Presidenza del Consiglio dei Ministri

VACCINES AND COVID-19:

ETHICAL ASPECTS

ON RESEARCH, COST AND DISTRIBUTION

27 November 2020

CONTENTS

Presentation

The Committee intends to propose a general ethical reflection on the issue of vaccines with particular reference to research, production and deployment in the context of the Covid-19 pandemic, starting from the awareness of the conditions of scientific and epidemiological uncertainty regarding the virus.

While taking note of the numerous trials in progress, the Italian Committee for Bioethics (ICB) highlights on the ethical level that the pandemic emergency should not lead to reducing the timeframe of trials, which is indispensable on a scientific, bioethical and bio-legal level, in order to ensure quality and the protection of participants.

The Committee believes that the vaccine should be considered a 'common good', whose production and deployment for the benefit of all countries of the world should not be regulated solely by market laws. This recommendation must not remain a mere hope, but rather it constitutes an obligation to be met by the International politics of States. The ICB also considers it essential for pharmaceutical companies to recognize their social responsibility in this serious pandemic.

The Committee draws attention to the indispensability of ethical reflection in the context of distribution choices. Given the uncertainties surrounding vaccines the Committee believes that the criteria, including the ethical criteria, for identifying priority categories, can only be potentially general at this time, and will require further specification in the light of new scientific knowledge on the vaccine and the quantity of doses initially available; knowing that it will not be possible to provide for everyone at the same time. The Committee, however, as of now, emphasises the importance of every choice regarding distribution to be based on the general moral, ethical and legal principle of the equal dignity of all human beings without any discrimination, as well as the integrative principle of equity, that pays special attention to vulnerability and specific needs.

The Committee believes that all efforts should be made to achieve and maintain optimal vaccination coverage, not excluding mandatory vaccination in the case of emergency, especially for professional groups more exposed to the infection and its transmission. The Committee hopes that this obligation will be lifted if there is no longer a major threat to society and by favouring and encouraging spontaneous adhesion to vaccination by the population. An essential condition so that the vaccine distribution plan may be ensued by an acceptance of vaccination by citizens, is the provision of information and public communication that is transparent, clear, understandable, consistent and coherent, and based on up to date scientific data. Specific attention should be paid to identifying sources of misinformation and false information.

With regard to the equitable distribution of vaccines, the Committee recommends a multidisciplinary discussion which includes ethical reflection geared towards the concrete situation.

The Opinion was prepared by the President of the ICB Lorenzo d'Avack and the Vice President Laura Palazzani, making use of the contributions of Cinzia Caporale, Silvio Garattini and Luca Savarino and the broad and intense participation of the entire Committee.

The opinion was voted by Profs. Salvatore Amato, Luisella Battaglia, Stefano Canestrari, Cinzia Caporale, Carlo Casonato, Bruno Dallapiccola, Antonio Da Re, Lorenzo d'Avack, Mario De Curtis, Gianpaolo Donzelli, Silvio Garattini, Mariapia Garavaglia, Marianna Gensabella, Maurizio Mori, Assunta Morresi, Laura

Palazzani, Tamar Pitch, Lucio Romano, Luca Savarino, Monica Toraldo Di Francia and Grazia Zuffa.

Despite their not having the right to vote assent was given by: Dr. Maurizio Benato, the delegate for the President of the National Federation of MDs and Dentists Colleges; Dr. Carla Bernasconi, the delegate for the President of the National Federation of the Orders of Italian Veterinarians; Dr. Amedeo Cesta, the delegate for the President of the National Research Council; Prof. Carlo Petrini, the delegate for the President of the National Institute of Health.

Vice President Riccardo Di Segni and Profs. Carlo Caltagirone, Francesco D'Agostino, Massimo Sargiacomo and Lucetta Scaraffia, absent from the plenary session, subsequently also espressed their support.

Prof. Lorenzo d'Avack
President of ICB

1. Introduction

International research is currently engaged in developing a vaccine which in the opinion of the World Health Organization and as believed by many virologists and scientists, should be the most important tool capable of stopping or at least significantly slowing down the transmission of the coronavirus. No drug under development has ever attracted so much widespread attention and debate around the world. This regards multiple aspects: scientific, economic, political and not least the ethical aspect.

