ACCADEMIA NAZIONALE DEI LINCEI

A GLOBAL STRATEGY FOR COORDINATED PRODUCTION AND EQUITABLE DISTRIBUTION OF VACCINES

Statement by the Lincei Committee on Covid-19

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

Executive Summary

Some candidate vaccines are at their last phase of validation, and we all hope that they will soon be safely administered to the population. It is also hoped that more than one vaccine will enter the market so that a wider number of doses and a plurality of sources are there to address the extremely high demand. However, many concrete issues as of production, storage, and distribution arise, as well as difficult choices in terms of priorities in administration of the vaccines according to the availabilities, at least at an initial stage. Costs are also an issue when we want to ensure fair access to vaccines. Moreover, until now states that financed specific projects, either individually or jointly, have undertaken individual agreements with producers, so that, in the event that a specific vaccine succeeds, these are recompensated for their support by priority supplies. No coordination exists at the international level if not partially, and even the most widespread cooperation initiatives were unable to attract some of the biggest states. If nothing is urgently done to cope with this anarchical approach, vaccines will be randomly distributed, and only rich (and lucky) countries will be able to obtain the essential vaccines to save lives and build up resilience of communities. Moreover, existing international rules on trade will strongly limit fair access to vaccines, since the current set of rules is not equipped to cope with the very specific circumstances that the pandemic has generated. On the basis of the situation so far and the proposals that have been launched until now by some institutions, in particular the European Commission, the COVID-19 Commission of the Accademia Nazionale di Lincei recommends several building blocks to establish a shared and articulated scheme for cooperation, involving both the public and the private sector in a joint partnership, and prompts Italy to lead this exercise during its presidency of the G-20 in 2021.

1. Introduction

On 5th November, the Accademia Nazionale dei Lincei (ANL) statement 'The COVID-19 Vaccines - November 2020 Report'[1] was published, containing an analysis of the status of development of candidate vaccines to date, and illustrating the different conceptual and technological strategies that are currently pursued in their preparation due to the many unknowns about this disease, as well as the risks that

[1] https://www.lincei.it/it/article/covid-19-vaccines-november-2020-report

are associated to fast track vaccine evaluation. Among others, the Report unfolds how, although any vaccine that will be registered in Europe and USA will be assessed on a long series of data for its efficacy and safety, it is likely that it will be a long time before industrial policies and national political issues could allow a solid comparative assessment of their efficacy. The comparison of the efficacy of different vaccines in inducing a protective response is hampered by the lack of shared standards. This current technological limitation makes it difficult to compare immune responses elicited by vaccines in different trials and may take to a plurality of alternative products which might not be efficiently exploited in the lack of coordination.

The ANL November 2020 Report identifies around 150 official vaccine projects. About 50 of them have already reached human experimentation and half a dozen of these are currently administered to some sectors of the general population. In the light of the challenges caused by urgency and the described inherent shortcomings in their assessment, the Report considers that in the initial phase of production and distribution, it might not be physically possible to make enough vaccines for the world's population. Various vaccines are already in production without being sure that they will be registered and distributed. In addition, political and economic constrains may limit vaccine access to the country that produces it or to the countries that can afford to pay for it. To make the new vaccines available to the global population will thus be challenging.

The ANL November 2020 Report concludes that, although we cannot fully predict when we will have vaccines to efficaciously control the SARS-CoV-2 virus, at that point in time the next burning issue will be the vaccine availability and its equitable distribution in all areas of the world. Predatory national politics aimed at ensuring that the first vaccine doses are made available to the population of their nation will clash with attempts of many international organizations to set up a more fair distribution in all countries of the world. This noble effort is severely contrasted by the political significance that the COVID-19 vaccine is assuming. The political leader or the country that produces a first salvific vaccine can exploit it to affirm its ability to protect its citizens as well as the inhabitants of friendly countries. The vaccine, thus, may become an inappropriate measure of power.

The issues of coordinated production and equitable distribution of vaccines were addressed at first in the ANL 'Report COVID-19: Fair

Access to vaccines'[2] of June 2020 (the ANL June 2020 Report), where the different challenges in production and distribution were assessed against the existing international legal and regulatory framework.

Not only the technologies that will be actually used to produce vaccines strongly vary, but they will require economic efforts and the availability of infrastructure which might in turn be very different. In addition, the 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 it easier to benefit of direct financing by States or international organizations servicing a specific region. 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.

The ANL June 2020 Report unfolded how 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 ensure equitable access to future COVID-19 vaccines, the Coalition for Epidemic Preparedness Innovations (CEPI), The Global Alliance for Vaccines and Immunization (GAVI), and World Health Organization (WHO) have launched the COVID-19 Vaccines Global Access

[2] https://www.lincei.it/it/article/covid-19-fair-access-vaccines

(COVAX) Facility, a global risk-sharing mechanism for pooled procurement and equitable distribution of eventual COVID-19 vaccines. To the same end, the European Commission elaborated an EU strategy for COVID-19 vaccines (including financing of several vaccine projects), to insert a joint EU action within a global framework, to enhance the potential for universal vaccination against COVID-19 and returning economic and social life to normality across the world.

