

# Executive summary

The COVID-19 pandemic is causing enormous human and economic costs in Spain and worldwide. An effective and safe vaccine in the short term to be used in a population strategy is essential to reduce the impact of the pandemic and restore the functioning of society.

The European Commission is leading the "EU Vaccine Strategy" for making COVID-19 vaccines available for all Member States of the European Union. Within this framework in which Spain actively participates, Advance Procurement Agreements (APA) with various pharmaceutical companies had been signed. At present, six APAs have been signed with the companies AstraZeneca / Oxford, SanofiGSK, Johnson & Johnson / Janssen and Pfizer / BioNTech, CureVac and Moderna / Lonza. Negotiations with Novavax are ongoing.

The vaccination strategy for Spain aims to reduce COVID-19 morbidity and mortality, taking into account the limited initial availability of vaccines and the evolution of knowledge about key aspects of this disease.

This document has been prepared with the information available at this time. It is intended to be a "living document" that will need to be updated as the knowledge of the candidate vaccines and those close to authorization increases, with the results of the clinical trials that are being carried out, the characteristics regarding logistics, storage and administration, as well as details on the immunity generated after the disease. For these purposes the Technical Working Group that has participated in the preparation of the strategy will continue to provide its support and advice to adapt or modify the proposal as new information or new events of relevance to the vaccination strategy become available.

The main pillars on which the vaccination strategy against COVID-19 is based are summarized below.

## 1. Epidemiology of COVID-19

In Spain, there is currently sustained community transmission. The estimated prevalence of IgG antibodies against SARS-CoV-2 was 5.2% in the third round of the seroprevalence study, in June 2020. The main risk factor identified for severe disease is age, as well as certain underlying diseases.

## 2. Development of vaccines

The current scientific evidence shows that neutralizing antibodies are generated as a result of SARSCoV-2 infection.

Estrategia de vacunación COVID-19 2 diciembre 2020 Grupo de trabajo técnico de vacunación COVID-19 10 As of November 10, 2020, 38 vaccines against the SARS-CoV-2 virus were under development in phase I of clinical trials, 14 in phase II and 11 in phase III. Six other vaccines from the Russian Federation and the Republic People's China had not completed phase III, and are being applied in restricted situations. There are different technological platforms producing different vaccines and some are not tested at international scale. Candidate vaccines can be divided into "traditional" (inactivated viruses), based on more recent strategies and already used in commercial vaccines (recombinant proteins and using viral vectors) and those that have never been widely used (DNA and RNA).

This document describes and analyzes the data of those vaccines that have published results and also those with a purchase agreement already signed, as well as those that with high probability a purchase agreement will be established as negotiations between European Commission and

pharmaceutical industries are ongoing. These are the vaccines from Moderna Inc (mRNA); Pfizer / BioNTech (mRNA); Oxford Vaccine Group / AstraZeneca (Chimpanzee Adenovirus); Janssen Vaccines & Prevention B.V./Johnson & Johnson (Adenovirus 26); Novavax (Nanoparticles with protein S) and Curevac (mRNA).

The vaccination generally consists of two doses and phase I and II clinical trials have shown an acceptable safety profile and the induction of neutralizing antibody response, even in the elderly, as well as cellular response. At this moment, there are no data on immunogenicity in some population groups (pregnant women, children, immunosuppressed), although this is the usual situation when a vaccine is authorized, since clinical experimentation in these particular groups usually starts when efficacy and safety of the vaccine has been already studied in other population groups. The clinical studies have not been designed to evaluate the role of immunity generated by vaccination in transmission, although some may induce sterilizing immunity. Some vaccines require very low storage and preservation temperatures.

All vaccines that are considered within the purchase agreement of the European Commission will be presented for authorization following the centralized procedure to the European Medicines Agency.

### 3. Prioritization of vaccination

The objective of vaccination is to prevent the disease and reduce its severity and mortality, in addition to reducing the impact of the pandemic on the healthcare system and the economy, especially protecting those groups with greater vulnerability.

Given that the first vaccines against COVID-19 will be available in limited quantity, that will gradually increase, it is necessary to establish the order of priority of the population groups to be vaccinated. An ethical framework where the principles of equality and dignity of rights, necessity, equity, protection of disabilities and minors, social benefit and reciprocity has been established. In addition, participation, transparency and accountability, importance of information and education are also considered, as well as the applicable legal norms and international recommendations.

Several stages have been described according to the estimated available vaccine doses. The population groups where prioritized for vaccination after evaluation of their risk of exposure, transmission and serious disease, as well as the socioeconomic impact of the pandemic. There is no authorized vaccine in the EU when the strategy has been developed. For this reason, the prioritization mentioned below could be modified depending on the indications, contraindications or precautions of administration finally included in the technical specifications of the authorized vaccines.

In a **first stage** where the quantity of vaccine doses available is limited, the following order of prioritization will be followed within this stage

1. Inmates and health and social health workers in elderly and disabled nursing homes. If necessary, vaccination will be prioritized in the most vulnerable ones (greater number of Estrategia de vacunación COVID-19 2 diciembre 2020 Grupo de trabajo técnico de vacunación COVID-19 11 inmates, less capacity to adopt prevention and control measures and / or those that have not had cases of COVID-19).
2. Front-line healthcare workers. If necessary, vaccination will be prioritized for those over 50 years of age or with high-risk conditions, those working in COVID-19 areas and in primary care.
3. Other health and social health workers.