For the purposes of careful evaluation by the Committee of the emerging ethical problems, some peculiarities of the current vaccine race should be considered: 1. the methods and timescales of testing and production, enormously faster than those known so far; 2. the existence of a large number of vaccines in competition with one another, produced using very different techniques, some traditional, others innovative; 3. the costs which, in order for the vaccine to be truly accessible to all, must be limited and controlled; 4. the need for the organization and worldwide distribution of vaccines, necessarily on a contingent basis, since, at least initially, the availability of individual vaccines will not be unlimited; 5. the importance of identifying reference principles and specific criteria for distribution priorities; 6. the defining of whether vaccination will be mandatory or not; 7. the planning of adequate information and communication.

The Committee intends to propose a preliminary and general ethical reflection on the issue, well aware that the current conditions of uncertainty (the lack of knowledge on the modes of development and transmission of the virus, the temporary absence of one or more vaccines, the paucity of knowledge on their effects and relative safety and efficacy etc.) compels us to undertake argumentation based on general principles and criteria with respect to situations that may evolve in an unpredictable way.

2. Research: general criteria

To date there are numerous proposals for vaccines against Covid-19 and there are numerous ongoing trials, which have reached different stages[1.] Huge and unprecedented investments have been made in order to develop safe and effective vaccines[2]. The projects are carried out by laboratories, both public and private, some with national funding, others with international funding. These different forms of financing may have an impact on the costs and deployment of the future vaccine. The research, production and distribution phases are strictly connected and must be tackled as components of the same problem.

Numerous countries are involved in this research. A study by the Accademia Nazionale dei Lincei highlighted, in the specific case of the pandemic, the political significance that the vaccine tends to take on. “The state that produces it first can

[1] 97 studies are underway, 79% of which are randomized, for a total of 438,938 participants. The ongoing studies are divided as follows: phase I: 34%, phase I / II: 32%, phase II: 9%, phase II / III: 3%, phase III: 22%. The different methods used are: Inactivated virus: 19%, Protein subunit: 21%, DNA: 6%, RNA: 14%, Bacterial/viable vector: 36%. The country where the number of ongoing trials is greatest is China (29 studies), followed by the United States of America (18 studies).

[2] For companies like Pfizer and BioNtech, analysts expect revenue of $ 3.5 billion in 2021. Next year, the global market for Covid-19 vaccines could be worth $ 9.5 billion (in "Internazionale", 20/26 November 2020, p. 51).

use it to affirm its scientific and technological excellence and demonstrate its ability to protect the inhabitants of its nation first and then the inhabitants of friendly countries. Economic competition thus also becomes political competition and a measure of power"[3].

Although normally the average time needed to put a new vaccine on the market is more than 2 years, the health emergency requires us to arrive at a safe and effective result as soon as possible. The political, economic and health factors mentioned so far could lead to the temptation to shorten the timeframe and phases of trials. Presently, although it is obvious that the quest for a scientifically valid and effective vaccine must have a fast track, in order to protect individual and public health, the emergency must not lead to reducing the timescale or even omitting phases of trials, defined by the international scientific community as indispensable requirements on a scientific, bioethical and bio-legal level, in order to ensure the quality, safety and efficacy of a drug[4]. The Committee has already expressed itself on this point in its Opinion on *Biomedical research for novel therapeutic treatments within the Covid-19 pandemic: ethical issues (22 October 2020)*[5].

Differently the possible shortening of the timeframe of trials can take place by allowing the vaccine a fast track, simplifying the administrative procedures for the review of research, eliminating administrative and bureaucratic inefficiencies[6].

With regard to the studies on volunteers, special attention should then be paid to the gratuitousness of the act and the exclusion of any form of payment or improper incentive, both direct or indirect, to participants, which may induce poor people to expose themselves to risks for purely economic objectives. Taking into account the exceptional nature of the contingency, if, in order to implement urgent

[3] Accademia Nazionale dei Lincei, *Accesso equo ai vaccini*, 1 giugno 2020, 2. See M. PEIRIS, G.M. LEUNG. *What can we Expect from First-generation COVID-19 Vaccines?,* in "The Lancet", 7 November 2020, 936, pp. 1467-1469.

