

COVID-19 SMA Vaccine Update Mexico - English February 19, 2021

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The Weekly Vaccine Update is designed to keep you informed regarding COVID-19 vaccine news in Mexico. It supplements and reinforces information provided through the COVID-19 SMA website or FB page, which should be read daily. Information comes from reliable sources, which are referenced throughout the article.

What is the current COVID-19 official status for Guanajuato?

The State of Guanajuato is still in Red. As there are thousands of confirmed cases, the State is in Scenario Three: All mass events are cancelled, all schools are closed, and until only 10% of workers are confirmed to have the virus in the past 7 days, all employment is officially closed. If an individual has to work, protection measures are detailed. <u>https://coronavirus.guanajuato.gob.mx/faq.php</u>

There are still five approved vaccines

Mexico has approved the Pfizer-BioNTech vaccine, the AstraZeneca vaccine, the Sputnik V vaccine, the CanSino and SinoVac. Detail on each of the approved vaccines is provided below. Mexico has not approved any other vaccine to date.

Vaccination in Mexico – the Federal Government

Vaccine availability and plans

According to the February 17, 2021 daily briefing, a total of **1,058,139 vaccine doses** have been applied to date. Vaccination in Mexico began on December 24, 2020. Mexico was the first country in Latin America, and one of the first 10 countries in the world to begin vaccination against COVID-19.

There are currently **708 vaccination points**. The most recent vaccine shipment received last Sunday was 870,000 doses from AstraZeneca/India. To date, 318,358 doses of that shipment have been applied. At that rate, the government estimates that the shipment will be completed in 7-10 days.

In the February15, 2021 daily briefing, Dr. Gatell informed that 2 million doses of the AstraZeneca vaccine being bottled in Mexico should be available by the end of March, beginning of April. It is also expected that the CanSino vaccine being bottled in Queterero will be available in April.

During the February 16, 2021 daily briefing, the government provided **updated information regarding expected shipments of vaccines from expected sources as follows (in doses).** The total below provides Mexico with 232.33 the million doses needed to cover the entire country.

- CoVax 15.5 million (not yet approved)
- AstraZeneca 77.4 million
- Pfizer 34.4 million
- CanSino 35 million
- Sputnik V 22 million
- SinoVac 22 million

Where are we now?

Phase 1: The Mexican government has extended Phase 1, vaccination of health personnel to ensure that all health personnel receive their second dose of the vaccine. According to the Daily Briefing, as of February 17, 2021, *16% of health personnel have received their second dose*. The Pfizer vaccine is only for the use of health worker's second dose, plus a small reserve for contingencies. As noted above, more of the Pfizer vaccine came last Sunday and more is expected this month.

• Health Personnel registration for the vaccine: If you are a health worker, the following link will take you to the government registration site for the vaccine: <u>https://vacunascovid.gob.mx/</u>. At the current time, the site states that the vaccine link is *exclusively for health personnel who work in COVID*.

Phase II: Vaccination of the elderly began on February nationwide on February 15 (except for two states whose climate has delayed start-up). All those over 60 years of age are eligible.

- **Registration of the elderly for the vaccine:** The government has set up a website that will allow those over 60 years of age to register for a vaccine. The site: <u>https://mivacuna.salud.gob.mx/</u>. The site is in Spanish. If you have trouble entering the site, try using a newer computer or a different device or browser, or just keep trying. The site is very busy. Once you are registered, someone from a Brigade and vaccination site near you will get in touch to give you an appointment. There is also a virtual button on the coronavirus.gov.mx website noted below. Here is a link to instructions on how to register: https://www.covid19sma.com/vaccination-registration-and-curp-instructions
- **Phone calls to the elderly:** Members of the vaccination brigades are calling the homes of the elderly to ask if they intend to take the vaccine and if they plan to go personally to the vaccination location nearest to their home. <u>https://coronavirus.gob.mx/vacunacion-covid/</u>
- Approach: According to the Mexico's National Vaccination Policy, Version 4, January 11, 2021 <u>https://coronavirus.gob.mx/wp-content/uploads/2021/01/PolVx_COVID_-11Ene2021.pdf</u>, Vaccinations for the elderly are being given by brigades made up of trained public servants and volunteers. The effort is referred to as Operativo Correcaminos. Each brigade will be set up in one of 10,000 Integrated Centers, to be located in the geographical center of 280,000 small, disperse communities in the country. There are currently over 700 of these centers nationwide.

