Ref: Answer to the request in the case: "DENTONE MENDEZ MAXIMILIANO MENDEZ v PRESIDENCY OF THE REPUBLIC AND OTHERS - AMPARO" I.U.E: 234539/2022.

The undersigned, Dr. Daniel Salinas, in his capacity as Minister of Public Health of the Eastern Republic of Uruguay, responds to the questions posed by the judge.

Question 1:
Apart from any contractual reservations, has the Uruguayan government conducted independent studies on the information provided by the manufacturers to verify the safety and efficacy of the vaccines in Uruguay? Have independent international studies also been conducted?

Answer 1:
Yes, regarding COVID-19, the Ministry of Health is conducting studies on the efficacy of the vaccine, whose objective is to monitor the effectiveness of vaccination, prevention of SARS-CoV-2 infection, severe illness and mortality. The results of the study were published in reports accessible on the Ministry's website.

We also relied on independent international studies that have reported on vaccine efficacy, such as the Thompson study (October 2021), which found that in 42 000 patients studied, the efficacy of a full vaccination schedule 14 days after the second dose was 89% in preventing hospitalization and 90% in preventing STD hospitalization.

Regarding the monitoring of the safety of vaccines used in Uruguay, two strategies will be followed: spontaneous (with follow-up of reported cases that were considered serious by the reporter or that prompted medical control); and from 12. January 2022, coinciding with the start of the vaccination campaign for children aged 5 to 11 years, active surveillance of adverse events allegedly due to vaccination and immunization (SAVI) has been implemented in this population at a national reference health center to raise awareness and increase the possibility of detecting potential cases.

Question 2:
Based on the caveat regarding the composition of the vaccines, how, if at all, were identity and quality checks performed on each shipment of imported vaccines when they arrived in our country? If yes, please provide a summary of the number of analyses and methodology.

Answer 2:
For each batch of vaccines imported into the country, including COVID-19 vaccines, the Drug Administration of the Ministry of Public Health reviews the vaccine batch release certificate issued by the title laboratory to verify that the vaccine batch meets the established quality specifications (appearance, labeling, dosage, sterility, etc.). After the vaccine release certificates are

verified, they remain in the custody of the Drug Administration. In this way, the Department ensures that it has the release documents for each batch of vaccine administered to the population.

In addition, Ministry staff are present at the airport when vaccines are received to monitor that the product received matches the description on the packing list (quantity, batch, date of manufacture, and expiration date), and to verify the temperature profiles during transport of the vaccines, as well as the proper storage of the vaccines in the warehouse.

Question 3:
Were and are all batches of vaccines injected the same way? Please justify whether or not your answer is based on actual knowledge of their ingredients.

Answer 3:
The Ministry of Public Health has an intimate knowledge of the composition of COVID-19 vaccines administered in our country, their ingredients, their function in the formulation, and the amount of each ingredient. For all batches of COVID-19 vaccines that have entered our country, the Ministry has verified compliance with the specifications established for batch release.

Pfizer-BioNTech's COVID-19 vaccine contains a molecule called messenger RNA (mRNA), which contains the instructions for making the spike protein (protein "S" or spike protein).

This is a protein found on the surface of the SARS-CoV-2 virus that the virus needs to enter the body's cells. Once a person receives the vaccine, some of their cells read the instructions in the messenger RNA and temporarily produce the spike protein. The person's immune system then recognizes this protein as foreign, produces antibodies, and activates T lymphocytes (white blood cells) to attack it. Later, when the person comes into contact with the SARS-CoV-2 virus, his or her immune system recognizes it and is ready to defend the body against it. The messenger RNA of the vaccine does not remain in the body, but is broken down shortly after vaccination.

In turn, the RNA is transported by lipid beads that pass through the cell membrane by endocytosis and release the genetic material into the cell.