[4] In the US there has been a 'paradigm shift': 9 pharmaceutical companies have asked the Food and Drug Administration (FDA) not to reduce the rigor of the assessments to accelerate the availability of vaccines (in general the pharmaceutical companies press to speed it up), concerned that speeding up approval could cause harm to the population by providing unsafe and ineffective vaccines: J. AVORN, A. KESSELHEIM, *Up is Down - Pharmaceutical Industry Caution vs. Federal Acceleration of COVID-19 Vaccine Approval*, in "New England Journal of Medicine", 2020, 383, pp. 1706-1708.

[5] Position of the European Network of Research Ethics Committees (EUREC) on the *Responsibility of Research Ethics Committees* during the COVID-19 Pandemic, 2020.

[6] To this end in Italy, the speed and accuracy of the process is ensured by the emergency procedures provided by the Government. The Technical Scientific Commission (CTS) of the Italian Medicines Agency (AIFA) has been commissioned to review all studies in the quest for Covid-19 treatments. The advisory opinion of the CTS is implemented by the Single National Ethics Committee for Covid-19, which, in turn, evaluates the study and issues a single national opinion. Art. 40 of the law decree 8 April 2020 n. 23 attributes this role to the Ethics Committee of the National Institute for Infectious Diseases "Lazzaro Spallanzani" - IRCCS. This model that is being tested for the Covid-19 pandemic allows for an acceleration of study approvals, while maintaining scientific requirements. It is a model which has proven to be successful and it could also be applied to other areas. We must point out again that a pandemic task force has been set up within European Medicines Agency (EMA) dedicated only to Covid-19, composed of experts indicated by the network of national regulatory authorities. They are responsible for evaluating the data produced for the development of anti-Covid drugs and vaccines. The companies have been authorized to send updated data and the task force has examined the submitted data without waiting for conclusion of the entire authorization dossier. In this way the time needed for the evaluation process has been reduced from 1 year to 3 months (see the statement by Guido Rasi, former executive director of the European Medicines Agency, in "Il Messaggero", 22 November 2020, p. 5).

measures for the protection of participants in a clinical study, expenses are expected to be borne by them, similarly to what is already allowed in extraordinary cases (for example studies on rare diseases), the sponsor is allowed to reimburse these expenses to the subjects. The expenses incurred must be adequately documented and risk coverage must be guaranteed[7]. Once the reliability and ability to protect against the disease have finally been proven, the vaccine will have to undergo assessment and then approval by the regulatory authorities and its effectiveness verified over time[8].

The State, before taking a vaccine and making it available to citizens, must therefore continue to make use of research for a comparison between approved vaccines and to establish a comparative benefit-risk ratio.

As part of the research, the growing importance of studies conducted by various international Consortia on genomics in the current pandemic must be taken into account. These Consortia, thanks to the continuous exchange of data and genomic information, have already achieved remarkable results that have made it possible to identify, on the basis of the presence of specific genetic mutations, subgroups of people that are particularly at risk, regardless of age, of developing severe forms of the disease[9].

3. The cost of a 'common good'

The Committee recommends that production rules allow the outcome of the research to be made available to everyone, within each country and all countries, supporting its fruition where necessary.

When the vaccine becomes available, the costs could be very high. For this reason it is necessary to work on a containment strategy together with other countries. The European Union is already recommending a strategy on vaccines with the dual purpose of containing costs and ensuring equitable distribution of these vaccines[10]. Removing vaccine patents is the path that the World Health Organization has repeatedly advocated, although the elimination of the patent is

[7] On this principle of gratuitousness, see AIFA Update Communication, published on 12 March 2020, *Clinical trials' management in Italy during the COVID-19 emergency* (*Coronavirus Disease 19*, Version 7 April 2020).