Centers are located where the elderly are accustomed to receive their pensions (a school, rural medical unit, a plaza, etc.). Each Center will vaccinate 300 elderly adults each week. In this way, Mexico will immunize a total of 3 million elderly persons in remote areas.

Once the Centers are installed, the persons will receive their vaccine when they receive their bi-monthly pension. If the person does not come, a brigadista will go to their home. A group of authorities from the communities surrounding each Center will send a report of the vaccination campaign to the capital of each state.

Following this, vaccinations will proceed in the 2,500 municipalities or municipal heads, and then the largest cities. When the same brigades reach the large cities, they will work together, with each brigade responsible for vaccinating 300 persons a week.

Once all of the elderly are vaccinated, vaccination will continue with persons under 60 who have chronic diseases, and with teachers under 60 years of age.

• Why is the government starting with rural areas?

During the Conferencia de Prensa Matutinta on February 16, 2021, the government explained why the vaccination plan focuses first on rural areas. Rural areas in Mexico have been traditionally underserved, and the rural population neglected. This has had repercussions only in health but also in access to education and economic opportunities. The impact of this inequity has also been felt during the COVID-19 epidemic. As a result, the rural population has death rates that are half again more than (12%) those of the urban population (8%).

• When will urban vaccination begin?

According to the February 17, 2021 daily briefing, **Pfizer will be sending additional shipments in February** to complete the vaccination of health workers. It is expected that **400,000 doses will be available from those shipments for the vaccination of the elderly in urban areas.** Pfizer has stringent refrigeration requirements which makes it ideal for urban areas, in comparison to the AstraZeneca vaccine which requires only normal refrigeration.

• Vaccination of Foreigners over 60 years of age living in Mexico:

The Mexican government has confirmed its intention to vaccinate all foreigners living in Mexico. Vaccines will be free. As explained above, foreign residents over 60 years of age should register for a vaccine on the site <u>https://mivacuna.salud.gob.mx/</u>.

It is important that you register so that the state of Guantajuato knows how many elderly persons it needs to vaccinate. The number of doses it receives from the national level depends on those estimates!

• You may not need a CURP number!

February 6, 2021: During the Coronavirus Daily Briefing, Director of Surveillance Epidemiology of Noncommunicable Diseases of the Ministry of Health, Gabriela del Carmen Nucamendi Cervantes stated that the migrant population is also considered in the vaccination strategy, and the lack of the Unique Population Registry Code (CURP) is not an impediment to receiving the vaccine. The National Vaccination Policy against the SARS-CoV-2 virus for the prevention of COVID-19 in Mexico is inclusive for all groups in vulnerable situations: "the right to health is universal."

In order to register for a vaccine, the current registration site still requires a CURP number. If you are a Permanent or Temporary Resident, you probably have one. CURP stands for *Clave Única de Registro de Población* in Spanish, or Unique Population Registration Code in English. It functions similarly to social security numbers or fiscal codes in other countries. Every number is unique to the person it identifies. Once you <u>acquire residency in Mexico</u>, you can request your CURP. Firstly, check this address to see if your CURP is already available online: <u>www.gob.mx/curp</u>. If it is not available from this site, then print out the form you used in your search online. You can use this when you request the CURP from your local immigration (INM) office. For instructions on locating or applying for your CURP, please visit: <u>https://www.covid19sma.com/vaccination-registration-and-curp-instructions</u>.

• What do I need to take with me when I go to get vaccinated?

At first vaccine points were taking people's photos and photos of their documents. This has caused some concern about the possible political use of the information, so in the February 17, 2021 daily briefing, Dr. Gatell announced that this would cease. He informed that the following information would be necessary, and used for follow-up:

- A legal document with your Name and CURP number
- Your address
- Telephone number

When you are there, they will take down health information, note the type of vaccine you had and the lot number (and probably when you need to come back), and your registration number.

When you go to get vaccinated, make sure you have eaten and are well hydrated. Take something to sit on and an umbrella as there may be lines.

• NOTE!!!

Dr. Gatell emphasized that people should NOT TRY TO GET VACCINATED IN A MUNICIPALITY WHERE THEY DO NOT LIVE as that is illegal. Each municipality gets their doses according to their population

So now I have my two vaccines....?

