

*Presidenza del Consiglio dei Ministri*



## **MOTION**

### **VACCINATION URGENCY: BIOETHICAL ASPECTS**

**12 March 2021**

## 1. Premise.

The Italian Committee for Bioethics (ICB) has intervened on many bioethical aspects concerning the Covid-19 pandemic and in particular it published an opinion on the ethical aspects of vaccination (*Vaccines and Covid-19: ethical aspects on research, cost and distribution*, 27 November 2020), shortly before the start of the vaccine deployment plan. In the meantime, the vaccination campaign has begun.

At present, the health situation in our country, as in many other countries in Europe and the world, is worsening due to the spread of variants that are difficult to contain and the wait for vaccines to become available for everyone. The spread of infections continues with the adoption, based on the epidemiological situation, of more or less restrictive measures, which have inevitable consequences on an economic, social, educational, psychological level. The number of deaths has now surpassed the 100,000 threshold. In these conditions, particularly in the absence of specific treatments of proven efficacy, vaccines represent the main strategy at our disposal to combat the pandemic. Therefore, any delay in mass vaccination may result in the loss of numerous lives.

## 2. The vaccination plan and distribution by categories.

In the light of the Covid-19 Vaccination Plan, subject to continuous updating<sup>1</sup>, the distribution of vaccines is outlined according to phases, categories and types. The diversity of available doses and the diversity of virus coverage effects of the different vaccines has already inevitably created disparity between those who have been vaccinated and those not yet vaccinated.

The ICB agrees with the defining of the Vaccination Plan in phases and categories, which establish an order of priority access to vaccines, according to analyzes based on the scientific studies available, assessing vulnerability<sup>2</sup>, in relation to pathologies, having more or less serious connotations, age, exposure to the virus, with reference to places and activities at highest risk (e.g. the teaching and non-teaching staff in schools and universities, the Armed Forces, Police and public rescue services, penitentiary services, and other residential communities listed as 'social-health communities, civil communities, religious communities'). Among the additions made to the Plan, the ICB certainly endorses: "the vaccination of cohabitants and caregivers who provide continuous assistance free of charge or those in contact with the severely disabled"; and the vaccination of parents / guardians / custodians "in the case of minors who meet the definition of extremely vulnerable and who cannot be vaccinated due to lack of vaccines suitable for their age group".

However, at the moment the phases of the National Plan (carried out at different times in the different Regions) are proceeding very slowly<sup>3</sup>. In view of

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<sup>1</sup> *Vaccinazione anti-Sars-Cov-2/Covid-19. Raccomandazioni ad interim sui gruppi target della vaccinazione anti-Sars-Cov-2-/Covid-19*, 10 March 2021. The previous one was issued by the Government in January 2021.

<sup>2</sup> Vulnerability is a concept and a principle in bioethics outlined in numerous documents: see *The Barcelona Declaration* (1995), Unesco, International Bioethics Committee, *Report of the IBC on the Principle of Respect for Human Vulnerability and Personal Integrity* (2013). Vulnerability includes medical, psychological and social dimensions.

<sup>3</sup> Phase 1 is still in progress in some Regions (healthcare professionals and social and health workers, staff and the guests of residential facilities for the elderly, the elderly over 80), especially as regards home vaccinations.

further vaccination plans related to the evolving situation (virus mutations, availability of new vaccines, increase in available doses), the ICB considers it useful to highlight some shortcomings which it hopes can be remedied.

With reference to equity of access, the ICB notes:

= Phase 1 of the vaccination for the elderly over 80 years of age (still being performed) has raised the problem in some Regions of the booking which can only be made online or by sms, for population groups which often lack the tools and skills to carry out the procedures.

= Phase 2 (category 1 and category 4)<sup>4</sup> relating to patients suffering from particular pathologies that expose them to greater clinical risks will require a considerable organizational and personal effort for already frail patients in order to obtain the certification of belonging to groups affected by diseases or clinically extremely vulnerable.

