



COVID-19 VACCINATION STRATEGY IN SPAIN

KEY POINTS

This document is under permanent revision according to the evolution and new information available on the infection by the novel coronavirus (SARS-CoV-2).

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1 Introduction

The COVID-19 pandemic is causing enormous human and economic costs in Spain and the world. Having an effective and safe vaccine available in the short term, which can be used for the population at large, will help to reduce the number of cases, hospitalizations and deaths by COVID-19 and will help us to gradually return to normal.

The development of such a vaccine, its acquisition and administration is an unprecedented challenge to the world. For this reason, the European Commission presented a strategy to speed up the development, manufacture and deployment of vaccines against COVID-19. The EU vaccine strategy aims to ensure the availability of quality, safe and effective vaccines in the European Union (EU) as well as an equal, rapid and equitable access to the available doses by all Member States and their citizens. This strategy ensures that the entire purchase and distribution process is conducted transparently and with equal standards of vaccine safety and efficacy among all Member States. Joint action at EU level is the safest, fastest and most efficient way to achieve these goals.

The Spanish Agency for Medicines and Healthcare Products (AEMPS) represents Spain in the body that makes decisions about every advance purchase process. This body monitors the development of vaccines and ensures transparency and good governance in the process of purchase and distribution. Within this framework, advance purchase agreements for vaccines have already been signed with five pharmaceutical companies: AstraZeneca/Oxford, Sanofi-GSK, Johnson & Johnson/Janssen, Pfizer/BioNTech and Curevac. Negotiations continue with Moderna/Lonza and Novavax. This is a broad portfolio of vaccines that will ensure that, if the authorization is granted, Europe and Spain will gradually have the necessary doses, at the same time, and for the entire population, so as to face this unprecedented situation.

The effort that the world's scientific community is making to achieve a safe and effective vaccine is unparalleled by any other before, and citizens should be aware that the vaccines that will eventually be used in the EU against COVID-19 will have the same levels of safety as any of those commonly used.

¹ <https://eur-lex.europa.eu/legal-content/ES/TXT/?qid=1597339415327&uri=CELEX:52020DC0245>

On October 15, 2020, the European Commission published a Communication on the preparation of COVID-19 vaccination strategies and vaccine deployment² which identifies key elements to be considered within national vaccination strategies.

This European Commission document and the recommendations of other international bodies have been taken into account for drawing up of the Vaccination Strategy for Spain³⁴. The main objective of the vaccination strategy is to reduce COVID-19 morbidity and mortality by vaccinating the population at large. Bearing in mind that the availability of vaccines will be progressive, it is necessary to establish the main lines that this vaccination strategy must follow, as well as the prioritization of different population groups.

The COVID-19 Vaccination Strategy in Spain has been devised with the information available at this moment and aims to be a live, agile and flexible document, which will be updated as knowledge increases on the results of the clinical trials being carried out with candidate vaccines, on the information related to the logistics, storage and administration requirements of the vaccines close to authorization, and on details about the immunity generated after the disease.

This is a country-wide strategy, which is driven by an ethical framework based on equity, with a solid technical base which will be coordinated on the basis of the common European framework, and it is born with the conviction that better acceptability results can be achieved if the vaccine is voluntary.

It should be noted that Spain has a great deal of experience in logistics, distribution and vaccination, both in systematic vaccination and in specific campaigns. Indeed, in the current flu vaccination campaign, in the context of a pandemic, vaccination levels have significantly increased in all territories.

² https://ec.europa.eu/health/sites/health/files/vaccination/docs/2020_strategies_deployment_en.pdf

³ <https://www.ecdc.europa.eu/sites/default/files/documents/Key-aspects-regarding-introduction-and-prioritisation-of-COVID-19-vaccination.pdf>

⁴ https://www.who.int/publications/i/item/WHO-2019-nCoV-Vaccine_deployment-2020.1

At the same time, lessons learned from the past 2009 influenza pandemic showed the importance of having an international regulatory framework that would strengthen global surveillance and response capacity, the inclusion of vaccines and antivirals in preparedness and response plans, or the development of stronger information systems. This experience ensures that the COVID-19 Vaccination Strategy can be successfully implemented.

The current document describes the main lines for establishing a COVID-19 Vaccination Strategy in Spain with the current knowledge, including the aspects described below.