4. People with disabilities who require intense support measures to develop their lives (large noninstitutionalized dependents).

Progressively, as more information becomes available, the population groups to be vaccinated will be added. Moreover, the simulation of current epidemiological situation in Spain on mathematical models and the impact of different scenarios, including vaccination of different population groups, may help in decision making of the vaccination strategy.

## 4. Logistics, supply and administration

Each licensed and purchased vaccine may have different storage requirements, so it is key to ensure that storage and distribution are carried out under optimal conditions to guarantee the quality of the vaccines throughout the process. It is essential to ensure the correct management of the vaccines.

Guides, protocols and information materials tailored for people in charge of the distribution and storage of vaccines, vaccination program managers and healthcare workers who administer the vaccines will be of great help. Training of all the staff involved is key for the proper development of the program.

Even though the available information regarding the vaccines that are being negotiated by the European Commission is limited, the key aspects of the logistics, distribution and administration of COVID-19 vaccines are reviewed. Example materials have been developed that will be adapted later to the real vaccines that are eventually authorized. Certain key points that must be considered in advance are highlighted in the examples.

The entire process will require full collaboration between public institutions and pharmaceutical companies in order to carry out an efficient distribution of the vaccines in an orderly manner. Communication flows should be previously defined.

It will be necessary to update the documentation as information on the quantity and characteristics of the vaccines are available. Staff training and planning for the reception and administration of the vaccines are essential aspects for the success of the vaccination strategy.

## 5. Communication

The vaccination strategy must include a communication strategy with the aim of creating a framework of truthfulness and transparency capable of responding to the doubts that may arise in relation to vaccination against COVID-19 in different population groups. The main principles that govern it are: truthfulness, transparency, participation, equity and evaluation.

Specific activities have been defined for providing adequate information to healthcare workers and the general population on main aspects regarding to vaccination against COVID-19 in the different stages of vaccine availability, as well as the evaluation of these activities.

A communication strategy should be developed and should start before the vaccine is available. It is considered important that it is preferably carried out by technical personnel and is focused on underlining the importance of citizen solidarity at the present time, specified in two fundamental premises. First, vaccine access is not only a right, but in order to make it fully effective, it is important to achieve group immunity, and this requires a high vaccination rate. Second, prioritizing the distribution of vaccines is an unavoidable requirement of the current moment of limited availability vaccines. This circumstance is obviously temporary but, as long as it occurs, it will be

essential to follow a prioritization strategy guided by the principle of necessity. Healthcare workers play a fundamental role in informing the public and offering accurate information on the safety of the vaccine.

In the first stage it is recommended to work on the following aspects:

- Prepare messages in relation to the accelerated development of vaccines and the regulatory mechanisms for their authorization and if this compromises their safety, the way in which the surveillance of safety and the impact of vaccination will be carried out, as well as the reasons why certain population groups are prioritized.
- Identify the concerns and needs of healthcare workers in the vaccination strategy through meetings with professional associations / scientific societies.
- Do not create false expectations regarding the start of the vaccination program against COVID-19. Depending on the authorization of the vaccines by the European Medicines Agency and the results of the clinical studies, the objective of the vaccination program will be established, as in any other vaccination program.
- Remember the importance of non-pharmacological measures in order to reduce the spread of the virus, regardless of whether a vaccine is available or not.
- Define the most appropriate channels to reach healthcare workers and the general population.

In addition, to work on communication aspects will be necessary once the vaccination starts.

## 6. Monitoring and evaluation of the vaccination

In order to monitor the vaccination strategy, it is essential to count on registries that guarantee that vaccination data is properly collected. These data will be useful for surveillance and follow-up activities. Furthermore, vaccination data will be necessary for the pharmacovigilance system to monitor and evaluate the safety of the vaccines that are being administered, and also for effectiveness studies. Finally, the acceptability of vaccination on the population will be monitored through specific studies on the reasons for trust or doubts on vaccination in the general population and in specific groups.

## 7. Next steps

- Continuously update the document with the new available evidence, especially with regard to any marketing authorization by the European Medicines Agency.
- Incorporate the new information and evidence that appear on the first available vaccines in the simulations carried out with mathematical models. This exercise will help to adjust the prioritization of population groups.
- Start with the training of vaccination staff and vaccination planning of the people who are going to be vaccinated, as well as the necessary materials (protocols, cards and other specific materials for each vaccine) in order to ensure the correct administration of the first available vaccines. • Develop a communication strategy with content to be updated to the stage of availability of vaccines against COVID-19. The purpose is to provide understandable information on the importance of vaccination (benefits and risks) to the general population and healthcare workers to ensure informed decisions. Test the COVID-19 vaccination registry with the autonomous communities, expand the development of the information system, design effectiveness studies and develop the indicators for the continuous evaluation of the strategy.