There is thus hope that more ambitious exercises of international coordination be established, whose possible underlying principles were already broadly highlighted in the ANL June 2020 Report. However, the current efforts for coordination are still quite partial, and possibly some present alliances unbalanced in terms of power and wealth of participating governments, with the risk that these become instrumental to power rather than a genuine tool for fair access to vaccines. On the other side, albeit the testing, authorization, production, distribution, and access to the vaccine should be jointly addressed as components of the same joint action, at this point in time many decisions have already been taken scatteredly.

Since the much-hoped coordination and synergy of all forces have not been established since the very beginning of the fight against the pandemic, we should now build upon what exists, starting in the first place from what the EU has put in place to build up a shared strategy throughout its Member States.

2. The EU Strategy

On 17th June 2020, the European Commission published the 'Communication from the Commission to the European Parliament, the European Council, the Council and the European Investment Bank, EU Strategy for COVID-19 vaccines'[3]. The strategy has the inter-linked objectives of ensuring the quality, safety, and efficacy of vaccines, of securing timely access to vaccines for the Member States and their population while leading the global solidarity effort, and of ensuring equitable access for all in the EU to an affordable vaccine as early as possible.

To reach such objectives, the strategy rests upon two pillars: in the first place, on securing sufficient production of vaccines in the EU and

[3] COM(2020) 245 final, https://ec.europa.eu/transparency/regdoc/rep/1/2020/EN/COM-2020-245-F1-EN-MAIN-PART-1.PDF

thereby sufficient supplies for its Member States through so-called Advance Purchase Agreements (APAs) with vaccine producers via a line of financing, the Emergency Support Instrument (ESI2). Additional financing and other forms of support can be made available on top of such agreements. In the second place, it rests upon adapting the EU regulatory framework to the current urgency and making use of existing regulatory flexibility to accelerate the development, authorization, and availability of vaccines.

The Communication acknowledges that an important step towards joint action between the Member States has already been taken in the formation of an inclusive vaccine alliance by France, Germany, Italy, and the Netherlands. This alliance was formed to pool the national resources of those countries and secure fair access to vaccine supplies for the European population. The proposal contained in the Communication builds upon the groundwork undertaken by that alliance. To scale this approach up to cover the whole EU, the Commission proposes to run a central procurement process, which is meant to create important advantages. All EU Member States will be able to benefit from an option to purchase vaccines via a single procurement action. On the other side, this process also offers vaccine producers a significantly simplified negotiation process with a single point of contact, thus reducing costs for all. Moreover, a truly European approach shall avoid competition between the Member States, and create solidarity between all of them, irrespective of the size of their population and their purchasing power. A pan-EU approach would increase the EU's leverage when negotiating with industry, as well as enable to combine the scientific and regulatory expertise of the Commission and the Member States. On the other hand, the strategy intends to propose a common EU approach that would respect the principle of subsidiarity and Member States' competences in health policy. Vaccination policies would indeed be planned to remain in the hands of the Member States.

The main qualities of the APA can be visualized as follows (table elaborated by ANL):

Right to buy a specified number of vaccine doses in a given timeframe and at a given price	In order to support companies in the swift development and production of a vaccine, the Commission enters into agreements with individual vaccine producers on behalf of Member States. In return for the right to buy a specified number of vaccine doses in a given timeframe and at a given price, part of the

	upfront costs faced by vaccines producers are financed from the ESI. These agreements are negotiated with individual companies according to their specific needs and with the aim of supporting and securing an adequate supply of vaccines. They will possibly de-risk the necessary investments related to both vaccine development and clinical trials, and the preparation of the at-scale production capacity along the entire vaccine production chain which is required for a rapid deployment of sufficient doses of an eventual vaccine in the EU and globally. The conditions of the contract are meant to reflect the balance between the prospect of the producer providing a safe and effective vaccine quickly and the investment needed to deploy the vaccine on the European market.
Other conditions	The aim of the negotiations is to conclude APAs with individual companies under the best possible conditions. These APAs will specify a number of details with respect to expected payments (such as payment amounts, schedule and financial structure), delivery details of the vaccine if and when successful (such as price per person vaccinated, quantity of vaccines and delivery timeline after approval) and any other relevant conditions (such as production capacity in the EU, possible availability of production facilities for the manufacturing of other vaccines or medicines in case of failure, or liability arrangements).
Governance of the partnership	The Commission proposes to enter into an Agreement with participating Member States to formalize their reciprocal commitments. All participating Member States will be represented in a steering board, which will assist the Commission on all aspects of the APA contract before signature. A joint negotiation team composed of the Commission and a small number of Member State experts will negotiate the APAs. The APAs will be concluded on behalf of all participating Member States.
Acquisition of the vaccine	Once any of the vaccines supported proves successful, Member States will be able to acquire that vaccine directly from the producer on the basis of the conditions laid down in the APA. Allocation of access to vaccine doses between Member States would be according to a population-based distribution key.
Responsibility for	While the Commission will be responsible for the procurement process and the APA contracts concluded, the liability for the

deployment and use of the vaccines	deployment and use of the vaccine, including any specific indemnification required by a given APA will remain with the purchasing Member States. For this reason, the assistance of the steering board on any liability issues will be essential.

