Making Collaboration Work to End Pandemics: A qualitative Analysis of the Covid-19 Technology Access Pool" (title translated into Spanish), we can conclude the following:

1) **There is clearly a lot of misinformation about C-TAP.**

Although the first approach we offered was well received by the research centers, none of them had any prior knowledge of the platform. There is therefore a clear need for further promotion of C-TAP by WHO and Member States. In this regard, the study prepared by WEMOS suggests the creation of more information material that can be used to update research institutes and other interested parties about the structure, benefits, procedures and standard requirements for licensing a product (sharing of intellectual property, R&D and clinical trial data, transparency requirements) and the necessary steps to participate. In the same vein, and in line with the WEMOS study, it is imperative that C-TAP actively searches for IPR holders of relevant research and products. In this regard, we believe that the platform should target and actively pursue these rights holders by providing them with information about C-TAP, thus encouraging their interest in licensing through its technology transfer mechanism.

2) **There is a lack of incentives for the promotion of joint technology mechanisms and technology transfer.**

It is clear from the interviews that technology transfer processes are cumbersome, costly and bureaucratic. In this sense, technology transfer mechanisms should not focus only on certain types of products or accept only products that have received regulatory approval. In practice, it is easier to persuade an IP holder to license the technology transfer mechanism in the early stages of research before it enters the market as an approved product. Therefore, it is important to promote open science by licensing research that may be useful in the future or that may contribute to the development of another product. Accordingly, C-TAP should actively seek and license products that are pending regulatory approval or research that may become useful.

The study also suggests that technology transfer mechanisms should not be overly bureaucratic. Leadership and delegation must be clear. There must be strict accountability, transparent requirements and processes. Work groups must remain adaptable and flexible to deal with emergency situations. Collaboration with external organizations such as the Medicines Patent Pool (MPP) should be encouraged but should not confuse third parties about the governance structure.

We believe that C-TAP can be a way to ease the burden of technology development, and if there is a way to facilitate the processes, especially in times of emergency, this mechanism could achieve greater participation and countries with productive capacity could benefit from open and transparent licensing.

The focus group also highlighted at least **five incentives for TTCs to participate in the initiative**:

- That the WHO's C- TAP can work with the States to collaborate or generate benefits when processing health authorizations for technologies that have been contributed.

- Creation of an exclusive fund by States or WHO to accelerate technologies offered to C-TAP.
- Disseminate the benefits and requirements of the mechanism to TTCs and promote the initiative.
- That national industrial property offices, such as the INAPI in Chile, can put into operation a fast-track with organizations that are linked to the C TAP. Also, that there be a patent exemption in this case, or that subsidies for these patents be encouraged.
- International solidarity as well as contributing to this or other patent pooling mechanisms be promoted at the public level.

3) Potential of C- TAP to benefit niche technologies.

According to the research, it is recommended that the WHO's C-TAP project in Chile focus on niche technologies or those in the early stages of development, as there are technologies that are in the patent process but have not yet been licensed. These technologies could be candidates to join C-TAP, which would allow them to gain other benefits such as impact, visibility and access to a global market.

It is also emphasized that C-TAP should target small companies or start-ups that focus on other countries, since in Chile it is not common to protect intellectual property in Latin American, African or Asian countries, but only in Europe and the United States.

RECOMMENDATIONS

- Member States that have signed the WHO's Solidarity Call To Action (SC2A) should reinforce their commitment to the implementation of C-TAP by adopting more concrete measures and actions in their countries.
- C-TAP and the States should strengthen the promotion of C-TAP at the national/regional level through measures such as: preparation of information support and dissemination, bringing together research centers and IP owners for information and collaboration.
- C-TAP and States can actively seek IP owners of relevant research or products by creating governance structures that facilitate interaction between national headquarters and international organizations, for example by establishing national focal points.
- States should promote open science through public policies that include incentives such as :

  - Simplification of administrative procedures (e.g., facilitation and/or acceleration of administrative processes and procedures, including exemption or subsidization of government fees for obtaining or maintaining intellectual property rights, license registrations, sanitary approvals);

  - Implementation of incentives related to import duties, procedures and tariffs (e.g., simplification and streamlining of import procedures and formalities, including reduction or suspension of tariffs for the import of sanitary products licensed through C-TAP);

  - Creation of a specific fund to accelerate the technologies offered to C-TAP;

  - Focus on technologies in early stages of development and not necessarily those already approved by regulators. For example, a program could be developed in which national industrial property offices, such as INAPI in Chile,

work with institutions that collaborate with C-TAP to establish a fast-track process that accelerates the evaluation of these technologies.

- WHO research has shown that the vast majority of Member States have introduced incentives for administrative and regulatory procedures, customs formalities, import tariffs and duties, competitive regulatory timelines, good regulatory practices, research and development funds, and incentives for other administrative fees. Thus, it is recommended that Chile follow this global trend to promote open science and access to healthcare.

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