• How protected am I from getting sick with symptoms?

Researchers estimate vaccine efficacy by comparing cases between those with the vaccine and those without in clinical trials. For instance, In the Pfizer trial there were 8 cases of COVID-19 that occurred in the 22,000 people who got the vaccine. (So in the trial the risk of getting ill, if you were vaccinated, was only around 8/22,000 = 0.04%.) This compared with 162 cases in the 22,000 people who got the placebo. Researchers allocated people at random, so we can be sure the vaccine caused this difference. Since 8/162 = 5%, we estimate the efficacy of the vaccine as 95% for symptomatic illness. AstraZeneca has an estimated efficacy of 70% for stopping symptomatic disease (3/101 cases). Your immune system is in full force 14 days after the second shot.

• Can I get the virus without symptoms and give it to other people?

There are two main types of immunity you can achieve with vaccines. One is so-called "effective" immunity, which can prevent a pathogen from causing serious disease, but can't stop it from entering the body or making more copies of itself. The other is "sterilizing immunity", which can thwart infections entirely, and even prevent asymptomatic cases. The latter is the aspiration of all vaccine research, but surprisingly rarely achieved. They can hide out in the nose or the back of the throat, from where they are able to infect others via sneezing, coughing, kissing, or sharing cigarettes or utensils. So far, the available Covid-19 vaccines have not been judged primarily on their ability to prevent transmission. Until we have that information and have achieved <u>herd immunity</u>, whereby the virus can't infect most of the population, we need to adhere to the standard risk mitigation protocols: masking, hand-washing, distancing, and avoiding poorly ventilated, crowded indoor spaces."

• Can I hug other vaccinated people?

We all want life to go back to normal. We all want to hug our loved ones, our friends, our grandchildren. Can we do that once we are vaccinated? This will depend on your tolerance for risk as far as I can tell. Some recommend that you should only hug others who have been vaccinated. Others say not even then because you don't know whether you or the other person has mounted an adequate immune response to the vaccine. Some say you can hug your grandchildren if you both wear masks.

New strains of the virus also add unknowns.

Viral Variants

Why are we looking for them?

According to CDC, viruses generally acquire mutations over time, giving rise to new variants, and their mutants. For instance, another variant has recently emerged in Nigeria. CDC is also monitoring this strain but, at this time, it has shown no concerning characteristics to public health experts. Some of the potential consequences of emerging variants are the following:

- Ability to spread more quickly in people. There is already evidence that one mutation, D614G, confers increased ability to spread more quickly than the wild-type SARS-CoV-2. In the laboratory, 614G variants (associated with the B.1 lineage) propagate more quickly in human respiratory epithelial cells, outcompeting 614D viruses. There also is epidemiologic evidence that the 614G variant spreads more quickly than viruses without the mutation.
- Ability to cause either milder or more severe disease in people. In January 2021, experts in the UK reported that the B.1.1.7 variant may be associated with an increased risk of death compared to other variants. More studies are needed to confirm this finding.
- Ability to evade detection by specific viral diagnostic tests. Most commercial reverse-transcription polymerase chain reaction (RT-PCR)-based tests have multiple targets to detect the virus, such that even if a mutation impacts one of the targets, the other RT-PCR targets will still work.
- Decreased susceptibility to therapeutic agents such as monoclonal antibodies.
- Ability to evade natural or vaccine-induced immunity. Both vaccination against and natural infection with SARS-CoV-2 produce a "polyclonal" response that targets several parts of the spike protein. The virus would likely need to accumulate multiple mutations in the spike protein to evade immunity induced by vaccines or by natural infection.

What are the main viral variants detected in the world so far?

According to a recent update from CDC dated February 2, 2021, Multiple SARS-CoV-2 variants are circulating globally. <u>https://www.cdc.gov/coronavirus/2019-ncov/transmission/variant.html.</u>Several new variants emerged in the fall of 2020, most notably:

- **B.1.1.7:** The United Kingdom (UK) identified a variant called B.1.1.7 with a large number of mutations in the fall of 2020. This variant spreads more easily and quickly than other variants. In January 2021, experts in the UK reported that this variant may be associated with an increased risk of death compared to other variant viruses, but more studies are needed to confirm this finding. It has since been detected in 70 countries around the world. This variant was first detected in the US at the end of December 2020.
- **B.1.351**: In South Africa, another variant of SARS-CoV-2 known as B.1.351 emerged independently of B.1.1.7. According to a non-peer-reviewed preprint article, this variant shares some mutations with B.1.1.7^[3]. Cases attributed to B.1.351 have been detected outside of South Africa, and this variant was first detected in the US at the end of January 2021. Preliminary evidence from non-peer-reviewed publications suggests that the Moderna mRNA-1273 vaccine currently used in the US may be less effective against this variant but additional studies are needed.
- P.1: In Brazil, a variant of SARS-CoV-2 known as P.1 emerged; it was first identified in January 2021 in travelers from Brazil who arrived in Japan. This variant was detected in the US at the end of January 2021¹. The P.1 variant has 17 unique mutations, including three in the receptor binding domain of the spike protein (K417T, E484K, and N501Y), according to non-peer-reviewed preprint articles. There is evidence to suggest that some of the mutations in the P.1 variant may affect the ability of antibodies (from natural infection or vaccination) to recognize and neutralize the variant virus, but additional studies are needed.

One specific mutation, called D614G, is shared by these three variants. It gives the variants the ability to spread more quickly than the predominant viruses, as described in a non-peer-reviewed preprint article. There also is epidemiologic evidence that variants with this specific mutation spread more quickly than viruses without the mutation. This mutation was one of the first documented in the US in the initial stages of the pandemic, after having initially circulated in Europe.

Viral Variants in Mexico

The UK Variant (B1.1.7) On January10, 2021 the Secretaria de Salud of Mexico confirmed the first case of a new COVID-19 variant in Mexico. It was brought into Mexico on December 29, 2020 by a 56 year-old traveler from Amsterdam who first arrived in Mexico City, then traveled to Tamaulipas. Upon arrival, the individual was confirmed positive for COVID-19 and the sample was sent to INDRE for sequencing. The individual arrived asymptomatic. Authorities conducted contact tracing with those persons who were at least 6 feet from the person for at least 20 minutes and had no protection. The affected individual was put into isolation and attended by a doctor. On January 4, 2021, the individual was admitted to hospital and is currently intubated. All Secretaries of State were notified. All contacts in both flights were tested and followed up for symptoms, including the crews. None showed evidence of the variant. 12 were lost to contact tracing. The case was reported to the WHO, as the first in Latin America. As of January 10, 2021, Indre has studied 500 samples in search of the UK variant, but has yet to find another.<u>https://coronavirus.gob.mx/.https://www.gob.mx/salud/prensa/009-confirma-secretaria-de-salud-primer-caso-de-nueva-variante-de-sars-cov-2?idiom=es</u>

Will current vaccines in Mexico protect against the new Variants?

At the present time, information is slowing coming in from reliable sources regarding the ability of vaccines approved in Mexico to protect against the UK variant, B117. Those will be reported as to you as soon as we find them.

<u>Pfizer:</u> Researchers tested 10 mutations of the B117 variant, which was first identified in the UK against the Pfizer vaccine. <u>The study, published on bioRxiv.org</u> prior to peer review, showed that antibodies in the blood of vaccinated patients were able to neutralize a version of the new variant. For the test, blood samples drawn from 16 vaccinated participants in prior clinical trials were exposed to a synthetic virus that was engineered to have the same surface proteins as B.1.1.7, sometimes referred to as "the UK variant." The team found that levels of antibodies against the coronavirus's spike protein declined over six months. But participants' levels of memory B cells specific for making antibodies against the spike protein remained constant. The researchers sampled the intestines of 14 participants 4 months after infection and found that half had persistent SARS-CoV-2 protein or RNA, potentially providing a continued source of stimulation to the immune system.

<u>AstraZeneca</u>: The AstraZeneca vaccine has run into trouble in South Africa, showing less protection there than elsewhere because a SARS-CoV-2 variant that can apparently dodge key antibodies has become widespread in that country. In the wake of the new finding, the country halted plans to next week to launch the country's first immunization campaign with AstraZeneca and may instead switch to a different one. The stakes are high globally for this particular vaccine because its makers, AstraZeneca and the University of Oxford, hope it will be widely used in developing countries; they project they can produce 3 billion doses this year for about \$3 each, far more product at a far lower price than any other vaccine shown to offer protection against COVID-19.