= The application of the same principles is complex with regard to identifying the range of "other priority categories regardless of age and pathology" and 'places of residential communities' (socio-sanitary, civil, religious) with the risk of different regional approaches as in fact is already occurring, as well as abuses also in the possible extension of eligibility to professional categories.

= Particular attention must be paid to informing citizens, so that everyone can consciously adhere to the vaccination campaign. The possibility of proceeding "in parallel" in the use of available vaccines<sup>5</sup> risks, if not clarified in the communication to citizens, creating suspicions of inequalities in those who have been vaccinated and those who are waiting to be vaccinated. The diversity of composition, efficacy and probable duration of the protection of the vaccines given market authorization (within the limits of the knowledge currently available) and the impossibility for citizens to choose them should also be considered.

= It is also certain that to give everyone the opportunity to get vaccinated and avoid inequalities - in order to achieve community immunity (so-called herd immunity) - a further effort will have to be made in applying the Vaccination Plan to those categories of people who for social, economic and cultural reasons are more exposed to the risk of contagion, but are not able to easily follow the administrative procedures to access the vaccine.

The ICB recommends careful monitoring of the side effects of vaccines (vaccine-vigilance) and the sharing of data on an international level, clarified in the communication to citizens. It also recommends that trials should continue as swiftly as possible and in the most shared manner, given the mutability of the virus and the fact that there are population groups, such as pregnant women and children / adolescents under 16, who have not been subjected to trials. It is essential for trials to proceed for these groups, both because contagion is increasing even in children and adolescents (with viral variants), and so as to protect their health and ensure a 'normal' life considering that fact that the pandemic has a strong psycho-social impact on them. The condition of pregnant women is a particularly delicate one for which the extrapolation of data is required in order to verify the basic conditions of safety and efficacy of the vaccines.

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<sup>4</sup> Category 1 refers to the most seriously ill and category 4 includes patients with the same pathologies, but in a less severe form.

<sup>5</sup> E.g. with AstraZeneca, initially indicated for adults up to the age of 55, the limit then raised to 65 years, finally also for over 65s.

### 3. National uniformity.

Along with the difficulty of insufficient doses, we must add the serious problem of the absence of uniform and unambiguous criteria throughout the country (Article 3 and Article 117, paragraph 2, letter m, of the Constitution). An effective Vaccination Plan, leading to community immunity as early as possible, must presuppose careful and sound organization and uniform criteria throughout the national territory, and meet criteria of justice and equity<sup>6</sup>, without having significant margins of discretion at the local level, which should only be entrusted with its operational implementation.

On the other hand, organization regarding the distribution of vaccines varies from region to region. At the moment the coordination of the various regional implementations of the vaccination campaign seems to be insufficient, resulting in misalignment. These different modalities create further serious discrimination. In the previous Vaccination Plan of January 2021, category 6 indicated "other essential services" that the Regions have interpreted each in a different way, indicating and giving the priority in vaccination to different categories (lawyers, judges, journalists, etc.), thereby creating ethically relevant discrimination. Simultaneously to removal of the entry "other essential services", from the new Vaccination Plan of March 2021, the Government gave a peremptory warning to the Regions to avoid leaping ahead and to adhere to the vaccination schedule based on age and health conditions.

The Regions should adapt to the decisions taken at central level, without considering their autonomy undermined, respecting the principle of subsidiarity and of loyal cooperation since these decisions involve international prophylaxis, security and public safety (Article 120, paragraph 2, of the Constitution), having a strong impact on the social life of the country and an ethical value. It is the right of all citizens and a fundamental ethical principle to be treated in the same way, according to the principles of equality, fairness, impartiality and transparency, as already indicated by the ICB<sup>7</sup>.

### 4. The production of vaccines.

The ICB is aware that the possibility of speeding up vaccination and preventing healthcare discrimination is conditioned primarily by the number of vaccine doses available. But this is a cause on which we can intervene by means of different procurement policies and an increase in production<sup>8</sup>.