Lipid spheres of a few nanometers (nanometer: a measure of length equal to one billionth of a meter), known as lipid nanoparticles (LNPs), have been developed that can effectively transport and release nucleic acids. Pfizer-BioNTech's COVID-19 vaccine uses lipid nanoparticles composed of three active ingredients: a cationic lipid, cholesterol and PEG (polyethylene glycol).

In addition, the vaccine formulation contains a cryoprotectant, sucrose and a buffered thromethamine (Tris) solution for pH adjustment. Finally, the excipient is water for injection.It does not contain any preservatives.

Pfizer-BioNTech COVID-19 vaccine for children aged 5-12 years, each vial of

vaccine contains as active ingredient, BNT162b2, in the amount of 130 mcg; and as excipients: ALC-315, ALC-0159, DSPC, cholesterol, sucrose, thromethamine (Tris base), tris-(hydroximethyl)-aminomethane hydrochloride (TrisHCl), sodium chloride, and water for injection.

Question 4:
Why were different types and brands of vaccines given to different populations (e.g., age groups, police, health care workers, minors, etc.)?

Answer 4:
Prioritization of key population groups was undertaken, with the primary goal of reducing severe illness and pandemic-related mortality and minimizing social disruption.

It was a population-based strategy based on three objectives: preventing the risk of severe illness and death, preventing occupational risks among key workers, and maintaining access to the health care system. Vaccination was implemented in a phased and staggered manner, depending on which groups were to be prioritized for vaccination, which vaccine platforms were available in Uruguay (depending on the arrival of each vaccine), and which evidence was most available. As more clinical trial data became available and vaccination progressed globally, new evidence emerged on vaccine efficacy, effectiveness, and safety that could expand indications.

This priority criterion is again defined in the World Health Organization (WHO) document that serves as a guide for vaccine use in the context of pandemics and difficult access to vaccines.

The technical recommendations for vaccine introduction and use and implementation in the country were supported by technical advice at various levels:

(a) The National Vaccine Advisory Commission (CNAV), which advises the country on the inclusion of the various vaccines in the regular program.

(b) An ad hoc advisory group to the National Vaccine Advisory Commission was formed to work on vaccines against COVID-19. This working group is composed of technical representatives from different institutions and with complementary profiles to ensure an interdisciplinary approach to the topic. Participating organizations: Faculty of Sciences, Faculty of Chemistry, Faculty of Medicine, Ministry of Public Health (Department of Epidemiology, Immunization, Department of Health Surveillance, Communication, Drugs).

(c) Uruguay was advised by a volunteer scientific advisory group (GACH), from which delegates were included in the ad hoc advisory group.

(d) Immunization Division of the Ministry of Public Health, Epidemiology Department.

(e) The Campaign Coordination Group, led by the Health Authorities and composed of experts from the various implementing units of the Ministry of Public Health, in coordination with other agencies.

(f) The Honorary Commission for the Control of Tuberculosis and Widespread Diseases (CHLA EP), which implements the National Immunization Plan, coordinates the country's immunization centers, conducts training, and oversees logistics. The Calmette Laboratory, part of the CHLA EP, is responsible for cold chain monitoring, distribution, and control at health centers.

It is important to note that the pace of vaccine arrival was part of the national vaccination plan against COVID-19.
The availability of vaccines against COVID-19 was the result of a determined decision guided by the belief that it would benefit the population and was achieved in an environment where access to vaccines was extremely difficult.

Among the characteristics of the available vaccines:

A. All available vaccines exceed the WHO requirement of 50% efficacy. The main criterion for allocation is age and availability based on fractionation on arrival.

B. Coronavac was originally licensed in Uruguay for persons aged 18 to 59 years, later extended to 70 years based on immunogenicity studies.

C. Pfizer -BioNtech was originally approved for use from 16 years of age with no upper age limit. It has subsequently been approved by international agencies such as the FDA, EMA, and WHO for adolescents 12 to 16 years of age and children 5 to 11 years of age (lower dose) and currently 6 months to 5 years of age.

D. Groups with high exposure and high risk of transmission (health care workers) were prioritized for vaccination with an mRNA vaccine.

