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- Ethics Committee Members

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Position of the Inserm Ethics Committee on COVID Vaccines Use

With the imminent arrival of the vaccines that represent our best short-term hope of controlling the COVID pandemic, the Inserm Ethics Committee (IEC) wishes to clarify its position in the debate that is currently raging in French society. A society whose doubts appear to have reached unprecedented levels. Indeed, while there is no question that safe and effective vaccines need to be developed as rapidly as possible, the urgency of the situation cannot justify the disregard of science and ethics – and what often connects the two.

Developing and rolling out one or more COVID-19 vaccines within remarkably short timescales is certainly a memorable scientific feat. Not only in terms of controlling this pandemic, but also in terms of implementing new therapeutic innovation platforms that could be useful now and in future epidemics. As at November 2020, less than one year after this novel virus emerged, there are no fewer than 11 vaccines in phase 3 clinical trials, with highly encouraging interim data for three of them. In parallel, consultation of the clinicaltrials.gov website lists a total of 1,239 registered COVID-19 clinical trials, 133 of which on vaccines.

The IEC wishes to stress the importance of:

- seeking and ensuring the transparency, impartiality, clarity and timely publication of information regarding the clinical trials, by establishing mechanisms to clarify, publish and better regulate conflicts of interest, without being limited to those that concern relations with pharmaceutical companies;
- making sure that this information, especially the provisions to ensure the safety and efficacy of products of research, is available and accessible to everyone: an essential condition in encouraging adherence to a national vaccination policy.

There are many obstacles to ensuring fair access to the products of SARS-CoV-2 research (particularly vaccines), the nature of which can be:

- technical and/or scientific: such as the confirmation of efficacy and safety; the capacity to produce and distribute the vaccines, the capacity to manage the cold chain; the qualification of the personnel; the costs of the entire process;
- societal: because the current environment is contaminated by the denial of scientific progress in vaccination; it is tainted by fake news, by political mistrust related to the countries of origin of the vaccines;
- ethical: in terms of guaranteeing that everyone has access to the products developed and the scientific data concerning them.

Likewise, the administration of the vaccines, which forms part of the vaccination strategy, remains a core question and also a source of suspicion. Then there is the number of vaccine batches that will of course be limited in the beginning, with priority assigned on a basis that will be clearly defined.

Whatever the stumbling blocks to the deployment of effective vaccination and whatever the reservations expressed, it is essential to remember that the protective benefits ripple out beyond the individual recipient of a vaccine to include those around him or her and, in turn, society as a whole. That is also why vaccination is ethical.

In its recent memo, entitled "Rethinking Health Innovation: Towards a Plural Ethical Approach" (<https://www.hal.inserm.fr/inserm-02996655v1>), the IEC offers an analysis of what the COVID-19 crisis has revealed in terms of health innovation. Among its numerous recommendations, the IEC "encourages the research community and health players to integrate the ethical questioning approach throughout the process that links research work and innovation developments".

The IEC also calls for reflection "on the place of public research and its connection with the private market sector in the field of health innovations." This brings us to the very heart of the debate because in terms of COVID vaccine innovations, the considerable financial resources allocated to research by the various countries have certainly enabled the rapid development of innovative vaccine approaches. However, entrusting the final phases of their development to a private market sector may create dissonance between the objectives of financial gain and public health, and constitute one of the reasons behind the growing mistrust observed in France.

What can be done to regain trust? First of all, let it be said that attempting to regain the trust of those who have opted to systematically oppose therapeutic innovation from an ideological standpoint is a waste of time. Therefore, we need to focus on those who have legitimate questions, questions that scientists have a duty to answer with clarity and precision. Each individual has a right to know the nature and utility of the ingredients used in the vaccines, the type of quality certification required for the sites producing the vaccines, the specific characteristics of the trial populations and their follow-up...

Therefore we must remember that the public authorities – through their structures that control the quality of marketed products and through the wealth of scientific expertise of their public research institutions – will have the capacity to guarantee the safety of these vaccines, insofar as the interests of the various stakeholders will be publicly and openly declared. And also that, thanks to a very generous healthcare system, the public authorities offer each citizen the possibility to get vaccinated free of charge, which many other countries do not. Finally, we need to encourage the public authorities to take back control of therapeutic innovation through a structure that federates the various endeavors, within which the public and private structures would anticipate new needs in terms of research on drugs and in terms of the process of producing those drugs in France.

It is through these responsible ethical and scientific initiatives that we could still regain this trust. Trust that is essential to the deployment of a major public health program to control the current pandemic. And trust that is essential to help free many French citizens from the great uncertainty generated by that pandemic.