



ACCADEMIA NAZIONALE DEI LINCEI

Covid-19: Fair Access to Vaccines

Statement by the Lincei Committee on Covid-19

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1. Issues related to the creation and sharing of vaccines

In the 150 days since the first identification of the COVID-19 virus by Chinese scientists, the international scientific community has worked with an intensity never seen before to acquire as much information as possible about this disease, and has made sure that the data obtained in any research center and in any part of the world are freely accessible to all. It is precisely these data, together with those obtained in the past concerning the SARS and MERS epidemics, both caused by fairly similar coronaviruses, that guided the design of the "candidate vaccines" to prevent COVID-19.

At the moment there is still no vaccine for COVID-19, but there are a great number of possible "candidate vaccines". The projects carried out by some laboratories, both public and private, were financed through either national, international, or private funds. It is likely that funds from alternative sources have also contributed or are contributing to the development of the same project.

The funding conditions, however, may differ considerably and affect subsequent availability of the vaccine. The constraints, the patent property and the availability of the results of the project are in fact influenced by the type of funding that each project receives.

For example, funding that first promoted and coordinated plans for an anti COVID-19 vaccine were those of the *Coalition for Epidemic Preparedness and Innovations* (CEPI), a foundation established in Oslo, and conceived in Davos in January 2017 during the World Economic Forum. This is composed of international partners, both private and public. A significant amount of funds has been injected into CEPI by the Bill & Melinda Gates

Foundation, the Wellcome Trust and the governments of numerous countries. Major multinational pharmaceutical companies have announced their collaboration. CEPI coordinated projects follow highly diversified conceptual strategies and technological platforms. This diversification immediately appeared essential precisely because, for many diseases, but mainly in the case of a new disease such as COVID-19, it is difficult to predict what the type of immune response will be, and therefore what is the type of vaccine that best protects against the infection.

The project run by the French SANOFI is instead funded by the *Biomedical Advanced Research and Development Authority* (BARDA), the research body of the US Government, which claims to have acquired the right to the first million doses of "vaccine candidate" it financed.

The European Commission, on its side, has allocated € 48.25 million to finance 18 research projects under the European Horizon 2020 program for research and innovation. 151 research teams from various European and non-European countries collaborate in these projects, with the aim of improving the readiness of the response to epidemics by developing more effective monitoring systems to prevent and control the spread of the virus as well as develop rapid diagnostic tests to allow a faster and more accurate diagnosis. The researchers are also working to identify new therapies and develop new vaccines. The research teams will share the results obtained in order to speed up the public health response against the virus. In March 2020, the European Commission offered € 80 million in funding to CureVac, a German company that develops innovative vaccines (mRNA-based). Support is given in the form of an EU guarantee for a loan from the European Investment Bank of the same amount, under the funding instrument called InnovFin for infectious diseases, under Horizon 2020¹.

Despite massive funding, it is not surprising that in the short time so far since the identification of SARS-CoV-2 we are still unable to predict whether and which of the numerous research projects currently underway² will actually lead to a new vaccine and which technology/ies will then have to be actually used for its production, nor therefore how much investment will eventually be needed.

However, while we see the first scooping attempts by some States or statements of potential producers who intend to direct sales towards certain countries, we actually have before us a number of issues - industrial, investment, on access to vaccines - which cannot but be addressed immediately and jointly under a global perspective.

¹ <https://www.europarl.europa.eu/news/it/headlines/priorities/risposta-ue-al-coronavirus/20200323STO75619/il-sostegno-dell-ue-per-la-ricerca-su-vaccini-e-care-against-covid-19>

² See. The Scientist Journal <https://www.the-scientist.com/news-opinion/covid-19-vaccine-frontrunners-67382>, as well as WHO Draft landscape of COVID-19 candidate vaccines, <https://www.who.int/who-documents-detail/draft-landscape-of-covid-19-candidate-vaccines>.

In the first place, in the event of a pandemic, much greater and much faster efforts than usual are needed by companies to reach a product as soon as possible. As known, these research efforts require huge investments, which are usually remunerated at a later stage by the patent subsequently obtained. This fact calls, at this point in time, for considerable funding for research whose outcome is uncertain. Probably, the projects that will lead competitively to the first COVID-19 vaccines have already acquired, at least in large part, the necessary funding for this phase of research development.