2 Objectives of the strategy

The global objective of the COVID-19 vaccination strategy in Spain is to reduce the morbidity and mortality caused by this disease, protecting the most vulnerable groups through vaccination in a context of progressive vaccine availability.

There are four operational objectives:

1. To establish an order of priority of the population groups to be vaccinated, taking into account scientific, ethical, legal and economic criteria, in a context of progressive availability of vaccine doses. It is necessary to prioritize the protection of the most vulnerable groups and those for which our legal system has assumed a specific and reinforced duty of protection.
2. To arrange the fundamental aspects related to logistics, distribution and administration of the vaccines that will be available for Spain in the coming months.
3. To establish the priority lines for the monitoring and evaluation of the vaccination, including the coverage, safety and effectiveness of the vaccines, as well as their impact on the epidemiology of COVID-19, which will allow the strategy to be assessed and adjusted in order to achieve the maximum benefit for the population.
4. To arrange the key aspects for the development of a communication strategy aimed at health personnel and the general population, which will give access to adequate and truthful information, increasing the population's trust in the process of authorization and use of the vaccine(s), and ultimately achieving high coverage.

The main objective of the COVID-19 vaccination strategy in Spain is to reduce the morbidity and mortality caused by this disease through vaccination against COVID-19, in a context of progressive availability of doses, and protecting the most vulnerable groups

3 Governance of the strategy

The preparation of the COVID-19 Vaccination Strategy in Spain is a mandate from the plenary session of the Inter-territorial Council of the National Health System (CISNS), a collegiate health body in which the health councilors of the autonomous communities and cities and the Minister of Health participate.

On 9 September the CISNS plenary session approved a declaration of Coordinated Actions in the field of Public Health which agreed:

- The implementation of a common vaccination strategy for all territories, drawn up jointly taking into account the opinion of experts in bioethics and scientific societies, approved by the CISNS plenary session.
- The provision by the Autonomous Communities of the equipment, resources and materials necessary for the administration of the vaccines provided by the Ministry of Health.
- The creation of a COVID-19 State Vaccination Register by the Ministry of Health in collaboration with the autonomous communities and cities, which will be fed with information from the vaccine registers and information systems, or any other system with information of interest on the autonomous communities and cities.

To this end, a COVID-19 Vaccination Technical Working Group (GTV) was created, depending on the CISNS Programme and Registry of Vaccinations Report (or Vaccination Committee), coordinated by the Ministry of Health, and which includes eight members of the Committee itself, specialists from scientific societies, experts in bioethics, sociology and methodology, as well as experts from the Carlos III Health Institute, the Spanish Agency for Medicines and Healthcare Products (AEMPS), the Health Alerts and Emergencies Coordination Centre (CCAES) and the Ministry's Occupational Health and Vaccination Programmes areas.

The GTV has elaborated a document of *Basis for the Strategy of COVID 19 Vaccination in Spain*, validated by the Programme and Registry of Vaccinations Committee.

The CISNS Vaccine Committee and the GTV are the technical bodies that will review and update the Basis of the Strategy as new knowledge on the characteristics and availability of vaccines and the implementation of the Strategy advance.

In addition, with the aim of supporting inter-sectoral coordination and promoting the effective planning and implementation of the Vaccination Strategy in the various priority groups, an inter-ministerial advisory group will be set up with the participation of technical teams from the Second Vice-Presidency and the Ministry of Social Rights and 2030 Agenda, the Ministries of Territorial Policy and the Civil Service, Defense, Home Affairs, Inclusion, Social Security and Migration, Labour and Social Economy, Education and Vocational Training, Industry, Trade and Tourism and Agriculture, Fisheries and Food.

The Ministry of Health will acquire the corresponding doses for Spain within the framework of the European strategy. Once the availability of doses authorized and purchased by the Ministry of Health is known, the final prioritization of the vaccination of certain population groups and the allocation of doses to each of the Autonomous Communities will be agreed upon in the plenary session of the CISNS, after discussion in the Vaccines Committee and the Public Health Commission. The vaccines will be administered free of charge through the National Health System (SNS).