E. Arrival of vaccines and availability of doses. The strategy is flexible and depends on the availability of the type and quantity of doses due to the fractional arrival of the vaccines.

Question 5:
Are there different evaluation criteria for efficacy and safety for the different brands (Pfizer, Sinovac or Coronavac)?

Answer 5:
Yes, the efficacy studies conducted in our country include analysis of both platforms. For these purposes, for the sake of brevity, we refer to what is on the Ministry's website and what has been added in writing, with the relevant bibliography and associated studies, in accordance with the judge's request in point 9 of Decree No. 1 189/2022.

Question 6:
Which vaccine is injected to minors, and what are the proven scientific criteria that lead to this vaccine being preferred to others?

Answer 6:
In Uruguay, the only vaccine administered to children aged 5 to 11 years is Pfizer-BioNtech's pediatric vaccine, as it is the only one approved at that time by the international reference authorities (FDA-EMA) for this age group, based on published Phase III studies. If the vaccination in adolescents, Pfizer-BioNtech was selected because it was the only drug approved for adolescents at that time and the phase III trial in Coronavac was ongoing but not yet completed.

Question 7:
Did the Department of Health follow up with the vaccinated and a control group of unvaccinated individuals to determine infection, reinfection, and death rates in both groups to obtain statistically valuable and generalizable data? If so, what was it, where can it be tested, by whom, and how?

Answer 7:
Yes, the Ministry of Public Health has conducted studies. The methodology of the efficacy studies posted on the Department's institutional website was a prospective observational cohort study. Eligible participants were individuals residing in Uruguay who were eligible for vaccination against SARS-CoV-2.

Elaboration excluded individuals with previous SARS-CoV2 infection in the 60 days before vaccination and individuals who had been vaccinated with the analyzed vaccine dose for less than 14 days.

The data sources used were: Vaccine Information System (SW), Immunization Data Monitor COVID, Health Surveillance Department Administrative System (SG-DEVISA), electronic death certificate, and population projections from the National Institute of Statistics (INE).Incidence density rates of COVID 19 cases, STI admissions, and deaths in the vaccinated and unvaccinated populations were calculated.

Question 8 (Part One):
It is already known that vaccines or some of them contain the so-called "spike protein". Are you aware of any short-, medium- or long-term adverse effects on the structure of the natural immune system of humans (in general and especially in children)?

Answer 8 (Part One):
The studies published to date provide no evidence that vaccines, and spike protein (protein S or spike protein) in particular, are toxic or harmful to the body.

In vaccines that contain protein S (CoronaVac), the expression of protein S is much lower than when infected with the virus.

In addition, the mRNA is very labile and degrades rapidly in the body. Thus, once it enters the cell and produces protein S in a single cycle, it is destroyed.

Question 8 (Part Two):
Is there a risk of autoimmunity? If you are convinced that there is no adverse effect, on what basis? If studies have been reviewed by the MOH (or other national health authority), what specifically are the studies, where did they come from, and who were the authors?

Answer 8 (Part Two):
Not only vaccines can cause autoimmune diseases, but also other products such as synthetic drugs, foods, etc. can cause autoimmune phenomena. These phenomena are complex, random, and depend on numerous factors, including individual factors that determine their occurrence.

The incidence of this phenomenon is very low, 0.9 per million doses administered.

In minors, autoimmunity phenomena possibly related to COVID-19 vaccination were the exception in our country, as NO phenomena were observed in the population aged 5 to 11 years.

In addition, the population with an autoimmune disease as a concomitant condition is strongly recommended to be vaccinated as a priority and to receive additional doses of the vaccine, as the benefits have been shown to far outweigh the potential risk.

Question 9:
Are you aware of any toxicity of the "spike protein" per se? If not, based on what information?