In the second place, the technologies that will be actually used to produce vaccines will strongly vary and require in turn economic efforts and the availability of infrastructure which might be very different. In addition, the vaccine or vaccines will have to be produced in huge quantities, sufficient to meet all the demand. This will require large production capacities, which implies adequate infrastructures. Furthermore, it will be necessary to evaluate a possible location of the production centers in more than one country to allow both rapid production and equally rapid distribution, which can take place according to different forms of collaboration. Such a dislocation could also make easier to benefit of direct investment by States or international institutions with a regional dimension. Once manufacturing and distribution problems are solved, the most challenging shall then have to be addressed: how to make the vaccine available in all countries, even the poorest, on equitable conditions.

Each of these problems has multiple forms of solution, each with different consequences for the parties involved and different effects on the overall picture to achieve the final outcome. Some, however, must be left to entrepreneurial autonomy, at a junction point between what is scientifically adequate to protect from the virus and what is economically efficient. Others instead require the direct involvement of the States, if investments, which bear a risk since no one is sure of the outcome in the experimental phases, are so high that they have to require necessarily an investment that exceeds the one usually provided by the market. Finally, others are necessarily common to all, so that the vaccine is effectively accessible under fair conditions to all. If we truly believe - as we all declare - that health is a global common good, these solutions have to be made jointly, taking into account both the needs of all States without distinction, as well as the needs and safeguards of the companies that produce and distribute the vaccines, in a global framework in which business and States work in synergy.

To these considerations, commonly shared by States, it is dangerously opposed, in the case of pandemic COVID-19, the political significance that the vaccine tends to assume. The State that gets first to the vaccine, a salvific product, can use it to affirm its scientific and technological excellence, and show its ability to protect first the people of its nation and then those of friendly countries. Economic competition thus also becomes political competition and a measure of power.

A synthesis is therefore needed that could help to reduce the tensions that trigger all the described matters, and within a framework of shared values that, at the end of the path, allow to reach the objective of equitable access to vaccines. This is not a zero-sum game, but a positive-sum game, however made difficult by the formation of coalitions of interests that can lead to sub-optimal results and the risk that this matter will become the subject of political confrontation instead of a common issue to be resolved urgently.

The *Global Compact* is a sort of framework agreement committing business to implement the *Sustainable Development Goals* (SDGs). The private sector has already adopted various measures within such framework and there are so far multiple forms of cooperation between States, international organizations and companies in order to advance the Agenda 2030. It is not difficult then to find seats for a joint dialogue. The final goals can also be easily shared. The commitments made within the World Health Organization (WHO) on 24 April 2020, to which we will return later, should bear witness to this.

The concrete solutions will instead require study, reflection and awareness of the various interests at stake, however under the common understanding that the final objective be that of ensuring access to vaccines by all and on equal terms. Among the critical points that seem essential for a synergistic solution of the issues – as mentioned here and that the *Accademia dei Lincei* COVID-19 Commission intends soon to articulate upon in support of this note - we highlight : i) the theme of the technologies that will be actually used to produce the vaccines, ii) the quantities of vaccines that will be produced and the infrastructures necessary to produce them in the desired quantity, iii) the theme of their distribution, with particular regard to areas with almost non-existent production infrastructures and inadequate distribution systems, so that the solutions to these determinants may lead to effective equal access to vaccines by all. Concrete solutions will also require collaboration between regulatory agencies both for the issue of authorizations according to homogeneous standards and for their monitoring. It will then be necessary to make innovative proposals for interventions at international level. This exercise must begin immediately, before individual companies or States move independently by adopting irreversible choices, which may not necessarily result into the most efficient ones and that can affect the rights of all others.

2. International context

The current crisis has evidenced the many critical aspects underlying the system of cooperation governed by the WHO in the management of the pandemic, as well as the limited powers of the organization. Production and management of vaccines in past crises do not allow much hope either. In particular, we all recall how much the decision of Indonesia was contested, at the time of the avian flu, when it released the so-called "Jakarta Declaration", affirming its intention not to share biological samples taken from patients through the network of laboratories coordinated by WHO for the monitoring of flu viruses.

The Indonesian government intended so to denounce what in its view was the iniquity of the international pandemic system. In particular, the Indonesian government at that juncture complained loudly that pharmaceutical companies could freely obtain patents on inventions made from shared biological samples, thereby achieving massive profits thanks to vaccines, diagnostic kits and antiviral drugs, while for many developing countries, including those who provided the biological samples, the price of vaccines and drugs was prohibitive.