As of today, the Commission reports having signed a number of APAs. On 14th August, it reached a first agreement with AstraZeneca to purchase 300 million doses of a potential vaccine against COVID-19. On 18th September, a second contract with Sanofi-GSK was signed, for an option that will allow all Member States to purchase up to 300 million doses of the Sanofi-GSK vaccine. On 8th October, the Commission approved an advance purchase agreement with Johnson&Johnson for 200 million doses.[4] On 16th November, a deal to purchase 405 million doses of a potential coronavirus vaccine from German biotech company CureVax was announced. A similar deal with German company BioNTech and Pfizer had been equally announced just a few days before, for an additional 300 million doses. Finally, the Commission declares that they are already working on a deal with Moderna for a sixth contract.[5] Since it is not yet positively known which potential vaccine will successfully complete the development and authorization process and thus meet efficacy and safety criteria to be placed on the EU market, the European Commission attempts to obtain a broad portfolio of vaccine candidates as to maximize the chances of quickly developing, manufacturing and deploying a vaccine for all Europeans. Such a portfolio will thus contain vaccines with different technological approaches to achieve the highest possible chances of finding a successful COVID-19 vaccine.

On 15th October 2020, the European Commission issued a second Communication, entitled 'Preparedness for COVID-19 vaccination strategies and vaccine deployment'[6], to complete the building blocks of its strategy by adding key elements as for vaccine deployment, notwithstanding this part is the responsibility of each Member State. An allocation methodology, to be agreed between the Commission and the

[4] https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/public-health/coronavirus-vaccines-strategy_en.
[5] VOA News, 16 November 2020, https://www.voanews.com/covid-19-pandemic/eu-signs-deal-405-million-doses-potential-german-covid-vaccine.
[6] Communication from the Commission to the European Parliament and the Council, Preparedness for COVID-19 vaccination strategies and vaccine deployment, COM(2020) 680 final, 15 October 2020, https://ec.europa.eu/health/sites/health/files/vaccination/docs/2020_strategies_deployment_en.pdf

Member States, is sketched in the Communication (Table elaborated by ANL):

EMA assessment and EU Marketing Authorization	The EU's regulatory framework, which set out high-standards and strict requirements, contains regulatory flexibilities to cater for urgencies. Vaccine developers are required to submit extensive documentation and data to the European Medicines Agency (EMA) through the EU Marketing Authorization procedure. This includes robust evidence from clinical trials. A comprehensive, independent, and scientific assessment is then conducted by the Agency and based on this evaluation, the European Commission can grant the necessary marketing authorization. For COVID-19, the EMA has put rapid review procedures in place to quickly deliver assessments of applications. Normally, all data on a medicine's effectiveness, safety, and quality, and all required documents must be submitted at the start of the evaluation in a formal application for marketing authorization. In the case of a rolling review, data is reviewed as they become available from ongoing studies before a formal application is submitted. That significantly shortens the normal assessment times, as most of the data is quickly reviewed, while maintaining the principles of quality, safety, and efficacy. Normally, once the data package is complete, the developer submits a formal marketing authorization application.
Delivery and distribution of vaccines by vaccination services in an orderly manner	Once one or more COVID-19 vaccines have become available, vaccination services must be able to deliver and distribute vaccines in an ordered manner, within a given timeframe and in line with a rapidly changing epidemiological situation. Member States should ensure that vaccination services have sufficient resources to carry out their task, both in terms of skilled workforce for the administration of COVID-19 vaccines and supply of the necessary medical and protective equipment. Building on this, vaccination services should be made easily accessible for target populations, both in terms of affordability – Member States are encouraged to consider providing COVID-19 vaccines free of charge – and with physical proximity. The practical steps for getting access to vaccines – including via centralized structures, where possible, and central points of contact – should be clearly communicated to citizens.
Infrastructure for transportation and storage	The planning of infrastructure should take into account that COVID-19 vaccines will have different characteristics, storage, and transport requirements, and that it is highly improbable that the same solution might fit all. Some

