Summary Report

"COVID-19 Technology Access Pool (C-TAP) – a dialogue with civil society organizations"

16 February, 14:00 to 16:00 CET

WHO COVID-19 Technology Access Pool vision – *Mariangela Simão*, Assistant Director General Access to Medicines and Health Products

During her welcoming words, Dr. Simão shared that C-TAP also working with CEPI and UNICEF to update the mapping the manufacturing capacity of vaccines, and with other partners mapping therapeutics and diagnostics manufacturing capacities as well. She also shared that C-TAP has already been in touch with most of the companies which have started regulatory approval for their COVID-19 vaccines. Dr. Simão concluded referring to one of the latest article in the Lancet, which talks about "a successful solution to the production bottleneck would probably require widespread technology transfer as few countries have the domestic capacity to rapidly-produce COVID-19 vaccines on their own".

Welcome remarks, *Philippe Duneton,* Executive Director Unitaid

Mr. Duneton referred to the three main challenges in access to COVID-19 health technologies: access to quality data which is even a stronger challenge now in light of variants, how to make vaccines available in terms of volume and prices and country preparedness. He also stressed the need to recognize the work of WHO and partners in shaping C-TAP. Additionally, he stressed the need to define what can be achieved and what´s the value proposition for the next 6 months, a year, but also on the need to think of mid-term and long-term solutions, as we do not know when the pandemic will end, so short-term solutions are not sufficient.

Civil society perspective – *Anna Marriot* - People´s Vaccine Initiative representative

Anna Marriot, OXFAM on behalf of the People´s Vaccine Initiative

Anna Marriot shared perspectives from the People´s Vaccine Initiative regarding the current 20% vaccination target agreed by COVAX, the vaccines pillar of the ACT-Accelerator which is co-led by Gavi, the Vaccine Alliance, CEPI and WHO. Anna expressed concerns that the target is at risk of not being met. Even more, meeting the target of 20% population coverage by the end of the year falls unacceptably short of meeting the vaccine needs of developing countries. Regarding C-TAP, she urged WHO to give it the same political profile it has given to COVAX and, although she appreciated the work of the current C-TAP secretariat, considered that resources were insufficient to advance its mandate, including human and financial resources, and the need to articulate a much clearer strategy. As well

as greater political leadership, she also suggested C-TAP to appoint a senior project lead to oversee the pool, including individuals with experienced negotiation skills from companies from all over the world, and not just big pharma. C-TAP should collate and publish information on existing and potential manufacturing capacity, especially in developing countries. C-TAP, according to her words, also needs a technical lead, someone with the practical skills in the transfer of technology and know-how for manufacturing. Lastly, she considered that the publication of clear guidelines and model agreements that C-TAP is seeking regarding sharing and tech-transfer is needed along with regular communications with external stakeholders, including civil society.

Panel I. How transparent and public health-driven voluntary licenses could contribute to respond to the pandemic?

What are the priorities in the therapeutic landscape by the ACT-A Tx Pillar?
Carmen Pérez Casas, Unitaid

Carmen Pérez informed that there are more than 600 products in the pipeline, and there will be more clarity on several candidates that look promising in the first months of 2021, including antivirals, among them some novel and repurposed medicines. For novel products, for which a high level of efficacy is expected, intellectual property challenges are expected as well. She also added that big volumes would be needed in a very short time for any antiviral to be sued in mild-cases, so preparations are needed now. Carmen acknowledged that some of the new variants may render monoclonal antibodies not to be effective but second-generation and combination of monoclonal antibodies may be. She confirmed that it is anticipated that multiple products will be needed, from novel biological products to older repurposed drugs. For some, intellectual property will need to be addressed.

2. How the Medicines Patent Pool's experience could contribute to IP licensing of COVID-19 Health Technologies? *Charles Gore*, MPP

Charles Gore informed that in May 2020, MPP expanded its mandate to cover *any technology for Covid-19* and they offered that expertise to C-TAP as an enabling partner. He reflected that companies not active in HIV, HepC, often do not have experience with access licensing and tend to rely on strategies they have used before (donations, contract manufacturing, tiered pricing, distribution partnerships). Additionally, he shared that there are significant challenges for biotherapeutics and vaccines, as compared to MPP's experience in relation to small molecules challenges - both in terms of investment and time it takes to reach markets. Gore admitted that at the moment they found little track of IP holders. He insisted that incentives are needed to bring companies to the table. Financial incentives did not go forward and public funding has not been tied to licensing or access. Contract manufacturing, donations and bilateral deals might be seen by many as safer and faster alternatives.