- **The COVID-19 Vaccination Strategy in Spain is based on the recommendations of the COVID-19 Vaccination Technical Working Group and the Vaccine Committee, and will be coordinated by the Inter-territorial Council of the National Health System (CISNS).**
- **The vaccines will be administered free of charge through the NHS.**

4 Development and availability of vaccines

Finding a safe and effective vaccine is a key element of the exit strategy from the pandemic. That is why an unprecedented collective effort is underway involving countries, institutions, researchers and companies around the world to make vaccines available at short notice.

Sixty-six days after the sequencing of the SARS-CoV-2 genome, a human was first injected with a candidate vaccine against the pandemic virus⁵.

At present, more than 250 different COVID-19 vaccine candidates⁶ are being developed worldwide, based on different technological platforms, ranging from the most common (inactivated viruses or purified protein sub-units of viruses), those based on more recent technologies and for which vaccines are already commercialized (replicative and non-replicative viral vectors), but also very new platforms that have never been commercialized until now (DNA and mRNA).

The Spanish government is also promoting research and production of vaccines, providing resources for the development of projects and programmes through the Carlos III Health Institute and the Spanish National Research Council (CSIC). There are currently 11 candidate vaccine projects.

The development of any vaccine covers different phases. Initially, an exploratory and pre-clinical phase is developed with studies on laboratory animals. Then, clinical trials in humans phase I, II and III are initiated to determine the optimal dose, explore initial safety and characterize the efficacy and safety profile. Finally, data are evaluated by the drug agencies, so that only if they prove to be effective and safe do the agencies grant marketing authorization and pharmacovigilance activities begin, which are maintained throughout the life cycle of the drug.

It is not yet known which of the more than 250 candidate projects will successfully go through pre-clinical and clinical studies until approval, nor when these vaccines will be available in sufficient quantities to allow their use in the population at large. For this reason, work is underway at the European level on a broad portfolio that includes vaccines from all platforms, thus maximizing the chances of having an effective and safe vaccine as soon as it becomes available and is authorized by the competent authorities.

The criteria for including vaccines in the portfolio include the solvency of the clinical development project and the consequent probability of being assessed for authorization and commercialization, the capacity and solvency of the company to manufacture it in a significant quantity, that can be produced in European territory or, for example, have the possibility of distributing vaccines as soon as they are authorized.

⁵ Callaway E. *The race for coronavirus vaccine*. Nature. April 2020. 580 no. 7805: 576-577. Available at: <https://doi.org/10.1038/d41586-020-01221-y> [accessed 10 November 2020]

⁶ https://vac-lshtm.shinyapps.io/ncov_vaccine_landscape/

At the moment, there are eleven vaccines on different platforms that have already started phase III of the clinical trials. Of these, five⁷ are in the European portfolio.

Table 1 lists the main characteristics and current state of development of the COVID-19 vaccines that are part of the European Vaccine Strategy.

Table 1: Summary of European SARS-CoV-2 vaccine candidates and current status of development (results published in peer review or preprint as of November 2020), subject to change.

Pharmaceutical companies	Platform	Schedule	Dose	Clinical Stage
Oxford/ Astra-Zeneca	Non-replicating chimpanzee adenovirus that carries the protein S	2 doses: 0-28 days	0.5ml dose IM	Phase III: UK, Brazil, South Africa, USA, among others.
BioN-Tech/ Pfizer	mRNA encoding S protein encapsulated in lipid nanoparticles	2 doses: 0-21 days	0.3ml dose IM	Phase III: USA, Brazil, Argentine, among others.
J&J/Janssen	Non replicating Ad26 vector carrying S proteing	1-2 ⁸ doses: 0-56 days	0.5ml dose IM	Phase III: USA, Argentine, Brazil, Philippines, Spain, among others.
Sanofi/GSK	Protein S purified with the adjuvant AS03	2 doses: 0-28 days	0.5ml dose IM	Phase I/II: USA. Phase III scheduled for December
Moderna	RNA encoding S protein encapsulated in lipid particles	2 doses: 0-28 days	0.5ml dose IM	Phase III: USA.
Novavax	S-protein nanoparticle with Matrix-M1 saponin as an adjuvant	2 doses: 0-21 days	0.5ml dose IM	Phase III: UK.
Curevac	mRNA encoding a stabilized form of S-protein encapsulated in lipid nanoparticles	2 doses: 0-28 days	0.6ml dose IM	Phase I: Belgium and Germany, amongst others. Phase II: Peru, Panama, among others.