	vaccines will have specific temperature requirements, and differences in vaccine characteristics are likely to translate into different sizes of packages and specific transport needs. Member States are therefore encouraged to review arrangements, bearing in mind that cold chains, cooled transport options, and both peripheral and central storage capacity may need to be increased. A deployment of a portfolio of vaccines with different characteristics and requirements is very likely. The Commission accepts to support Member States in this process, putting all Union instruments with logistical and transport capabilities, such as the Union Civil Protection Mechanism, at their disposal.
Monitoring of the performance of the vaccination strategies	The EMA, in close collaboration with the Member States, the Commission, European and international partners, is establishing enhanced safety monitoring activities specifically for COVID-19 vaccines. Member States will be invited to share their national surveillance data on unintended side-effects, if relevant, with the other Member States and the European Authorities. In addition to safety, the monitoring and control of COVID-19 will require strengthened surveillance systems at EU level, integrating both data on the epidemiology of the disease as well as on vaccination coverage rates among target groups. The European Data Protection Board (EDPB) shall play an active coordinating role between the EU's data protection authorities to contribute to the consistent application of data protection rules throughout the EU in times of crisis. High levels of vaccination coverages will also be a key indicator of vaccine acceptance and accessibility. As it can be expected that several COVID-19 vaccines will require two doses, it will be important for the Member States to institute an effective recall system.
Building public confidence in vaccines	The lack of confidence has in the recent past led to an insufficient uptake of, for example, key childhood vaccines and consequently, new outbreaks of vaccine-preventable diseases, such as measles, have occurred. The disinformation phenomenon is an issue that the Commission announces to address in the European Democracy Action Plan by end of 2020. However, it is important that the Member States already start providing citizens with objective, accurate, factual, and targeted information about the importance of COVID-19 vaccines.
Coordination of national responses to the pandemic	While the responsibility for health policy lies with Member States, and national strategies may differ due to several contributing factors such as different healthcare system capacities, population structure or epidemiological situation, it is nevertheless important to ensure the

	coordination of national responses to the pandemic. This includes the distribution and deployment of COVID-19 vaccines once authorized. In this context, it is important to ensure cooperation between the health authorities of the Member States and the civil protection authorities. The EU Emergency Response Coordination Centre could support Member States in this regard as well as through monitoring and information sharing. The Commission has been working closely with the Member States to define needs, explore strategies, and to exchange information and best practices. In addition, modernizing public administration and services, including health, is one of the proposed flagships of the Recovery and Resilience Facility.
Prioritization of accesses according to circumstances but based on guiding principles	When effective and safe vaccines against COVID-19 will become available, the immediate stages of the delivery will depend on the available production capacities. Member States will need to make decisions on which groups should have priority access to the COVID-19 vaccines to save as many lives as possible. The Commission points to two criteria that should drive decisions: to protect the most vulnerable groups and individuals and to slow down and eventually stop the spread of the disease.

Finally, on 11th November 2020, the EU Commission published a further Communication going beyond a specific strategy for access to vaccines, entitled 'Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats'[7] and building upon the criticalities and shortcomings that emerged in the management of the COVID-19 pandemic, so to strengthen the resilience of the Union in case of any similar situation. The Communication elaborates on the existing legal and institutional EU framework and includes, together with other proposals[8], the establishment of a new European authority, the EU Health Emergency Preparedness and Response Authority (HERA).

The goal of the new agency is to enable the EU and its Member States to rapidly deploy the most advanced medical and other measures in the event of a health emergency, by covering the whole value chain from conception to distribution and use. To that effect, according to the Commission, it will, for example, undertake horizon scanning and foresight to anticipate specific threats, identify promising potential

[7] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats, COM(2020), 721 final, https://ec.europa.eu/education/sites/education/files/document-library-docs/eea-communication-sept2020_en.pdf

[8] These include a proposal to extend the mandate of the European Medicines Agency (EMA) and a proposal to extend the mandate of the European Centre for Disease Prevention and Control (ECDC).

countermeasures and underpinning competencies, and generate and disseminate knowledge on these. Moreover, it will monitor and pool production capacity and development facilities, raw material requirements and availability, and ensure that supply chain vulnerabilities are addressed. It will support the development of cross-cutting technologies and solutions sustaining multiple potential future threat responses (e.g. vaccine platform technologies, or the application of digital tools and artificial intelligence) as well as the development of specific countermeasures, including through clinical trials and data infrastructure. It will ensure that sufficient production capacity will be available when necessary, as well as arrangements for stockpiling and distribution.

In the intention of the Commission, the European authority shall be able to plan, coordinate, and assemble ecosystems of public and private capabilities that jointly enable a rapid response when the need arises.[9]

The EU disposes of an institutional and legal structure unknown to the international arena. This is so even if health policy is within the domain of competence of Member States. In the EU, notwithstanding several relevant differences, there is some level of homogeneity as for economic and social skeleton of Member States. However, and despite possible disagreements that may arise for each specific policy choice underlying the EU strategy, this can function as benchmark for an international coordination attempt.

3. International coordination so far

As briefly mentioned above and illustrated in the ANL Report on access to vaccines of June 2020, some public-private alliances exist at international level to finance some vaccines projects, which also imply plans for commonly agreed production and distribution. These are yet still scattered and involve only a few stakeholders.