Answer 9:
Spike protein (protein "S" or spike protein) is not toxic and has been extensively tested in Phase I and Phase 2 studies. In addition to being extensively studied in preclinical studies, it has also been evaluated as a vaccine candidate for other coronaviruses such as SARSCOVI and MERS-CoV and is a suitable antigen for use in vaccines.
There are no reports of toxicity of the vaccine-specific protein in humans.

In the initial phase of clinical trials, different dosages are used and a range of innocuousness and efficacy is determined. Therefore, once they have passed through the Phase I and Phase II filters, we can be confident that the levels of spiked protein produced by the vaccines are completely safe.

Question 10:
Is Covid-19, SarsCov-2, a disease that can be defined as highly or significantly aggressive for children, and does it cause severe effects on average, or do mild effects predominate in the pediatric population? If statistical severity is claimed

for the above effects, based on what studies?

Answer 10:
The clinical presentation of COVID is mild and asymptomatic in all age groups, and most cases are treated as outpatients, as reported in national epidemiologic reports and international field reports. However, the possibility of complications, severe illness, and death is well described and discussed.

These risks, although higher in the adult population, are now also described in children and adolescents, especially those NOT vaccinated.

Children account for about 14-15% of COVID-19 cases in Uruguay, with between 130,000 and 140,000 cases currently.

In children, the disease usually occurs in a mild form. However, in children with concomitant diseases (pulmonary, cardiovascular, neurological, cancer or other diseases), more severe forms occur, and in them the infection is not a mild disease. Overall, only a very small percentage (less than 1%) of children with COVID-19 have required ICU admission, but children younger than 15 years have died from the disease.

In addition, one form of the disease has been described as an inflammatory process involving multiple organs or systems, termed "multisystem inflammatory syndrome SIM-C," which is a severe form of the disease. This form was originally identified in children, and it is most common in children. It can affect multiple organs and systems, including the heart (myocarditis) and the digestive system, but it can also affect hematologic, dermatologic, neurologic, respiratory, and renal systems. And it can occur in patients who have had both symptomatic and asymptomatic disease.

According to reports from the U.S. Centers for Diseases Control (CDC), the incidence of infection is 1 in 3,200 cases. Between 1% and 2% of patients with SIDS-C may die. Most notably, in the 5- to 11-year-old age group, 20% of children in this age group died of MIDS in the United States.

The other aspect is that COVID-19 leaves a percentage of those affected with symptoms that last varying lengths of time, from months to more than a year; this is called prolonged COVID-19, which also occurs in children and leaves them with persistent symptoms such as fatigue, decreased physical performance, and periods of muscle and joint pain, as well as signs of decay and decreased concentration, sleep disturbances, and difficulty with mental performance.
Prolonged COVID can occur in patients who have had an acute symptomatic episode as well as in asymptomatic patients.

Data from the United Kingdom show that:
(a) 9.8% of children aged 2-11 years diagnosed with COVID19 have symptoms 5 weeks after infection.
(b) 13% of 12-16-year-olds have symptoms 5 weeks after infection.

(c) 7.4% of children aged 2 to -ll years have symptoms 12 weeks after infection.
(d) 8.2% of 12-16 year olds have symptoms 12 weeks after infection.
An Italian study conducted from March to November 2020 found higher incidences:
(a) 66% (patients followed between 60 and 120 days).
(b) 51.40/0 (patients observed for more than 120 days).

Children and adolescents with this syndrome were found to be at higher risk for depression, anxiety, and post-traumatic stress disorder compared to adults.

In 2021, 65% of cases in children nationwide were asymptomatic. The most common symptoms were general nonspecific respiratory symptoms. Comorbidity was present in 4.1% of cases, with obesity and cardiovascular disease being the most common. During the same period, the hospitalization rate was 1% and the ICU admission rate was 0.1 0/0.
Three COVID-19-related deaths were recorded in children with a history of comorbidities.

Therefore, although most healthy children have mild forms of the disease, the disease cannot be considered mild overall, as children with preexisting conditions have more severe forms and those with persistent COVID-19 symptoms are more severely affected.