[8] To date, we do not know if and for how long you become immune to SARS-CoV-2, and this could affect the efforts and outcomes of research for a vaccine. For other coronaviruses, such as those that cause the common cold, immune memory lasts a little less than a year, then it seems to vanish, exposing us to the disease again. For SARS, whose coronavirus has several elements in common with the current one, the immunization period appears to be longer.

[9] Italian Committee for Bioethics (ICB) and Italian Committee for Biosafety, Biotechnology and Sciences of Life (CNBBV), *Bioethical reflections on precision medicine and diagnostic-therapeutic developments*, 19 november 2020.

[10] It should be remembered that the Comité Consultative National d'Etique in France in the opinion *Enjeux éthiques face à une pandémie* (March 13, 2020) stressed the collective responsibility of the pharmaceutical industry, inviting it to "integrate a collective vision into their practices, going beyond strictly economic considerations". The Nuffield Council on Bioethics in England in the document *Fair and Equitable Access to COVID-19 Treatments and Vaccines* advocates "a fair and just access to treatments and vaccines" (May 29, 2020), in the context of international cooperation and collaboration to share the benefits of research and avoid monopolies. The theme of equity and solidarity is highlighted by international documents: European Group on Ethics in Science and New Technologies (European Commission), *Statement on European Solidarity and the Protection of Fundamental Rights in the COVID-19 Pandemic* (2020); Council of Europe Bioethics Committee (DH-BIO), *Statement in the Context of the COVID-19 Crisis* (2020); International Bioethics Committee and COMEST (UNESCO), *Statement on Covid-19: Ethical Considerations from a Global Perspective* (2020).

likely to significantly slowdown research and decrease the number of competitors.

If, however, the patent is allowed, at least in the most dramatic early stages of the pandemic, its suspension should be envisaged and at the same time provision should be made for the granting of compulsory licenses, regulated by international agreements. There is currently the Covax global program for the distribution of future vaccines according to fairness criteria, led by the World Health Organization, Cepi (*Coalition for Epidemic Preparedness Innovations*) and the Gavi alliance (*Gavi The Vaccine Alliance*). Covax should guarantee access to doses to all countries and prevent rich countries from snapping up the vaccine[11].

The Committee therefore, in recommending that the vaccine be considered a 'common good', attributes to politics the task of intervening and controlling production and distribution so that they are not regulated solely by market laws. This recommendation must not remain a mere desire, but rather it is an obligation which the international politics of States must meet. Europe has the opportunity to do something unique if it wants all its countries and all the countries of the world to have the vaccine[12].

We do not know how the pandemic will evolve, but for now in the world the virus has caused hundreds of thousands of deaths, provoking the most varied scientific, ethical, economic, legal and political reactions which can be summarized in two opposing attitudes: helping each other based on the intention of solidarity, or closing off and defending ourselves from others, irrationally invoking claims of self-sufficiency, considering that no country is in fact in a position to defeat the virus alone. The Committee considers it ethically necessary to recommend global collaboration, scientific and economic openness as the only valid path to overcome this crisis which humanity is called upon to face. The ICB also considers it essential that pharmaceutical companies recognize their social responsibility in this serious pandemic condition, also considering the huge economic contribution borne by the public.

The Committee hopes that attention to equitable distribution of the anti-Covid-19 vaccine will not remain an isolated case, but that it will become an opportunity to build international solidarity in order to end to the serious limitations in the protection of health that still exist in many Countries.

[11] More than 180 countries have joined the project so far, including China but not the United States yet. Among these there are 94 high-income states, each of which has made binding commitments. They will all have access to the vaccines on the Covax list and each will pay for their own doses. The remaining low-income countries will receive it for free.

[12] One could recall the three objectives of *The People's Vaccine* coalition made up of several international humanitarian organizations defending against inequalities: a mandatory global sharing of knowledge, data and technologies on Covid-19 to ensure that each nation can produce or buy sufficient doses of vaccines , treatments and tests; the rapid establishment of a fair global production and distribution of vaccines, treatments and tests, founded by rich nations, which guarantees transparency and supplies, according to needs and not the ability to pay, according to the principle of substantial equality; a guarantee that Covid-19 vaccines, treatments and tests are provided free of charge to everyone and everywhere https://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2020/may/20200514_covid19-vaccine.