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<sup>6</sup> The Constitutional Court has repeatedly reiterated that in matters of "international prophylaxis" only the State has exclusive competence. The principle of loyal cooperation between the State and the Regions is reaffirmed and the Government can take the place of regional bodies, in the event of serious threats to safety and in particular for the protection of the essential levels of benefits concerning civil and social rights (see Constitutional Court, February 25, 2021).

<sup>7</sup> Italian Committee for Bioethics (ICB), *Vaccines and Covid-19: ethical aspects on respect, cost and distribution*, 27 November 2020

<sup>8</sup> In consideration of the number of inhabitants, Italy should have received 13.4% of the doses purchased by the European Commission. Then a joint action of the 27 countries was decided in order to have greater bargaining power (*Agreement with Member States on procuring Covid 19 vaccine*). A negotiation that could not work as the doses received and distributed were not sufficient for the needs of the countries. Furthermore, contractual guarantees for delivery obligations are also lacking, given that the wording used is that the pharmaceutical company "will do everything possible", but no penalty has been established in the event of non-supply.

The European strategy has prohibited parallel purchasing by Member States. However, Germany, France and, more recently, Austria and other Eastern European countries, faced with the shortage of vaccines, have deemed it necessary to proceed also independently with the purchase and production of vaccines. A path on which no obstacles should be placed and it would be desirable for Italy to contribute more incisively to the European project for the common management of the vaccination emergency and the right to health within an ethical and legal vision of solidarity<sup>9</sup>. It must not be forgotten that public health is at stake and that the vaccine is a 'common good'.

Increasing the companies available to produce anti-Covid vaccines in our country is therefore appropriate.

Italy already has the technological capability to contribute to the vaccine manufacturing chain, which can be further enhanced with public funds; regulatory procedures must be identified to reduce bureaucratic complexity, while maintaining the necessary safety levels, and collaborations must be encouraged with companies involved in this sector in the various countries<sup>10</sup>.

The ICB considers it essential for drug companies to recognize their social responsibility in this serious pandemic crisis, also considering the huge economic contribution made by the public sector. Given that local production of vaccines cannot be achieved immediately, a process of development and adaptation of our companies' skills is desirable in collaboration with the multinational vaccine manufacturers, in order to allow our country to progressively start its own production.

Italy cannot therefore forgo the production of vaccines, considering the size of its population and the fact that we do not know how long the duration of vaccine-induced protection will last, we do not know if an annual vaccination will be necessary, we cannot ignore the moral obligation of contributing to vaccination in low-income countries and, finally, we do not know the effect in the coming years of virus variants that may not be sensitive to the action of vaccines<sup>11</sup>. The scarcity of vaccines today points to the question of short and long-term "preparedness"<sup>12</sup> the bioethical significance of which the ICB has already drawn attention to in its previous opinions on Covid: vaccination will probably need to be given annually. It is necessary to look to the future. As long as the virus continues to circulate around the world, we are all at risk, because globalization favours the spread of variants, which could require the production of new vaccines or revision of existing ones. It should therefore be considered that these would be strategic investments also in the long term.

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<sup>9</sup> See: UNESCO, International Bioethics Committee (IBC) and World Commission on the Ethics of Scientific Knowledge and Technology (COMEST), Joint Statement, *Call for Global Vaccines Equity and Solidarity*, 10 February 2021; The World Health Federation of Public Health Associations (WFPHA) *Statement. The Global Civil Society Claims for Equitable Access to Vaccines against Covid-19*, 2021.

<sup>10</sup> E.g. Pantheon Thermo Fisher, a multinational drug company, has signed a letter of intent with the Italian government for the production of a vaccine in our country. Some Italian companies have been contacted for the production of the Sputnik vaccine in our country. In addition, the all-Italian ReiThera vaccine could go into production in June (*Repubblica*, 13 March 2021).