Question 11:
Has the association between disease incidence and vaccination been studied at the national level in those affected who have already been vaccinated? That is, infection and development of the disease in such cases.

Answer 11:
Vaccination interventions aim to reduce the lethality and mortality associated with the event and to contribute to the reduction of new cases of the immune-preventable disease.

With regard to COVID-19 and to evaluate these aspects, the Ministry of Health has conducted studies on the effectiveness of the vaccine against SARS-CoV-2, the objective of which is to monitor the effectiveness of vaccination in preventing SARS-CoV-2 infection, severe illness and death.

The study is a prospective, observational cohort study. The study population is individuals residing in Uruguay who are eligible for SARS-CoV-2 vaccination.

Individuals with previous SARS-CoV-2 infection in the 60 days prior to vaccination and cases that occurred less than 14 days after vaccination with the vaccine dose studied were excluded.

The data sources used are: Vaccine Information System (SIV), COVID Vaccination Data Monitor, Health Surveillance Agency Administrative System (SG-DEVISA), electronic death certificate, and population projections from the

National Institute of Statistics (INE).

Incidence density rates for COVID 19 cases, STI admissions, and deaths in vaccinated and unvaccinated populations were calculated.

Trend analysis was performed with the linear segmented regression method using Joinpoint Regression Program software, version 4.9.

The results of the study were published in reports accessible on the Department's website.

The results highlight the decline in incidence in June 2021, when vaccination coverage with at least one dose of vaccine exceeded 50%. A turning point in the incidence of COVID-19 was observed at baseline, when vaccination coverage reached 64% with one dose and 36% with two doses.

In all efficacy studies, the incidence rate of cases and of hospitalizations and deaths from STIs was significantly lower in vaccinated individuals than in unvaccinated individuals for all platforms.

Question 12:
Did Covid 19 cases in minors, regardless of severity, increase after vaccination compared with before (for the same age group, of course) during the period between the first implementation of the health emergency in 2020 and the start of vaccination of minors? If an increase in cases among minors was reported after vaccination, were the causes investigated? How?

Answer 12:
To answer this question, it is necessary to analyze the evolution of the epidemic curve in the country, especially considering the impact of the emergence of new variants of concern. Since the emergence of SARS-CoV-2 and through genomic surveillance procedures, several variants of the same virus have been identified, which are considered of concern or interest by WHO depending on their characteristics (transmissibility, virulence, immune evasion, etc.). These arise from the occurrence of mutations within the genetic structure of the virus, which is a natural and expected process in the evolution of viruses.

In the COVID-19 epidemiological report of January 3, 2021, at which time there were no SARS-CoV-2 variants in Uruguay, 2,052 cumulative cases were reported in children under 15 years of age.

In the COVID-19 epidemiologic report of June 3, 2021, when PI (gamma variant) was circulating, 41 043 cumulative cases were reported in children younger than 15 years.

In the November 21, 2021 COVID-19 epidemiologic report, when the delta variant was circulating, 60,160 cumulative cases were reported in children younger than 15 years of age.

Being 15 years old.
In the February 20, 2022 COVID-19 epidemiologic report, when the Omicron variant was circulating, 1,18,096 cumulative cases were reported in children younger than 15 years of age.

In the May 21, 2022, COVID-19 epidemiologic report, at which time the Omicron variant and BA.2 subvariant were circulating, 132,417 cumulative cases were reported in children younger than 15 years.

A comparison of the number of COVID-19 cases diagnosed in the population aged 5 to II years during January to June 2022 shows that the number of unvaccinated cases was 25,290, whereas the number of vaccinated cases was 13,695.

In order to interpret the above data correctly, it is important to remember that the public health control measures (non-pharmacological measures) implemented by the government were modified throughout the pandemic, especially in children, and that in 2020 mobility was significantly reduced, which contributed to the reduced spread of this virus and other seasonal viral pathogens.

Question 13:
During the duration of an epidemic, does vaccination increase the variability of mutations in viral proteins and in any way affect the natural response of the immune system of those vaccinated, particularly children?