3. Who could be early adopters of C-TAP model? What incentives could be used to promote sharing? *Karrar Karrar*, Save the Children (CSO representative on COVAX for access and allocation)

Karrar Karrar considered that incentives need to articulate the benefits to private sector but also to easy reservation around the threat to the business model explaining is a time-bound intervention. He also suggested to make proposals to facilitate de-risk investments to increase supply through Public Private Partnerships. He also reminded how important is to make clear to industry that this is an opportunity cost for them: the longer it takes to scale-up supply, the more you delay revenues.

Mr. Karrar considered that C-TAP should target companies with public commitments or previous collaboration examples with MPP, for example. Moderna, Gilead or AbbVie. Those companies could be early adopters. He also considered that targeting South-South Transfer should be also prioritized to facilitate tech transfer from those countries that already have that capacity like Cuba. Lastly, he claimed the need to undertake a robust mapping of vaccine manufacturing capacity, what vaccine candidate can they produce, see their capacity needs for engagement as well their financial needs and explore who could fund it to build a practical case to present to industry as well as donors so we get a pharmaceutical rebuttal.

What are the good terms and conditions that should be included to support scaling up and response to COVID-19? Differences between licensing for therapeutics, diagnostics or vaccines? Prof. *Brook Baker,* Northeastern University School of Law

Brook Baker started his presentation highlighting the need for a full patent and intellectual property landscape to understand the freedom to operate, including in relation to trade secrets involving complex manufacturing process and biologic resources (including cell lines) especially relevant for vaccines and monoclonal antibodies. Regarding geographic limitations in the terms and conditions on potential C-TAP licenses, Baker considers that they preferentially be global but should aim as a minimum to include all low- and middle-income countries. He also stressed that there should be no compromise on quality for licensing and technology transfer agreements. They should ensure full approval or emergency use authorization/listing by stringent health authorities or the WHO Prequalification Programme. Baker also mentioned that licensed manufacturers must commit to registering broadly and not preferentially only in better-resourced countries and that licensees commit to distributing licensing technologies equitably. Lastly, he also supported that originator companies should be eligible for adequate remuneration for intellectual property and technology transfer, e.g., single-digit public-interest rates plus costs of technology transfer. He reminded that differential tiered royalties might be appropriate, especially as a trade-off for increased geographic coverage.

5. How can LMICS benefit from licensing of new biotherapeutic products? How to support LMICs to scale up needed technologies? *K.M. Gopakumar*, TWN

Gopakumpar referred to the regulatory barriers limiting access to biosimilars where demand is the most. The one-million-dollar question according to him is if the WHO will do away comparative clinical trial requirements for biosimilar marketing approval. He considered that Under current guidelines, there is no competition in the market, due to time and resource constraints to obtain from the originator. Regarding vaccines, he explained that there is no abbreviated/accelerated pathway and therefore every time there is a change of strain, companies need to redo the process. Gopakumar suggested that WHO could constitute an export group free from conflict of interest and online consultation to look at the scientific possibilities of an abbreviated regulatory pathway. He also suggested that WHO could ask regulatory agencies to share the dossiers to promote non-originator production of BP and vaccines while carrying out regulatory reforms and use information available with it to develop an abbreviated pathway for Covid-19 vaccines.

Soumya Swaminathan, Chief Scientist WHO

Soumya Swaminathan started her contribution sharing the type of information that the Global Health R&D Observatory is already tracking such as the investments into research acquiring to what the companies disclose. However, she admitted that the type of contracts and the access clauses s is something the Observatory cannot track although she would like. Ms. Swaminathan also referred to the Nagoya protocol and the rapid and timely sharing and access of sequences and samples. She admitted the need for an international treaty that looks at pandemics and certain mechanisms to share samples and benefits.