The Framework for Pandemic Potential Influenza Viruses

The diplomatic crisis following the Jakarta Declaration resulted in the approval by WHO of the well-known *Pandemic Influenza Preparedness Framework for the Sharing of Viruses and Access to Vaccines and Other Benefits* in 2011. The *Framework* ensures that influenza viruses with pandemic potential are shared through the network of laboratories under WHO monitoring, so as to be promptly accessible to the scientific community, as was the case in COVID-19. A more equitable access to vaccines and antivirals by developing countries should instead be guaranteed by the fact that laboratories and research centers undertake, in turn, to transfer to the WHO part of the results of research deriving from the use of genetic resources included within the *Framework*. This is done on the basis of some options, including: the obligation to donate 10% of the vaccines/antivirals produced to WHO, that of selling a 10% at a preferential price, the concession, to companies in developing countries or WHO itself, of free licenses or otherwise licenses based on accessible royalties. However, there is no limitation on the possibility of these laboratories or research centers to obtain intellectual property rights on products and processes created thanks to access to shared materials.

The *Framework* is limited in scope and in the alternatives for research centers to offer the vaccine under favorable conditions. In fact, a similar controversy arose already in 2013, based on the accusation by Saudi Arabia of lack of sharing of some samples of coronavirus MERS.

On the other side, the Nagoya Protocol³, in force since 2015, which is indeed intended to favor the sharing of the results of scientific research deriving from genetic resources, including pathogens, obliges companies that will produce vaccines to agree with national governments for the compensation due for the isolated virus in that State by way of agreements that could yet slow down the race for the marketing of the new vaccine, with serious health consequences.

TRIPS and compulsory licenses

³ Nagoya Protocol on Access to Genetic Resources and the fair sharing of the benefits deriving from their use, protocol to the Convention on Biological Biodiversity.

Neither current international treaties on intellectual property - which also include patents – offer shared solutions of a general nature on how to ensure equitable access to vaccines. The TRIPS Agreement, that is to say the agreement on intellectual property within the World Trade Organization (WTO) agreements, leaves it up to States to determine what is patentable, only establishing a few common standards. This is rather the task of the World Intellectual Property Organization (WIPO), where cultures, often very far from each other, however often collide. Instead, the TRIPS Agreement deals primarily with intellectual property (IP) protection. Moreover, the regulatory system of the TRIPS Agreement is based on the determination of certain protections to the rights covered by intellectual property, and granting the State the power to protect public health only through the application of exceptions to the general principles of the Agreement. In addition, these are rules designed for contingent and territorially limited situations.

Moreover, the disputes over the application of TRIPS rules are well known. For example, in the past there have been strong tensions between South Africa and the United States because of the decision of the Ministry of Health of South Africa, in the nineties of the last century, to obtain supplies of anti-HIV drugs for the national health service at a lower price from third countries rather than buying directly from those US pharmaceutical companies established in its territory and holding the relevant patents. This resulted in various disputes between pharmaceutical companies and the government of South Africa, which also amounted to strong tensions between the two countries and which culminated in concrete sanctions by the United States, until the affair ended with a compromise agreement. A sense of frustration over a problem that remained factually open despite the specific solution, emerged again when India tried to strengthen its measures on the use of generic drugs.

On the other hand, the described disputes produced the effect that during the Doha Round, a round of negotiations of the World Trade Organization that otherwise had very little success and that depicts a momentum of severe crisis of the organization as a whole, the TRIPS-Plus was adopted (November 2001). This recognizes the right of States to protect public health and allows certain measures to ease the IP rights, for example by extending compulsory licenses.

However, it is certainly not with an instrument of such a limited scope that the question of accessibility to vaccines can be resolved today. This tool, in any case limited in its use, would possibly make the vaccine accessible, but without solving the problem upstream of the investment necessary to obtain it quickly and effectively. As such, it would actually act as a disincentive for producers. It would also be geographically limited, since it has territorial value (each State would decide internally to impose a compulsory license in its territory).