⁷ BioNTech/Pfizer, Moderna/Lonza, Johnson&Johnson/Janssen, Astra-Zeneca/Oxford y Novavax.

⁸ J&J/Janssen está llevando a cabo un gran ensayo fase III en Estados Unidos con una sola dosis (que en principio será la dosis seleccionada para la autorización inicial) y otro gran ensayo fase III multinacional con la misma vacuna, pero a dos dosis.

Within the framework of the European Vaccine Strategy, which provides for advance purchase agreements, four contracts have already been signed: with Astra-Zeneca / Oxford, Sanofi / GSK, J & J / Janssen and Pfizer / BioNTech. In addition, there is already an agreement with CureVac and the contract will be signed shortly, other agreements are still being negotiated with Moderna / Lonza and Novavax. If all the agreements are completed, the EU will have secured, should vaccines be licensed, around 1.4 billion doses (or immunizations for around 800 million people) available from various manufacturers for the EU population, but also outside of it.

Advance Purchase Agreements within the European Vaccine Strategy reserve or grant Member States the right to purchase a specified number of doses of vaccination at a price stipulated at the time the vaccine in question is available. All Member States will have access to COVID-19 vaccines at the same time and according to the size of their population.

For a vaccine to be available to the population, it must be previously authorized by the European Commission after a positive scientific and technical opinion from the Committee for Medicinal Products for Human Use of the European Medicines Agency (EMA) and based on the usual criteria with which the quality, safety and efficacy of the drugs are guaranteed. The authorization granted in this way is identical and valid throughout the EU.

The time frame for the development of a vaccine is shortened for several reasons. First, because the companies develop the vaccine by performing several phases in parallel that would normally be carried out sequentially. Secondly, because companies begin to manufacture "at risk" –supported by advance payments of purchase agreements– so that they can have doses from the very moment they are authorized. Finally, because to speed up the evaluation process in a health emergency situation like this, the EMA has launched the rolling review process, whereby its Committee for Medicinal Products for Human Use reviews the data as soon as they are available, in a ongoing review that enables applications for authorisation to be quickly assessed while ensuring sound scientific advice. In this way, the vaccine evaluation process is accelerated to a great extent without compromising the safety requirements for its authorization at any time.

Citizens should know that the vaccines that will ultimately be used to get immunized against COVID-19 will have the same levels of safety as any other that are commonly used. And that the levels of effectiveness will comply with the standards required for its use to be authorized. We are relying on more teams and more resources. And all the initiatives underway to obtain vaccines are undergoing the same procedures followed by all the vaccines authorized so far.

Based on all established reviews, some vaccine manufacturers have announced that the first deliveries of vaccine doses to EU Member States would be available possibly before the end of 2020, provided the vaccines have a marketing authorisation in the EU .

In addition, to facilitate early access to the vaccine, aspects such as the labeling of medicines or actions at the national level have also been simplified to the maximum, so that when a vaccine is authorized by the European Commission, the Spanish Agency for Medicines and Medical Products (AEMPS) will grant the national code immediately so that the vaccination can begin.

Table 2 summarizes the status of negotiations with the different companies, for which marketing authorization is being requested in the EU and for which early availability may be possible or a sufficient number of vaccine doses could be available to initiate a nationwide vaccination campaign for priority groups.

Table 2: Status of the negotiations and approval schedule expected to November 2020, subject to change.

Pharmaceutical company	EU agreement	Total number of doses	Number of doses for Spain	Expected approval schedule
Oxford/ Astra-Zeneca	Contract signed in August 2020	300M (+100M optional)	31,555,469 doses	Rolling review initiated October 2020
Sanofi/GSK	Contract signed September 2020 (acquisition right)	300M	It will be decided when phase I / II ends	2021
BioN-Tech/ Pfizer	Contract signed in November 2020	200 M (+100 M optional)	20.873.941 doses	Rolling review initiated October 2020
J&J/Janssen	Contract signed in November 2020	200 M (+200 M optional)	Pending*	2021
Curevac	Contract signed in October 2020	225 M (+180 M optional)	Pending*	2021
Moderna	Very advanced negotiation	80M (+80M optional)	Pending*	Rolling review initiated October 2020
Novavax	Ongoing negotiation	-	-	2021

*Spain represents 10.57% of the population of the EU without the countries of the European Economic Area (EEA) and 10.44% including the EEA countries (Norway, Iceland and Liechtenstein).