As also reported in the ANL Report of June 2020, in April 2020 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".[10]

[9] A conclusive proposal has been announced for late 2021.

[10] 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:

Indeed, to achieve such goal, the WHO Strategic Advisory Group of Experts (SAGE) on Immunization has first published a 'Framework for the allocation and prioritization of COVID-19 vaccination' (Values Framework), based on core principles and built around different objectives[11], and further a 'Roadmap for Prioritizing uses of COVID-19 vaccines in the context of limited supply'[12] (Roadmap), as part of a three stages guiding exercise[13].[14]

The SAGE Values Framework of 14th September 2020 offers guidance globally on the allocation of COVID-19 vaccines between countries, as well as nationally on the prioritization of groups for vaccination within countries while supply is limited. The Framework is intended to be helpful to policy makers and expert advisors at the global, regional, and national level as they make allocation and prioritization decisions about COVID-19 vaccines.

The Framework articulates the overall goal of COVID-19 vaccine deployment and provides six core principles that should guide distribution and twelve objectives that further specify the six principles (Table 1 at p. 4 of the Values Framework):

Goal statement	COVID-19 vaccines must be a global public good. The overarching goal is for COVID-19 vaccines to contribute significantly to the equitable protection and promotion of human well-being among all people of the world.
Principles	**Objectives**
Human Well-Being	Reduce deaths and disease burden from the COVID-19 pandemic;
	Reduce societal and economic disruption by containing transmission, reducing severe disease and death, or a combination of these strategies;
	Protect the continuing functioning of essential services, including health services.

https://www.who.int/who-documents-detail/access-to-covid-19-tools-(act)-accelerator.

[11] https://apps.who.int/iris/bitstream/handle/10665/334299/WHO-2019-nCoV-SAGE_Framework-Allocation_and_prioritization-2020.1-eng.pdf?ua=1&ua=1.

[12] https://www.who.int/immunization/sage/covid-19_documents/en/.

[13] SAGE is undertaking a three-step process to provide guidance for overall programme strategy as well as vaccine-specific recommendations:
Step 1: A Values Framework.
Step 2: Roadmap for prioritizing uses of Covid-19 vaccines.
Step 3: Vaccine-specific recommendations. As market-authorized vaccines become available, specific recommendations for the use of these vaccines will be issued. These recommendations may be updated as additional evidence of effectiveness and safety of market-authorized vaccines (as well as other interventions) becomes available, and as epidemiologic and other contextual conditions evolve.

[14] Moreover, the National Academies of Sciences, Engineering, and Medicine has recently released its final report recommending a four-phased allocation framework for the US: 'Framework for equitable allocation of COVID-19 vaccine, Washington, DC, https://www.doi.org/10.17226/25917.

Equal Respect	Treat the interests of all individuals and groups with equal consideration as allocation and priority-setting decisions are being taken and implemented; Offer a meaningful opportunity to be vaccinated to all individuals and groups who qualify under prioritization criteria.
	Treat the interests of all individuals and groups with equal consideration as allocation and priority-setting decisions are being taken and implemented; Offer a meaningful opportunity to be vaccinated to all individuals and groups who qualify under prioritization criteria.
Global Equity	Ensure that vaccine allocation takes into account the special epidemic risks and needs of all countries; particularly low-and middle-income countries; Ensure that all countries commit to meeting the needs of people living in countries that cannot secure vaccine for their populations on their own, particularly low- and middle-income countries.
	Ensure that vaccine allocation takes into account the special epidemic risks and needs of all countries; particularly low-and middle-income countries; Ensure that all countries commit to meeting the needs of people living in countries that cannot secure vaccine for their populations on their own, particularly low- and middle-income countries.
National Equity	Ensure that vaccine prioritization within countries takes into account the vulnerabilities, risks, and needs of groups who, because of underlying societal, geographic or biomedical factors, are at risk of experiencing greater burdens from the COVID-19 pandemic; Develop the immunization delivery systems and infrastructure required to ensure COVID-19 vaccines access to priority populations and take proactive action to ensure equal access to everyone who qualifies under a priority group, particularly socially disadvantaged populations.
	Ensure that vaccine prioritization within countries takes into account the vulnerabilities, risks, and needs of groups who, because of underlying societal, geographic or biomedical factors, are at risk of experiencing greater burdens from the COVID-19 pandemic; Develop the immunization delivery systems and infrastructure required to ensure COVID-19 vaccines access to priority populations and take proactive action to ensure equal access to everyone who qualifies under a priority group, particularly socially disadvantaged populations.
Reciprocity	Protect those who bear significant additional risks and burdens of COVID-19 to safeguard the welfare of others, including health and other essential workers.
Legitimacy	Engage all countries in a transparent consultation process for determining what scientific, public health, and values criteria should

	be used to make decisions about vaccine allocation between countries; Employ best available scientific evidence, expertise, and significant engagement with relevant stakeholders for vaccine prioritization between various groups within each country, using transparent, accountable, unbiased processes, to engender deserved trust in prioritization decisions.
	Engage all countries in a transparent consultation process for determining what scientific, public health, and values criteria should be used to make decisions about vaccine allocation between countries; Employ best available scientific evidence, expertise, and significant engagement with relevant stakeholders for vaccine prioritization between various groups within each country, using transparent, accountable, unbiased processes, to engender deserved trust in prioritization decisions.