4. Deployment, obligation and information

When a vaccine is approved, other challenges will have to be addressed. Some are of a practical and economic nature so as not to run the risk of being unprepared in the collection and distribution of the vaccine: = produce sufficient quantities to make it available to the population; = ensure sufficient organization and health care provision for immunization; = ensure coordination with the Regions and set up suitable facilities to ensure shipment and delivery to the administration sites; = have premises reserved for this purpose and the vaccination personnel; = promptly ensure the supply of material where necessary (swabs, sterile syringes, needles, disinfectants, gloves, etc.) and set up an IT system for data management (booking, registration, monitoring). The latter data, if acquired at a regional level, must be immediately transferred to a single centralized database for immediate verification of the actual national health coverage.

To accurately estimate the number of people to be vaccinated is complicated and much will depend on the assessments of the individual States and available amounts of vaccines. Experts say that the immunity percentage threshold requires the involvement of at least 60-70 percent of the population in order to significantly reduce the spread of the epidemic. Although this percentage also includes people who get sick and recover, these data still imply the need to vaccinate millions of people in every country[13].

Given these estimates, the question of the distribution of resources, which will initially be limited, must be treated in a differentiated manner according to the production and quantity of vaccine available[14]. The ICB recalls the importance and indispensability of ethical reflection in the context of distribution choices, so that these are made in compliance with fundamental bioethical principles and according to clear and well-defined criteria.

The Committee intends to reiterate on the ethical level - as already stated in the previous opinion *Covid 19: clinical decision-making in conditions of resource shortage and the "pandemic emergency triage" criterion* (8 April 2020) –that every distribution choice must be based on the general moral, deontological and juridical principle of the equal dignity of every human being and the absence of any discrimination and the integrative moral principle of equity, a principle also sanctioned by the Constitution in art. 3, which guarantees substantial equality when faced with unequal starting conditions, in consideration of vulnerability and specific needs.

Furthermore, it will be particularly important to explain to the population in a transparent way that the criteria for priority in vaccinations are established on the basis of identification of 'at risk' groups due to the type of work or age and health conditions: the exclusive objective of determining priorities consists in the ethical need to protect every person as much as possible, in compliance with the principles of equality, in the light of social solidarity duties (Articles 2 and 3 of the Constitution).

The ICB therefore excludes from this very moment resort to lotteries or the

[13] Furthermore, a vaccine is never one hundred percent effective, so the calculation will have to take into account the individuals who will receive it, but will still not develop an immune response that protects them. If the period of immunity turns out to be limited and the pandemic continues, vaccination may be necessary several times.

[14] https://www.imperial.ac.uk/mrc-global-infectious-disease-analysis/covid-19/report-33-vaccine/

first come, *first served* criterion: the first because it is based on randomness and does not take into account existing differences and particular vulnerabilities; the second because it would end up facilitating, in a discriminatory way, those who have easier access to vaccines, for logistical reasons or the possibility of acquiring information.

In general, in the treatment with prophylactic measures, it is necessary to consider both clinical ethics and public health ethics in the balancing of direct and indirect risks/benefits. Direct risk refers to the risk with respect to one's own individual health (risk of mortality, severity of the pathology in terms of hospitalization, admission to intensive care, ventilation); indirect risk refers to the transmission rate of the infection, with consequences for society. The direct benefit relates to the immunization of the subject (with reference to the degree and duration of immunity) and the indirect benefit concerns collective immunization, an objective which must be clarified, on a scientific basis, to the population[15]. Every consideration must always keep in mind the determinants of health from a bio-psycho-social perspective: the risks and benefits should not be considered only with reference to the physical dimension but also taking into account the impact of and on the psychological and social conditions of individuals[16].

At the moment it is not known which vaccine or which vaccines will be deployed and the scientific data on their safety and efficacy are not yet available, with reference to the specific population on which they were tested, the duration of immunity, the degree and level of immunity reachable in the different segments of the population (also as regards those who are already infected), and the possibility of re-infection and transmission of the virus (even after vaccination). Furthermore, we do not know what the status of the spread of the virus will be at the time of the start of vaccinations (with the relative risks of transmission). The Committee therefore believes that the criteria for identifying the categories or groups to be given priority for vaccination can for now only be general, to be modulated and applied within the various possible contexts, revisable with continuous adaptation also regarding ethical reflection, according to new experiences and scientific knowledge[17].