<sup>11</sup> As happens in the case of the AstraZeneca vaccine with regard to the "South African" variant.

<sup>12</sup> Known in English language health literature as "preparedness" which it is not only an organizational phenomenon, but it has a political dimension.

## 5. Organization<sup>13</sup>.

Given the seriousness of the risks associated with the slow pace of vaccinations, the ICB intervenes to urge the Authorities to improve organization in the deployment of vaccines. The ethical principles of justice and equity in access to vaccines for the protection of health can only be achieved with better and more efficient organization.

To this end, it may be appropriate to provide other and more effective interventions on the domestic front in the context of preparedness: recruitment of health personnel, adequate supply of doses, vaccine doses administered 7 days a week, a greater number of vaccination sites (e.g. the sites already used for screening, pharmacies, companies and industrial districts, gyms, parking lots), greater ease of booking, easier physical access to the vaccination site, especially for the elderly, who cannot always count on the help of the family; a shorter wait for home vaccination, which can at least be partially solved with the help of family doctors, paediatricians of free choice and the voluntary sector. In addition, vaccination in the workplace could be encouraged, giving priority to the sectors and individual jobs most exposed to the risk of contagion. It would also be appropriate to reach in a widespread manner small mountain towns and isolated villages, where larger facilities have difficulties working, also by making use of the civil protection (army and volunteers).

## 6. Transparency.

There is an absolute need for comprehensive, clear and continuous information, as already recommended by the ICB<sup>14</sup>.

To maintain citizens' trust, it is necessary to make public all the data which enables an understanding of what is happening (e. g. the numbers of regional deaths compared to residents, mortality linked to causes, etc.). Therefore, the Committee recommends the publication, respecting the privacy of those concerned, of all data on the incidence of Covid-19 which may prove useful to understand and counter what is happening and fight against the pandemic.

The correctness and completeness of the information is of bioethical importance for the protection of the exercise of enforceable rights, the protection of life, individual health and public health.

The information must, therefore, be adequately disseminated throughout the territory, accessible and understandable for every citizen, and also spread through local medical facilities (e. g. through dedicated websites used locally for providing information to citizens on preventive screening)<sup>15</sup>.

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The draft was drawn up by Profs. Lorenzo d'Avack, Silvio Garattini and Laura Palazzani, with contributions from Profs: Salvatore Amato, Luisella Battaglia,

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<sup>13</sup> While the text of the motion is being published, the plan of Commissioner Lt. Gen. Figliuolo has been announced, with the operational guidelines of the vaccination campaign, which also addresses various critical issues identified by the Committee.

<sup>14</sup> ICB, *Vaccines and Covid-19*, cit.

<sup>15</sup> In the current moment of serious public health crisis, the daily information given by the mass media plays an important role, which deserves special consideration, which the ICB reserves the right to address at another time

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The discussion was integrated with the valuable contribution provided by the hearing of Dr. Nicola Magrini, Director General of the Italian Medicines Agency (AIFA).

The Motion was approved in the plenary session on 12 March 2021 by Profs: Salvatore Amato, Luisella Battaglia, Stefano Canestrari, Carlo Casonato, Antonio Da Re, Lorenzo d'Avack, Riccardo Di Segni, Mariapia Garavaglia, Marianna Gensabella, Assunta Morresi, Laura Palazzani, Tamar Pitch, Lucio Romano, Monica Toraldo di Francia, Grazia Zuffa.

Prof. Maurizio Mori abstained.

Despite their not having the right to vote assent was given by: 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.

Profs: Bruno Dallapiccola, Carlo Caltagirone, Mario De Curtis, Cinzia Caporale, Silvio Garattini, Luca Savarino, Massimo Sargiacomo, Lucetta Scaraffia, absent at the time of voting, subsequently assented.

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; Prof. Paola Di Giulio, the delegate for the President of the Superior Health Council, absent from the session, subsequently assented.