- **Countries, institutions, researchers and companies around the world are making an unprecedented effort to develop a safe and effective vaccine in a short period of time.**
- **If the agreements are completed, the EU will have secured 1,400 M doses or 800 M of immunizations and all Member States will have access to it at the same time to a quantity according to its population.**
- **Citizens should know that the vaccines that will ultimately be used to immunize against COVID-19 will have the same levels of security as any of those commonly used.**

5 Prioritization of vaccination

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

Given that the first vaccines against COVID-19 will be available in limited quantity, and will increase progressively, three stages have been identified according to availability at any particular time:

- First stage. Initial and very limited supply of vaccine doses.
- Second stage. Progressive increase in the availability of vaccines will allow to increase the number of people to be vaccinated.
- Third stage. Increase in the number of doses and vaccines available to cover all priority groups.

Due to the gradual availability of vaccine doses, it is necessary to prioritize the population groups to be vaccinated in each of the stages set out. To this end, an ethical framework has been established where prevail, in this order, principles of equality and dignity of rights, necessity, equity, protection of disabilities and minors, social benefit and reciprocity. In addition, the following more procedural principles have also been taken into account: participation, transparency and accountability.

The evaluation of the different population groups is based on this framework, also taking into account the applicable legal regulations and international recommendations.

To set out the prioritization of the groups to be vaccinated in each of the stages, an evaluation has been carried out based on the following criteria: risk of severe morbidity and mortality, exposure, socioeconomic impact and transmission, in addition to feasibility and acceptance.

Based on this evaluation, the following group prioritization has been established for the first stage:

1. Residents and health and social care personnel in care homes for the elderly and the disabled.
2. Front-line health personnel.
3. Other health and social health personnel.
4. Dependent people with disabilities who require intensive support measures (non-institutionalized highly dependents).

Once the availability of one or more of the authorized and acquired vaccines by the Ministry of Health is known, the final prioritization of vaccination to certain population groups will be agreed in the Plenary of the CISNS, after discussion in the Presentation of Vaccines and Vaccination Registry and in the Public Health Commission,

- **Due to the gradual availability of vaccine doses, it is necessary to prioritize the population groups to be vaccinated based on to an established ethical framework and risk criteria.**
- **The Plenary of the CISNS will agree on the final prioritization of vaccination of the various groups of population.**

6 Logistics, distribution and administration

The vaccination program against COVID-19 entails several critical points different from the usual vaccination programs. These have to do with the requirement of extraordinary cold conditions in the transport and storage of some vaccines, their distribution in multi-dose vials that require planning of appointments to avoid dose loss, the possible coincidence of use of different vaccines with different formats and specific handling instructions and that to complete vaccination coverage may require one or two doses, the need to maintain physical distance and preventive measures during the process (for which the experience during the influenza vaccination campaign serves as a reference), the special characteristics of the Immunization Registry or the need to consider possible vaccination sites in addition to the usual ones.

To facilitate the correct functioning of the vaccination process, it is therefore paramount to ensure that the storage, distribution and administration of each vaccine are carried out in optimal conditions that guarantee the quality of the vaccines throughout the process. The COVID-19 Vaccination Technical Working Group has evaluated the fundamental aspects to take into account from the authorization of the use of vaccines to their administration, as outlined in Figure 1:

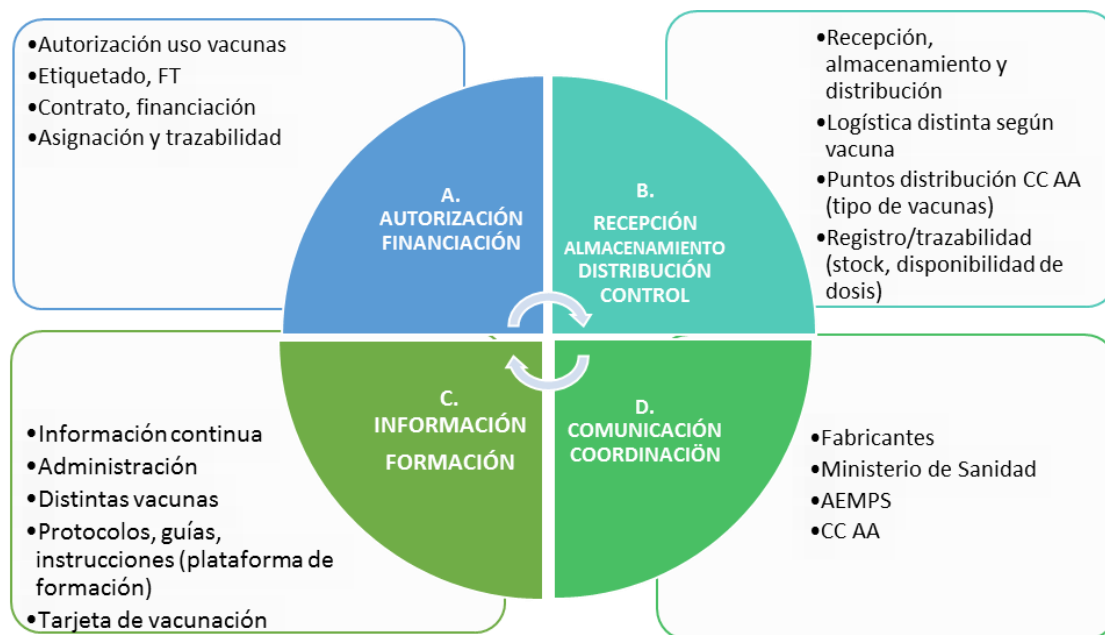


Gráfico:

- A. Financing, Authorization
authorization for use of vaccines; labeling FT; Contract, Financing; Allocation and traceability
- B. Reception, Storage, Distribution, Control
Reception, storage and distribution; Different logistics depending on the vaccine; Distribution points Autonomous Communities (type of vaccines); Registration/Traceability (stock, dose availability)
- C. Information, Training
Continuous information; Administration; Different vaccines; Protocols, guides, instructions (training platform); Vaccination card
- D. Communication, Coordination
Manufacturers; Ministry of Health; AEMPS; Autonomous Communities

The Ministry of Health is working with the autonomous communities on different alternatives of vaccination centers, taking into account the experience of Primary Care. As information on the availability of vaccines becomes available, it will be necessary to update the processes and establish where, who and how the vaccination will be carried out.

Vaccine distribution will require full collaboration and coordination between public institutions, authorized distributors and pharmaceutical companies so that supply chain logistics are carried out in an efficient and orderly manner in a process validated at all times by the Ministry of Health. To this end, protocols will be developed to control the traceability of distribution, assign process managers and define clear communication flows.

The administration of the vaccines will be carried out initially with confirmed appointment to avoid the waste of doses and following the safety protocols. The vaccine doses administered will be included in the registration systems and the date

and data of the vaccine received will be included in the clinical history of the vaccinated person.

All vaccinated persons shall receive adequate information on the vaccine administered and a vaccination card, or similar, which shall state the type of vaccine administered and the lot number, date of vaccination and date for the administration of the second dose, if applicable, as well as how to proceed with any suspected adverse reaction.

- The logistic, distribution and administration processes of the vaccines against COVID-19 are complex and associate several critical points that are being technically prepared in advance of the arrival of the first vaccines.

- The distribution of the vaccines will require full collaboration and coordination between public institutions and pharmaceutical companies so that the logistics of the supply chain are carried out in an efficient and orderly manner in a process validated at all times by the Ministry of Health.

7 Monitoring and Evaluation

Adequate records to ensure that vaccination data is properly collected and to assist in surveillance and follow-up activities are essential for monitoring the vaccination strategy.

The National Health System's COVID-19 Vaccination Registry aims to keep track of the doses and types of COVID-19 vaccines administered to different population groups. This registry will be used to calculate the vaccination coverage achieved and will include the entire target population that is being prioritized.

The Ministry of Health is working with the Autonomous Communities on the standardized and structured confluence of information systems and regional records into a single registry that will house COVID-19 vaccination data for the entire country and will be interoperable with other registries implemented during the pandemic.