Panel II. Technology Transfer to scale up production for global needs

How technology transfer could support vaccines manufacturing and scale up? What are the challenges and opportunities for C-TAP impact? *Martin Friede*, WHO

Martin Friede started his intervention referring to the information needed to decide which vaccine to promote we should know which technology is best for COVID and COVID mutations: how long will take to produce, willingness to share know-how, yield per facility, infrastructure and biosafety requirements, IP and technical suitability…. He stated that mRna vaccines have high efficacy but complex to make, complex IP but possibly FTO in LMIC. Tech transfer for COVID however may take time. He concluded saying that the next steps should be gathering evidence regarding what are the bottle necks for which vaccine and at which facility, identify which companies are willing and free to share know how. In the long term every region needs sustainable capacity to respond to outbreaks.

How can technology transfer can contribute to scaling up production in LMIC? Marco Krieger, Fiocruz

Marco Krieger started his intervention highlighting that in the PAHO region 80% of vaccines come from vaccine manufacturers in developing countries. He referred to Brazil where 300 million doses will be distributed in 2021 and a large part of this comes from local producers, Fiocruz and Butantán, that uses technology transfer agreement that allows for local production. This significantly reduces technology and regulatory costs associated with the new vaccines like this. Mr. Krieger admitted that as a result of the technical agreement with AstraZeneca they will receive a new vaccine platform which is also an opportunity to start a new problem to develop new vaccines such as those for neglected tropical diseases.

What are the best practices in technology transfer agreements? Jamie Love, KEI

Jamie Love acknowledged during his presentation that there are several smaller firms that do not have t capacity for technology transfer and therefore o C-TAP should partner with intermediaries to identify and work with different platforms. He agreed with previous speaker the need to message more clearly that there are commercial opportunities to scale-up production with royalties via licensing.

The MSF experience in the field promoting technology transfer to improve access? *Yuanqion Hu*, MSF

Yuan Hu stressed that what constitutes meaningful and full transfer of technologies is a bigger scheme than just voluntary license. It is a multifaceted policy intervention which should include infrastructure and capacity development, public investment. IP management is only a small part. According to her presentation, it is important to think on the policy objective. In the short term might be to ensure global production to fight COVID-19, but in the long term should be to be better prepared to fight future pandemics. Ms. Hu considered that industry-led actions on tech transfer are limited. And there is also lack of government interventions. Many of the HIC who host mayor pharma industry continue relying on voluntary and firm-level of actions and there is confusion between contract manufacturing and technology transfer. Therefor according to Yuan Hu, there is a need for a bold vision and framework to tie short term intervention in COVID_19 with longer term solution in which South-South collaboration and sustainable tech transfer is facilitated, with government led mandatory transfer requirements and addressing transparency and open and world-wide coverage in voluntary based initiatives.

Concluding Remarks

Role of civil society in promoting C-TAP engagement y various stakeholders. *Ellen t'Hoen*, Medicines Law and Policy

Ellen T´Hoen started by admitting that the main leverage for C-TAP would have been government funding for R&D granted with the condition to share the know how developed with the funding. However, Ms. T´Hoen considered

that C-TAP can be rebooted if a couple of things happen: WHO is clear about the next steps for CTAP and present a clear plan and proposition; WHO assists in direct Technology Transfer possibly with others, identifying manufacturing potential; WHO offer swift PQ focused on taking away regulatory barriers; Government use all leverage they have to persuade right holders to collaborate with C-TAP.

Mandeep Dhaliwal, Director of HIV, Health and Development Group, UNDP

Mandeep Dhaliwal stressed UNDP supports to the C-TAP approach. She also stressed that there are other options and countries should be pragmatic, looking at all the options available, and bring technology holders and seekers to the table. She reminded that there are other options available for countries in TRIPS Agreement and Doha, and discussions at WTO. Ms. Dhaliwal acknowledged that there is probably a lot to learn from the lessons of the HIV epidemic. CSOs played a central role, but all institutions should be working together: governments, CSOs and IGOs should be looking at an international response.

Mariangela Simão, Assistant Director General on Access to Medicines and Health Products, WHO

Mariangela Simão thanked everyone for the very interesting contributions and announce that new consultation will be organized in a month or so to discuss specific proposals and to ger the inputs on how to make C-TAP work.