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Vaccination against Covid-19: for hope to take shape!

Press release from the French National Academy of Medicine

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While the second wave of Covid-19 severely affects the European continent, vaccination strategies against SARS-CoV-2 have been presented by the European Commission (EC), outlining for the first time the conditions under which a safe and effective vaccine could be made available to Member States [1]. The objective was twofold: (i) to ensure a timely access to vaccines while leading the global solidarity effort; (ii) to adapt the EU regulatory framework to the emergency situation in order to speed up the development, authorization and availability of vaccines, in compliance with quality, safety and efficacy standards.

Meanwhile, the proliferation of early purchase contracts is fueling the competition between vaccine producers and generating announcement effects. On November 9, the US laboratory Pfizer and its German partner BioNTech claimed 90% efficacy for their BNT162b2 candidate vaccine after 94 cases of Covid-19 occurred among participants in the randomized trial. Two days later, the Russian research institute Gamaleya declared an efficacy rate of 92% for its Sputnik V vaccine. Despite a resounding media echo, these preliminary data have not yet been backed up by published and controllable scientific data.

The EC, which had already reserved 300 million doses of the candidate vaccine at Sanofi-GSK, 400 million doses at AstraZeneca, 225 million doses at CureVac, 200 million doses at Johnson & Johnson and 80 million doses at Moderna, announced on November 11 that it had reached an agreement to supply 200 million doses of the Pfizer-BioNTech candidate vaccine with an option for a further 100 million doses. In total, these six agreements would make more than 1.5 billion doses of vaccine available for the entire European Union. Faced with this international scientific and commercial competition, exacerbated between companies whose candidate vaccines have reached phase 3 of development, the legitimate need to anticipate the implementation of a vaccination against Covid-19 in each of the Member States requires time for reflection.

The six agreements initiated by the EC correspond to first-generation vaccines developed on different platforms: recombinant protein (Sanofi-GSK), non-replicative viral vector (AstraZeneca, Johnson & Johnson), messenger RNA (CureVac, Moderna, Pfizer-BioNTech). Despite the interim results of already published preclinical and clinical studies, the accelerated development process for pandemic vaccines does not yet allow neither the level and duration of protection, including by age group, nor their medium- and long-term safety to be prejudged.

Moreover, the comparison between these candidate vaccines is difficult, as the efficacy studies were conducted separately and according to different criteria. In order to define a

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national immunization strategy, it is essential that several crucial questions be clarified, concerning:

- the clinical efficacy, in terms of morbidity and mortality, vaccine safety, especially in the elderly and people with co-morbidities, which should be considered a priority [2];

- the duration of vaccine-induced protection and the need for booster doses;

- the epidemiological impact potentially linked to reduced transmission;

- the constraints imposed on the storage, distribution and administration of vaccines given their thermostability.

While the European Medicines Agency declares itself ready to give a favorable agreement on a first Covid vaccine by the end of the year, aware that only the implementation of a global vaccination program will restore a pre-pandemic health situation, the **French National Academy of Medicine** urges the health authorities to define a safe and effective vaccination strategy including:

- a vaccination plan detailing the logistics organization for the distribution and administration of the vaccine and the human resources to be mobilized;

- a strong involvement of professionals from the private sector in the national vaccination campaign and in the organization of collective immunization sessions;

- an ethical and operational definition of the priority categories of people for vaccination [3];

- a recall protocol when the vaccination schedule requires the administration of two doses;

- a dedicated pharmacovigilance system to identify any possible side effect not detected during Phase 3 clinical trials;

- a comprehensive information and communication plan for the general public and healthcare professionals, setting out the objectives, procedures and results of the vaccination program in a simple and transparent manner;

- a regular evaluation of the acceptability of the vaccine by the different categories of population targeted by the program, in particular healthcare professionals, including analysis of the arguments put forward for not being vaccinated.

In addition, **the National Academy of Medicine recommends**:

- to maintain and strengthen the individual and collective measures to combat SARS-CoV-2 transmission as long as the epidemiological indicators show its circulation;

- to adapt the initial vaccination strategy as scientific advances make it possible to incorporate improvements such as heterologous booster shots to maintain or amplify the immune responses induced by the primary vaccination, or the use of mucosal vaccines to induce early protection against infection.

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References

[1] European Commission: Communication on the EU strategy for vaccines against Covid-19, COM 2020 (245), 17 June 2020

[2] Haute autorité de santé: Framing note on Covid-19 vaccination strategy, 23 July 2020

[3] CARE – Comité scientifique COVID-19 – Comité Vaccin COVID-19. Vaccines against SARS-CoV-2, a vaccination strategy, 9 July 2020

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