Priority groups cannot be simply read off from the above list of objectives, not only because the objectives are not themselves rank-ordered by SAGE, but also because which objectives are most salient and most able to be met, will depend on multiple contextual features, including the epidemiology of COVID-19, the characteristics of specific vaccine products, and the level of societal and economic disruption at the time vaccine is available.

However, the Value Framework identifies 20 population sub-groups and attempts to highlight how the mentioned principles and objectives could affect them (table 2 at p. 9 of the Values Framework):

Principle	Objective	Groups and other considerations
Human well-being	Reduce deaths and disease burden	*Populations with significantly elevated risk of severe disease or death:* • Older adults defined by age-based risk - may vary by country/region, specific cutoff to be decided at the country level by national health experts/NITAGs based on differential mortality by age. • Older adults in high-risk living situations (examples: long term care facility, those unable to physically distance). • Groups with comorbidities or health states (e.g. pregnancy/lactation) determined to be at

		significantly higher risk of severe disease or death (list to be developed later). • Sociodemographic groups at disproportionately higher risk of severe disease or death. *Populations with significantly elevated risk of being infected*: • Health workers at high or very high risk, as defined by interim guidance forthcoming from WHO and ILO. • Employment categories unable to physically distance • Social groups unable to physically distance • Groups living in dense urban neighborhoods • Groups living in multigenerational households
	Reduce societal and economic disruption	Age groups at high risk of transmitting SARS-CoV-2 • Non-age-based population groups with significantly elevated risk of infection and transmission • School-aged children to minimize disruption of education and socioemotional development • Groups targeted as part of an emergency outbreak response using emergency vaccine reserves • Workers in non-essential but economically critical sectors, particularly in occupations that do not permit remote work or physical distancing while working
	Protect the continuing functioning of essential services, including health services	Health workers • Essential workers outside health sector (examples: police officers and frontline emergency responders, municipal services, teachers, childcare providers, agriculture and food workers, transportation workers) • Government leaders and administrative and technical personnel critically needed for indispensable functions of the state (this group should be narrowly interpreted to include a very small number of individuals) • Personnel needed for vaccines, therapeutics, diagnostics production

Equal respect	Treat the interests of all individuals and groups with equal consideration	The equal respect principle requires that careful attention be given to the question of who should be eligible for inclusion in national immunization programs, so that no one is left out of consideration for unjustifiable reasons. The equal respect principle also requires that everyone who satisfies the criteria and reasoning supporting the prioritization of a certain group be included within that group.
	Offer a meaningful opportunity to be vaccinated to all individuals and groups who qualify	
Global equity	Ensure that vaccine allocation takes into account the special epidemic risks and needs of all countries	Priority groups that are identified through this values framework process inform allocation decisions at the global level, with special attention to the needs of low-and middle-income countries.
	Ensure that all countries commit to meeting the needs of people living in countries that cannot secure vaccine	Countries with sufficient financial resources should refrain from undermining vaccine access to low and middle-income countries by contributing to market conditions that substantially disadvantage countries with less economic power. Financially able countries should participate and support approaches to ensure access to COVID-19 vaccine for resource constrained populations
National equity	Ensure that vaccine prioritization within countries takes into account the vulnerabilities, risks, and needs of groups who, because of underlying societal, geographic or biomedical factors, are at risk of experiencing greater burdens	• People living in poverty, especially extreme poverty • Homeless people and those living in informal settlements or urban slums • Disadvantaged or persecuted ethnic, racial, gender, and religious groups, and sexual minorities and people living with disabilities • Low-income migrant workers, refugees, internally displaced persons, asylum seekers, populations in conflict setting or those affected by humanitarian emergencies, vulnerable migrants in irregular situations, nomadic populations • Hard to reach population groups
	Develop the immunization delivery systems and infrastructure required to ensure COVID-19 vaccines	

	access to priority populations and take proactive action to ensure equal access	
Reciprocity	Protect those who bear significant additional risks and burdens of COVID-19 to safeguard the welfare of others	• Health workers at high or very high risk, as defined by interim guidance forthcoming from WHO and ILO • Health workers at low or moderate risk, as defined by interim guidance forthcoming from WHO and ILO • Essential workers outside the health sector (see above) who are at high or very high risk of infection • Essential workers outside the health sector (see above) who are at low or moderate elevated risk of infection • COVID-19 vaccine clinical trial participants who did not receive an effective vaccine (examples: placebo recipients, recipient of vaccine products that did not show efficacy)
Legitimacy	Engage all countries in a transparent consultation process Employ best available scientific evidence, and engagement with relevant stakeholders for vaccine prioritization	The legitimacy principle provides guidance on how the process of prioritization should proceed, with safeguards to ensure trust, and to help protect against corruption and self-dealing.