The ICB calls for this specific allocation to individual groups at different phases[18] to be determined, according to the criteria recommended above, on the

[15] The risk /benefit balance must also be referred to the possible side effects on the basis of the trials and the safety and efficacy outcomes in relation to the characteristics of those being tested: e.g. minors, elderly people, pregnant women, excluded from trials could constitute higher risk groups, as the specific side effects are not known.

[16] As highlighted by the ICB in the Opinion *Covid-19: public health, individual freedom, social solidarity*, 28 May 2020.

[17] World Health Organization (WHO), *Concept for Fair Access and Equitable Allocation of COVID-19 Health Products*. Final working version, 10 October 2020; WHO, *SAGE Values Framework for the Allocation and Prioritization of COVID-19 Vaccination*, 14 September 2020; WHO, *Coronavirus Disease (COVID-19): Vaccine Access and Allocation,* 2020; WHO, *Ethics and Covid 19: Resource Allocation and Priority Setting*, 2020; National Academies of Sciences, *Engineering and Medicine, Framework for Equitable Allocation of COVID-19 Vaccine*, The National Academies Press, Washington DC 2020.

[18] As of now and in general, among the various groups of citizens to be vaccinated, it is possible to consider as priority groups, in the continuation of serious pandemic events, the following: = People who in carrying out their work are in direct contact with Covid-19 patients, exposed to direct and indirect risks (doctors, nurses, health workers, auxiliary personnel, ambulance drivers, researchers, etc.); = Persons indispensable for the maintenance of essential services of public utility and necessary for the maintenance of public order and social functions (army, police,

basis of multidisciplinary expertise (doctors, bioethicists, lawyers, patient representatives, sociologists, statisticians, etc.) so that it is ~~It is~~ possible to assess the actual situation at the moment, in particular with reference to the needs of individual Regions, epidemiological dynamics, its impact on different sections of the population, the quality and quantity of available vaccine, the risks/benefits balance as stated above.

At the international level, coordination must also be provided for the deployment of vaccines, in the awareness that no country will be completely protected if the world is not protected. In this sense it will also be necessary to reflect on the duty of each country to donate doses and in what proportion to low-income countries[19]. And with regard to the latter, also to be considered are vaccine storage and the organization for their deployment to the population which have high costs and therefore necessary financial aid must be provided[20].

The different countries of the world in pandemic events like this will generally have to face the legal and ethical problem of making vaccination compulsory. This problem also arises in our country.

With regard to the importance of vaccinations in the face of situations which endanger the health of the country, the Committee has already had occasion to underline in its motion *The importance of immunisation* (24 April 2015) that vaccines constitute one of the most effective preventive measures, having a risk/benefit ratio which is among the highest with regard to drugs currently available, as well as underlining how vaccination is of value not only to health but it also has an extremely important intrinsic ethical value.

In general, the Committee always advocates respect for the principle that no one should undergo medical treatment against their will and, therefore, tendentially it prefers spontaneous adhesion to authoritative imposition, where diffusion of a sense of individual responsibility and the overall conditions of the spread of the pandemic permit. However, the Committee is also aware that forms of mandatory health treatment, such as vaccines, are recognized by law in our legal system and are ethically legitimate in case of necessity and threat to individual and collective health.

Therefore, in the case of this pandemic, which puts individual and public life and health at risk, even more so if no treatment is available, the Committee considers it ethically necessary for all efforts to be made to achieve and maintain optimal vaccination coverage through conscious adhesion. In the event that the seriousness of the health situation and the long-term unsustainability of the limitations on social and economic activities persist, the Committee also believes that - in the face of a vaccine that is validated and approved by the competent authorities – its being made mandatory should not be excluded, especially for professional groups that are at risk of infection and transmission of viruses. This obligation should be discussed within the professional associations themselves and should be withdrawn if there is no longer a significant danger to the community.