Answer 13:
To fully understand the behavior of the epidemic in Uruguay, it is necessary to analyze the evolution of the epidemic curve in the country and its relationship with the behavior in the region and the world.

In particular, it is necessary to consider the impact of the emergence of new variants of reoccupation. Since the emergence of SARS-CoV-2 and through genomic surveillance processes, several variants of the same virus have been identified, even before vaccination strategies were initiated, which are classified as of concern or interest by WHO depending on their characteristics (transmissibility, virulence, immune evasion, and others).

These arise from the occurrence of mutations within the genetic structure of the virus, which is a natural and expected process in the evolution of viruses. Since the first genomic characterization of SARS CoV-2, this virus has been divided into different genetic groups or clades.

Available scientific evidence clearly shows that the risk of emergence of new variants is increased in scenarios of high virus circulation and low vaccination coverage, which is why WHO has issued several communications on this situation urging countries to achieve high vaccination coverage in the shortest possible time.

As with other vaccines, vaccination does not impair the natural immune response, but rather enhances it by promoting memory immunity.

Question 14:
Has there been any investigation into whether the usual three-year trial protocols with control groups were followed for the vaccines delivered in Uruguay? Are you aware that Pfizer eliminated its control groups or prevented their conduct and development in any way in connection with the vaccine supplied to minors in Uruguay?

Answer 14:
Yes, the usual research protocols were followed with preclinical and clinical phases up to phases III and IV. The speed at which this process occurred is due to the overlap of clinical phases. This scenario does not affect the quality and methodological rigor of the process, nor the validity of the results, as each study met the required scientific standards.

It is important to note that after billions of doses administered worldwide, safety and efficacy have been comprehensively demonstrated in a short and unprecedented period of time.

Eliminating a placebo group is not the same as eliminating the control group. If the results of the study show benefit in the intervention group, it would be unethical by international standards to continue the research with a placebo group.

Emergency authorization is a mechanism to facilitate the availability and use of medical interventions, including vaccines, in public health emergencies, such as the current Covid 19 pandemic.

Emergency authorization does not imply a spontaneous or uninformed decision. Rather, it is an extremely rigorous review in which the product has been tested on thousands of people according to standards required by international health authorities.

In order to receive approval, as with all vaccines approved to date, Phase I, II and III results, or preliminary results, will be submitted to evaluate the vaccine's efficacy and safety.

Once regulators have reviewed all the evidence and conclude that the benefits outweigh the risks, they may approve the vaccine without restriction, as was done with Pfizer/BioNTech's vaccine, which was the first in the world to be approved by FDA (unrestricted approval).

Question 15:
If the answer to the previous question shows that the effects of vaccines have not been analyzed with the appropriate safety protocols, could it technically be argued that vaccination is a risk factor, even a relative risk, or not (and if so,

why)?

Answer 15:
Not applicable based on the answers to the previous question.

Question 16:
Are you aware of any international reports, e.g., VAERS (or others), reporting deaths or serious adverse events, of any age, associated with vaccines administered in Uruguay? If so, have they been investigated by the Uruguayan state, at what level, by whom, and with what results?

Answer 16:
Yes, we are aware of regional and international reports of adverse events of varying magnitude.

The Pharmacovigilance Unit of the Ministry of Public Health reviews the periodic safety reports of the international reference agencies: EMA (European Medicines Agency), AEMPS (Spanish Agency for Medicines and Health Products), FDA (Food and Drug Administration) and CDC (Centers for Disease Control and Prevention) in the United States, Health Canada and the French agency (AFSSAPS), to name a few.

Similarly, consolidated regional and global information on suspected adverse effects of vaccines and immunizations (VASI) related to COVID-19 and other updates submitted by PAHO and WHO will be received and analyzed.

At the regional level, reports from the following agencies are regularly reviewed: ANMAT (Argentina); INVIMA (Colombia); ANVISA (Brazil); ISPCH (Chile).