The 'Roadmap for Prioritizing uses of COVID-19 vaccines in the context of limited supply' of 20th October 2020 intends to support countries in planning by suggesting public health strategies and target priority groups for different levels of vaccine availability and epidemiologic settings.[15] This is intended to serve as guidance on preparing for vaccine prioritization decisions within countries. To that end, the three proposed broad epidemiologic settings are: (i) Community Transmission, (ii) Sporadic Cases or Clusters of Cases, and (iii) No Cases. Moreover, three scenarios of constrained vaccine supply were considered: a Stage I scenario of very limited vaccine availability (ranging from 1–10% of each

[15] The Roadmap will be updated, as necessary, to accommodate the dynamic nature of the pandemic and evolving evidence about vaccine impact.

country's total population) for initial distribution; a Stage II scenario as vaccine supply increases but availability remains limited, (ranging from 11–20% of each country's total population); and a Stage III scenario as vaccine supply reaches moderate availability (ranging from 21–50% of each country's total population). How each of these three vaccine supply scenarios could be considered in recommendations for use in priority groups is illustrated in Table 1 of the Roadmap. SAGE recommends overall public health strategies, grounded in the Values Framework, for each of the three epidemiologic scenarios proposed. The strategies intend to accommodate the dynamic nature of vaccine supply and epidemiologic conditions in each country.

Although the Values Framework does include the principle of global equity, the Roadmap does not directly address global allocation decisions, while a COVAX Facility allocation mechanism for countries participating in the COVAX Facility has been proposed, although it aligns some of its results to those of the COVAX Facility (which yet involves only a limited part of possible stakeholders).

The Roadmap shall be updated according to circumstances, and the third expected deliverable of the WHO SAGE plan will be released hopefully soon. Despite of their high value and the commitment of the members of SAGE, they cannot address all open issues at stake.

4. The way forward at international level

The works of the WHO SAGE are an extremely promising example of the way countries can coordinate on the basis of the existing framework of international cooperation in the health sector, and are essential in order to achieve a shared approach at least at national level.

However,

i) in the first place they do not cope with global allocation issues, which are yet of the essence to grant equitable access to all as well as to permit to defeat a pandemic, which affects the world in its entirety.
ii) In the second place, they do not address the organizational issues of authorization, production, and distribution of vaccines, which instead would need to be part of a common strategy to permit the established principles and objectives to be actually implemented.

iii) Finally, they do not call upon the private sector, which yet plays a pivotal role in the global governance of these issues.

Their results need thus to be complemented and inserted in a wider cooperation structure that considers all relevant elements holistically.

It is thus recommended as building blocks of a common solution of what is inherently and unescapably a global issue:

Make concrete sense of the declaration that vaccines are a global public good

SAGE Values Framework qualifies COVID-19 vaccines as a global public good. This is often repeated by many stakeholders. Saying that COVID-19 vaccines are a global public good means that they are part of a common solution to a global issue, and consequently need to be regulated and managed by taking into consideration the common good, and the need to ensure a fair access to them by all.

It should be uncontroversial that considering vaccines as a global public good means that the solution to a common – and dramatic – problem is the responsibility of all. This should be irrespective of the country each stakeholder belongs to. If for some players, the research for vaccines has taken the shape of a race, transforming it into a sign of power and primacy, such an approach cannot be deemed consistent with the values and principles governing international law and global governance and conflicts with the statement that global threats are a global concern. On the contrary, a fair access to vaccines should be considered as a right, since this ensures equal chances of survival to individuals and resiliency to societies.

Extend a cooperative model along the lines of the one adopted at EU level for global coordination of production and distribution

To guarantee such right requires many interventions, many of which embed in fact structural reforms.

On the other side, there are no specific international instruments within which coordination and collaboration at international level could be effectively implemented. However, leaving possible structural reforms for the times when emergency has been reduced, it appears that substantial results can still be achieved articulating on and strengthening what already exists.

In particular, the WHO is organized by regional centers, whose autonomy and power is great. A concrete plan for authorization, production, and distribution of vaccines roughly following the lines of the EU strategy could be implemented through a high-level coordination and supported by the WHO at the central level. It could then be implemented at regional level through such regional centers, or at least through their coordination. That would ensure consistency while offering flexibility and the elaboration of tailor-made solutions according to specificities of individual regions.

Finance developing countries to participate into the scheme as far as necessary

Moreover, since the financing of countries not able to autonomously acquire vaccines as needed has to be addressed to ensure a concrete access by everyone, organizations such as the World Bank could intervene and contribute to the scheme. It is known that the World Bank can support both States through the IBDR and companies through the IFC.