Limits to States grabbing practices

If neither the TRIPS Agreement nor other WTO agreements regulating Phyto-sanitary goods, with more specific rules than the TRIPS on goods that have a direct impact on public

health, are able to offer immediate solutions of a general value, at least the WTO agreements as a whole set limits to the freedom of States to restrict the cross-border flows of goods. Of course, States have the right to protect their communities in emergency situations, but any measure must be taken as an exception to the general rules and remain proportionate to the needs. Unqualified restrictions in the circulation of goods are thus subject to limits. However, the commitments imposed by the World Trade Organization concern only the behavior of States, not of business, which are not directly bound by international law.

On the other hand, as for TRIPS, also other agreements within the World Trade Organization were not conceived to handle situations like the present one. It is therefore not in these agreements that we may find any direct solution to the question of the distribution of post-COVID-19 pandemic vaccines.

3. Need for a step forward and global agreements between States and industry

Immediate solutions to the problem of production and access to vaccines against COVID-19 cannot thus be found in the wake of existing instruments to govern the international economic order.

In the wake of the Sustainable Development Goals (SDGs) and the Global Compact

In the wake instead of a possible renewed cooperation going beyond the WHO Framework of 2011, and furtherly making leverage on the commitments in the context of the Sustainable Development Goals as for health protection, that have been undertaken by the private sector through the mentioned *Global Compact*, there is an urgent need to devise new approaches and immediately begin negotiations to reach a pact that could simultaneously allow the creation and production of vaccines, in the most efficient ways possible and supported by the necessary investments, as well as guarantee their access to all under equitable conditions.

Giving concrete content to the commitments made on April 24 within the WHO to accelerate access to tools against COVID-19

History taught us that the WHO has always made concrete progress following an epidemic or a pandemic. The results of the recent WHO general assembly did not give particularly positive signs of the intention to make significant progress in the light of this latest emergency. However, a concrete and ambitious project such as that of full sharing of production management and access to vaccines against COVID-19 could be a real opportunity for its revitalization.

On April 24, the WHO obtained from several Heads of State and private organizations involved with health, the commitment to work together for an "equitable global access to all the tools to prevent, detect, treat and defeat COVID- 19".⁴

Therefore, the conditions exist to attempt a more ambitious exercise than in the past. Not only is synergy necessary to reconcile all the interests involved, but the participation of those who have the knowledge capable of evaluating the complexity of the problems is equally indispensable. Above all, the testing, authorization, production, distribution and access to the vaccine must be jointly addressed as components of the same joint action.

States, research centers and business entities that have joined the commitments of April 24 have undertaken the following:

"1. We commit to the shared aim of equitable global access to innovative tools for COVID-19 for all.

2. We commit to an unprecedented level of partnership - proactively engaging stakeholders, aligning and coordinating efforts, building on existing collaborations, collectively devising solutions, and grounding our partnership in transparency and science.

3. We commit to create a strong unified voice to maximize impact, recognizing this is not about singular decision-making authority, but rather collective problem-solving, interconnectedness and inclusivity, where all stakeholders can connect and benefit from the expertise, knowledge and activities of this shared action-oriented platform.

4. We commit to build on past experiences towards achieving this objective, including ensuring that every activity we undertake is executed through the lens of equitable global access, and that the voices of the communities most affected are heard.

5. We commit to be accountable to the world, to communities, and to one another. We are coming together in the spirit of solidarity, and in the service of humanity, to achieve our mission and vision."

However, the call for the commitments undertaken on 24 April 2020 requires a concrete content, to be implemented in a coordinated and coherent way. It is not enough to invoke a common responsibility, nor - as indicated - can one simply base oneself on existing international standards. Instead, a framework of principles is needed to guide in the joint implementation of a plan of truly 'global' interventions and actions, even though they are carried out in an articulated way according to the needs and the parties involved from time to time.

⁴ Access to Covid-19 Tools (ACT) Accelerator - A Global Collaboration to Accelerate the Development, Production and Equitable Access to New COVID-19 diagnostics, therapeutics and vaccines, April 24, 2020: [https://www.who.int/who-documents-detail/access-to-covid-19-tools-\(act\)-accelerator](https://www.who.int/who-documents-detail/access-to-covid-19-tools-(act)-accelerator).

The steps taken in Davos in 2017 for the establishment of the CEPI had gained political impetus from the G-20. In anticipation of Italy's G-20 Presidency in 2021, it is hoped that Italy will assume, as of now, a decisive role in this essential matter for the survival and good of all.

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Responsibility for the information and views expressed in this document lies solely with the Covid-19 Committee