As Uruguay is a member of the WHO International Drug Monitoring Program, it has access to the WHO-UMC international database through the Vigilyze tool, which provides access to reports from member countries.

The information collected from the above sources contributes to the analysis of reported cases.

The Ministry has already implemented a strategy for surveillance of healthcare-associated infections prior to the health emergency, which is carried out regularly in this context. This applies to all age groups and all vaccines (including non-COVID-19).

The Ministry, in turn, analyzes all available information from the official media and scientific pharmacovigilance reports that confirm the safety of vaccination to date. Serious adverse reactions need to be clarified, as their objective definition can be misrepresented. A serious adverse reaction is defined as an effect that requires non-ambulatory treatment. For example, if severe vomiting occurs after vaccination and hospitalization is required, this would be considered serious.

No deaths have been recorded in Uruguay as a result of vaccination.

Question 17:
Are there any studies in Uruguay that suggest that vaccination against Covid-19 in children is beneficial rather than risky? If so, at what level, by whom, and with what results?

Answer 17:
Yes, they have been studied. At the national level, the main example is the Ministry of Public Health through the work of the National Advisory Commission on Vaccines and the Ad Hoc Group.

This group is interdisciplinary and interagency and is made up of experts who work on aspects of public health decision making related to vaccines.

For example, some results emerge from the analysis of the distribution of CTI cases and hospitalizations related to COVID-19 in the population under 12 years of age in the period January-June 2022 according to vaccination status. It highlights that 51,057 cases and 44 admissions to ITC were recorded in unvaccinated or incompletely vaccinated individuals (1 dose); and 1,948 cases and 5 admissions to ITC in individuals vaccinated with 2 doses.

Question 18:
Has the Uruguayan State considered the report of the "Committee of Pharmacology and Therapeutics of the Uruguayan Society of Pediatrics" of 9.XI.2021 (signed by seven university professors), which points out the risks of vaccination in children under 12 years of age? If so, what scientific and technical reasons would have led the MOH to reject it (in practice)?

Answer 18:
The Ministry of Public Health strictly follows all scientific evidence published by national and international academic institutions. Among other things, the report published on November 9, 2021, clearly points out the presence of higher risk groups in children (especially in immunocompromised individuals), although it is known that at the time of writing the infection had a rather harmless course compared to adults.

At the same time, there was new evidence worldwide about the impact of the disease in children who may be severely ill. And in turn, solid evidence of the vaccine's safety and efficacy in children was approved for emergency use on October 29, 2021, and a Phase III trial was published in peer-reviewed journals.

As far as we consulted the Uruguayan Society of Pediatrics (SUP), it received a request to discuss the topic of "COVID vaccines in children" in the CNAV, whereupon the Board of Directors asked the Committee on Infectious Diseases and Vaccines for its opinion and position on this issue.

The SEA received the document requested by the Committee on Infectious Diseases and Vaccines, in which the arguments were presented with the relevant references, and on the basis of this analysis - which also included considerations from other committees - the Uruguayan Society of Pediatrics adopted a unanimous resolution in support of voluntary vaccination, which is the priority for children at risk and whose recommendation will be updated depending on the available evidence, which is thus the official position adopted at the CNAV meeting.

Therefore, the Ministry of Health, through the members of the CNAV representing the SEA, had the reports and the official position of the Uruguayan Society of Pediatrics. This included a detailed risk-benefit analysis of COVID vaccination in children, which concluded that the benefits of vaccinating this age group clearly outweighed the risks. On the other hand, as mentioned above, this official opinion of the SEA included some aspects that were not included in the report of the Pharmacology and Therapeutics Committee of the
Uruguayan Society of Pediatrics.

Therefore, it is inaccurate to state that the Ministry of Public Health "rejected it."

Without further ado, I am at your disposal for further information or clarification.

DR. DANIEL SALINAS
MINISTER
MINISTRY OF PUBLIC HEALTH