Similarly, many regional development banks can contribute for the specific region of their reach. International and regional development banks are used to these forms of cooperation and have already diverted many of their programs towards the battle against COVID-19.

Provide technical assistance so that every country be on board and follow a shared understanding

On the other side, organizations like the OECD provide studies and assessments of the public health service in many countries, using indexes that can easily accommodate the needs of a common strategy to cope with the pandemic. They could provide the needed background information to inform such decisions following common patterns, as well as assist in states that would need advice and support.

Recognize the pivotal role of private actors active in the creation, production, and distribution of vaccines as well as the role of their joint contribution to the solution of the problem

Producers and distributors of vaccines are called to play a pivotal role in the solution to this pandemic. The Global Compact mentioned in the ANL Report on fair access to vaccines of June

2020, represents a forum where Sustainable Development Goals (SDGs) are implemented through various forms of cooperation and where businesses voluntarily take upon them the responsibility to achieve the SDGs. The World Economic Forum (WEF) has built the platform 'Shaping the future of Global Public Goods' to integrate and aggregate the efforts of businesses, governments and civil societies.[16] Within such latter framework, the COVID-Action platform selected three priorities: protect people's livelihoods and facilitate business continuity, galvanize the global business community for collective action, and mobilize cooperation and business support for the COVID-19 response. These commitments show consciousness by the market of the role that they have to play under these dramatic circumstances and readiness to respond to the expectations that are placed on them to exit from the emergency.

Establish consistent patterns for contractual regulation of distribution of vaccines, albeit minding of specificities for each vaccine and producer

Although purchase agreements might require to be tailor-made for each vaccine provider according to circumstances, some common grounds can form the basis for negotiation.

What has been done at regional scale by the EU Commission with APAs can for instance be somehow replicated at international level, with a wider audience and a broader geographical scope. If this sounds unrealistic, at least coordination in practices and some level of transparency across the existing agreements between individual countries and pharmaceutical companies should be established, to permit the actual implementation of the Value Principles of the WHO.

Favor decentralization and outsourcing as needed to ensure availability in all territories

This might also require agreements on decentralization of production and distribution, possibly by outsourcing to third companies. This shall be a matter for the producers and distributors themselves, but some consideration on transfer of know-how and assignment of rights on patents must be given as far as necessary to ensure a smooth production and distribution of the vaccines.

[16] https://www.weforum.org/platforms/shaping-the-future-of-global-public-goods

This might also require reconsideration of the fact that the duty to register the same patent in all territories where the vaccine is traded may result cumbersome and slow the process of making the vaccines available. In this case, too, some general agreement must be reached to accommodate the need for protection and safety that patent registration ensures, on the one hand, and the urgency we are facing to rapidly distribute vaccines where most needed, on the other. Possible existing restraints on trade under current international laws should be reconsidered within such context.

Address consistently the matters of logistics, storage, and distribution

It appears that at least some of the vaccines will require adequate storage, possibly in conditions (such as extremely low temperature) that cannot be accommodated under normal circumstances. Since it should be assumed that outsourcing and decentralization of production could not fully solve this issue under all contexts, infrastructures by the host state may be needed to store and further distribute the vaccines.

Be mindful of the need to mitigate some of the results of a plain application of rules on international trade

Rules on international trade as currently established, either in multilateral treaties (as the World Trade Organization, WTO) or bilateral agreements (as Free Trade Agreements, FTA), were not conceived for situations like the one at stake. Some exceptions and derogations do exist to address emergencies, but these were meant to address situations either temporarily or geographically limited. This applies also to the use of vaccines, which are subject to trade and privity rights. These need to be reconsidered in the light of the specific circumstances. [17]

Indeed, public-private partnerships in the governance of pandemics require a re-balancing of rights and duties, which should not produce undue compression of business freedom but that should equally consider the responsibility that the private sector share with governments and any other stakeholder to defeat the pandemic and help building resilience.

[17] Reference to the current international legislation on patents and the challenges suffered by the attempts to depart from them in the past is found in the ANL Report June 2020. A number of countries (South Africa, India, Kenya and Eswatini) urge members of the WTO TRIPS Agreement to adopt a COVID-19 waiver to the general principles on protection of privity rights under the TRIPS.

Take urgently the lead to coordinate all needed efforts

The above-sketched framework enlightening the major issues to be addressed, requires a joint and articulated effort, to be implemented at various levels consistently, although by applying subsidiarity as long as this is permissible against consistency, as flexibility according to the circumstances and the specificities of each context, is of the essence in a scheme of such complexity as the one at stake.

Italy will be chair of the G-20 in 2021. This is the exact time and the exact forum where to lead this exercise and accelerate the existing efforts for coordination, as well as for widening the stakeholders involved to all extents. The EU Commission, in its strategy, affirms that its plans must be a building block of a wider coordination effort at international level, and called for an international conference in Rome in 2021 to address such issues. All is ready for showing foresight and determination.

20 November 2020