The Spanish Pharmacovigilance System, coordinated by the AEMPS, has developed a specific Plan for the safety surveillance of COVID-19 vaccines that will continuously analyze the reports of suspected adverse reactions made by both health professionals and the vaccinated citizens themselves, sharing information with the rest of European agencies and the WHO.

The Strategy contemplates the development of different studies of vaccine effectiveness in the vaccinated population that complement the data of the studies carried out by the pharmaceutical companies, as well as studies of the effect of the introduction of the vaccine on the epidemic wave.

Spain will participate together with seven countries in the European project ACCESS coordinated by the European Medicines Agency on coverage, effectiveness and safety of vaccines through the BIFAB Program, a computerized database of the clinical history of Primary Care for pharmacoepidemiological research.

The Strategy also foresees studies of the acceptability of vaccination and processes of continuous evaluation of the Strategy that allow monitoring and dynamic adaptation of the same.

- - **The Strategy foresees different tools and studies that will allow monitoring and evaluation of the coverage, safety and effectiveness of the vaccines.**
- **The Spanish Pharmacovigilance System, coordinated by the AEMPS, has developed a specific Plan for the safety surveillance of COVID-19 vaccines that will continuously analyze the reports of suspected adverse reactions made by both health professionals and the vaccinated citizens themselves, sharing information with the rest of the European agencies and the WHO.**

8 Communication

The development of a communication strategy must contribute to effective, equitable, and ethically sound access to vaccination, and be developed with full respect for transparency, as the fundamental axis of all public decisions and policies, especially those adopted in the field of public health, as set forth in the General Law on Public Health.

It is considered a facilitator of these objectives that the communication is carried out preferably by technical personnel and that it is focused on the transmission of the criterion of solidarity, that is, to inform that the vaccination will be prioritized to the population that needs it the most, taking into account the safety of the vaccines. Health personnel play a fundamental role in informing the public.

In short, it is a matter of generating a high level of confidence that will translate into better coverage.

This communication strategy will be governed by the application of the following principles:

- Veracity: information based on available scientific evidence on the benefits and risks of vaccination.
- Transparency: truthful information shall be provided at all times in a clear and accessible manner that also includes uncertainties.
- Participation: the doubts of the population and health personnel will be heard in order to direct the communication strategy to respond to existing needs.
- Equity: messages will be adapted to the audience to ensure that it is accessible. Specific attention will be given to people with disabilities.
- Evaluation: information will be periodically re-evaluated.

The communication strategy will create a framework of truthfulness, transparency and trust with differentiated objectives for health personnel and the general population.

1. Healthcare personnel must be informed about the development, authorization, procurement procedures, distribution and use of COVID-19 vaccines at the different stages of availability of the vaccines, establishing synergies with key actors in the vaccination and transmission of accurate information (participation of professional associations). The following objectives have been established:

- a) To ensure confidence in the evaluation, authorization and surveillance process after the administration of the vaccines (continuous evaluation in the benefit-risk relationship).
- b) To help understand the difference between the usual vaccine authorization process and the one used in the current situation by the regulatory agencies (EMA and AEMPS).
- c) Raise awareness of the need to prioritize vaccination as a criterion of solidarity and in line with the safety and efficacy data of the vaccines.
- d) Raise awareness on the deontological commitment towards vaccines, so that they transmit to the population the example of protecting their health to protect others.
- e) Remember the importance of reporting adverse events that may occur after vaccination.

2. The general population should be informed about the development, authorization, distribution and use of COVID-19 vaccines, with the participation of population associations (patient associations):

- a) Communicate about the process of evaluation, authorization of the vaccines and continuous surveillance after their authorization, as well as answering questions.
- b) Explain the reasons for prioritization as a criterion of solidarity
- c) Inform about the scientific evidence of the vaccines, their history and the scientific characteristics of the vaccines to be distributed.
- d) Inform about the adverse reactions of the vaccines identified before and after their authorization. In this sense, to have data on the adverse reactions that occur in other vaccines.

- The development of a communication strategy should contribute to the effective and equitable access to the vaccination, complying with ethical principles and developed with full respect to transparency. - The general objective of the strategy is to generate a high level of trust that translates into better coverage, and for this purpose health personnel play a fundamental role.