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transport, teachers, food suppliers, entrepreneurs, etc.); = Elderly, but also adults and minors, with serious vulnerabilities and with a high risk of foreseeable deterioration of health conditions if they become infected with the Sars-Cov-2 virus.

[19] *V. retro* n. 10 about Covax.

[20] "El Pais" recently reported that the Mexican government announced that it cannot purchase or receive the vaccine because it does not have the necessary infrastructure to store the doses and distribute them.

An indispensable premise, for the planning of vaccine deployment to be ensued by a desirable acceptance of vaccination by citizens, is the provision of adequate information and communication. Public communication should be transparent, clear, understandable, consistent and coherent, and based on evidence and up to date scientific data. Public communication, that is not propaganda and is non-paternalistic, should leave no room for uncertainty and indicate the expected benefits and risks. The expected benefits refer to the immunity attainable, the degree of immunity and its duration, how long the virus protection is foreseeable to last, to prevention or reduction of transmission and protection against possible re-infection. Potential risks relate to side effects and adverse reactions.

Given the speed imposed by our urgent need, our knowledge of the risks and benefits of vaccines may be incomplete. Even with these limitations, it is necessary to know, for each type of proposed vaccine, all the data available, from those on efficacy to those on risk, this data must be verified, updated and communicated promptly. It is essential to establish that 'therapeutic alliance' in which the physician, with the necessary expertise and knowledge to properly inform about the risks and benefits of treatments and drugs, has the responsibility for providing information on the health of the patient and the community as a whole.

A further purpose of communication is to avoid creating and spreading unrealistic expectations as well as the promotion of preventive behaviours which presumably will still have to be continued in the first period of vaccination.

There are many possible strategies generally recommended for communication in the field of health, all aimed at winning the trust of citizens: engaging the population through eminent public figures, mass media campaigns, behaviour monitoring strategies, logistical facilities for vaccination. The Committee believes that the strategies must be planned and studied specifically by experts in the sector (in the field of communication sciences, behavioural sciences, etc.) from an interdisciplinary perspective; underlining the ethical priority of providing adequate information to citizens to increase critical awareness and the importance of appropriately training the health personnel who will be in contact with citizens and who will have to respond to their doubts and hesitancy (considering vaccination refusal and the so-called 'vaccination hesitancy' phenomenon)[21].

The dissemination of information must extend throughout the whole national territory, also with 'inclusive' information and education materials, that do not exclude anyone from communication initiatives (also considering people from other countries and with difficulties in understanding our language and people with disabilities, such as for example the blind and the deaf, etc.). A public discussion on the issue should be promoted through dialogue between experts and citizens (in line with so-called *'public engagement'*), paying specific attention to the concerns of the population.

[21] Vaccination hesitancy, differs from those radical positions held by those opposed to any kind of vaccine (no vax), today this hesitancy indicated in our country in a percentage higher than 30%, is a complex phenomenon, closely connected to the individual and social perception of risk related to Covid-19 vaccination also given the conflicting information received during the production of the vaccine itself. This phenomenon of indecision can result in a postponement of the decision to get vaccinated and go as far as vaccination refusal. On this phenomenon see National Academies of Sciences, Engineering, and Medicine, *Framework for Equitable Allocation of COVID-19 Vaccine*, cit.; WHO, *Improving Vaccination Demand and Addressing Hesitancy*, 17 June 2020.

Particular attention should also be paid to identifying sources of disinformation and false information (to avoid the spread of fake news), through careful monitoring.

In addition, adequate informed consent, possibly uniform throughout the national territory, must be prepared in the vaccination facilities, bearing complete, clear and understandable information on the type of vaccination and on safety and efficacy, benefits and risks. This information with the above requirements is essential for citizens/patients in order to make informed, autonomous, responsible and supportive choices.

Constant ad hoc monitoring of any adverse effects must also be arranged, given both the novelty of the vaccine (some RNA or DNA vaccines represent a new modality in vaccination methodology), and the quantity of doses administered. Long term monitoring must be planned and adequate compensation coverage must be ensured for any damage.

5. Recommendations

The Committee recommends:

In general:

= that vaccinations are to be considered in society as one of the most effective preventive measures, with a particularly positive risk/benefit ratio, recognizing not only their value as regards health but also their particularly important intrinsic ethical value.

With regard to research:

= that the trials, despite the pressure to accelerate, must respect the usual scientific, ethical and legal criteria, in order to guarantee quality, safety and efficacy, respecting the balance between expected benefits and potential risks both with reference to individuals and to society;

= that the sharing of research results and scientific knowledge be promoted, with a view to an international collaboration of our country, with a specific commitment to contributing to helping low-income countries;

= that research continues to compare approved vaccines and establish a comparative benefit-risk ratio.

With regard to production and costs:

= that the production rules allow the results of the research to be made available to all the countries of the world, that the vaccine be considered a 'common good' and that politics takes on the task of implementing control measures in the production and deployment of the vaccine, based on the ethical and constitutional principles of equality, equity, justice, responsibility and solidarity;

= that the Government follows the development of the most promising vaccines and promptly implements an approach to negotiation in the various fora with the Governments of the countries concerned, in order to make a pact that

simultaneously allows the creation and production of vaccines and guarantees their equitable distribution to citizens;

= that the social responsibility of pharmaceutical companies is to be highlighted and the obligation to swiftly make available the data and results of vaccine trials because strategies and priorities can be formulated only by knowing them in a clear and comprehensive manner.

With regard to distribution:

= that the vaccination program should be planned in advance so as not to be faced with structural and organizational deficiencies, in particular in order to avoid available doses of vaccine from remaining in storage for not having prepared in advance the necessary measures to ensure their rapid distribution, and clearly identifying the professional skills necessary to administer the vaccine;

= that, especially in the presence of limited resources, the distribution of vaccines must respect the ethical and constitutional principles of equality and equity, balancing direct and indirect risks, paying specific attention to avoiding a negative impact on those who are most vulnerable on a bio-psychic-social level, and that vaccine deployment meets transparent, motivated and reasonable criteria;

= that for this purpose discussion should be promoted involving multidisciplinary expertise (doctors, sociologists, bioethicists, jurists, patient representatives, etc.) regarding the concrete situation at the moment of the availability of vaccines (the needs of individual regions, the epidemiological dynamics and its impact on the different population groups, the quality and quantity of vaccine available, attention to the methods of storage and distribution of vaccines) and that interdisciplinary and dynamic guidelines are to be drawn up based on accurate scientific assessment which takes ethical reflection into account, at every moment.

With regard to obligation:

= that the principle advocating that no one should undergo medical treatment against their will should be respected, preferring spontaneous adhesion to authoritative imposition, where diffusion of the sense of individual responsibility and the overall conditions of the spread of the pandemic permit;

= that, in the event that the seriousness of the health situation and the long-term unsustainability of restrictions on social and economic activities persist, mandatory vaccination should not be excluded, especially for professional groups that are at risk of infection and transmission of viruses; this obligation must be withdrawn if there is no longer a significant danger to the community.

With regard to information:

= that an adequate, accurate, transparent and coherent information campaign for citizens should be promoted, for a correct understanding of the individual and social meaning of vaccinations, specifying the risks and benefits, in order to increase spontaneous adhesion and participation and create a climate of trust in health and in political institutions;

= that the benefits and limitations of the vaccination should be clearly explained to citizens, underlining that vaccines do not replace prevention by

means of other measures aimed at ensuring containment of the spread and protection against the virus;

= that vaccination refusal and hesitancy should be taken into consideration, and specific information initiatives planned in order to respond to the concerns expressed by citizens and provide for the monitoring of false information and disinformation;

= that careful monitoring of the application of vaccines is to be provided, taking into account in particular that some RNA or DNA vaccines represent a new modality in vaccination methodology; monitoring must be scheduled in the long term and adequate coverage must be ensured for the compensation of any adverse events.

Finally, the Committee recommends:

= that the State adopts, at the same time, all the other economic and social policies necessary to combat the pandemic as a whole.