Detail on the five approved vaccines

The SARS-CoV-2 virus is studded with proteins that it uses to enter human cells. These so-called *spike proteins* make a tempting target for potential vaccines and treatments.

<u>The Pfizer vaccine</u> is an mRNA (messenger ribonucleic acid) vaccine. The AstraZeneca and the Sputnik V vaccines are viral-vector vaccines. These vaccines contain instructions for the COVID-19 spike proteins carried in vectors that dissolve, leaving the spike protein instructions to trigger an immune response.

Unlike the Pfizer vaccine, which stores the instructions for the spike protein in single-stranded RNA, <u>the</u> <u>AstraZeneca</u> vaccine uses double-stranded DNA. The DNA for the spike protein is added to another virus called an adenovirus. Adenoviruses are common viruses that typically cause colds or flu-like symptoms. The AstraZeneca vaccine uses a modified version of a chimpanzee adenovirus that causes colds in chimpanzees. It can enter human cells, but it can't replicate inside them.

<u>Sputnik V</u> has one key, clever difference from the AstraZeneca vaccine: It uses one adenovirus for the first dose (adenovirus-26) and a different adenovirus (adenovirus-5) for the second dose. In this way, it avoids the possibility of immunity to the first dose impacting the ability of the second dose to work efficiently. One issue is that a large percentage of people have pre-existing immunity to adenovirus-5, but that's not a huge drawback if the efficacy is very high. A potentially promising alternative would be to try a combination of adenovirus-26 for the first shot and AstraZeneca's adenoviral vector – made from a chimp adenovirus – for the second, which is exactly what the AstraZeneca and Sputnik V have agreed to do in a collaboration announced on Dec.11, 2020.

<u>CanSino:</u> AD5-nCOV, trade-named Convidicea, is a single dose COVID-19 vaccine developed by the Chinese biopharmaceutical company CanSino Biologics. Development of AD5-nCOV began in early 2020 and entered Phase I testing in March and Phase II testing in April. Beginning in August 2020, it has been in global Phase III trials. Convidicea is a viral vector vaccine similar to AstraZeneca and Sputnik V. It uses the adenovirus-5 as the viral vector.

<u>SinoVac</u>: SinoVac, trade named CoronaVac is different from the other four vaccines approved to date in Mexico in that is not an mRNA or a viral vector vaccine. Instead, it is a *whole virus, inactivated vaccine*. Whole virus vaccines use a weakened (attenuated) or deactivated form of the pathogen that causes a disease to trigger protective immunity to it. There are two types of whole virus vaccines. *Live attenuated* vaccines use a weakened form of the virus, which can still grow and replicate, but does not cause illness. *Inactivated vaccines* contain viruses whose genetic material has been destroyed by heat, chemicals or radiation so they cannot infect cells and replicate, but can still trigger an immune response. Both are tried and tested vaccination strategies, which form the basis of many existing vaccines – including those for yellow fever and measles (live attenuated vaccines), or seasonal influenza and hepatitis A (inactivated vaccines).

Phase Three Trials

All vaccines have gone through or are going through three phase trials. Scientific data has been submitted and approved by the Mexican equivalent of the US FDA, which is called the Comision Federal para la Proteccion Contra Riesgos Sanitarios (COFEPRIS). Given the seriousness of the COVID-19 virus and its virulence, the third phase trial requirement has been shortened for emergency approval here in Mexico, as it has been in the US. If no significant negative impact on human subjects is detected during the third phase, the vaccine can be considered for emergency approval.

<u>Pfizer</u>: Pfizer randomly assigned 37,000 trial participants to receive either two shots of the vaccine or two saline shots (placebo). They waited for 7 days after the second shot for the immune response to occur and then counted any COVID-19 cases that occurred 7 days *after that* in both groups. Out of the 170 cases that occurred, only 8 were in the group vaccinated and the rest were in the group given the placebo. Four cases of Bell's Palsy occurred, and an allergic reaction occurred in 3 individuals within around 10 minutes after they were given the shot. These were mainly in those who had prior allergic reactions to other drugs, but not all. Otherwise, the only negative reactions were fatigue and headaches after the second dose, pain at the injection site and muscle pain. To date, the occurrence of negative reactions has not been frequent or serious enough to prevent approval or take the vaccine off of the market.

<u>AstraZeneca</u>: The University of Oxford partnered with the British-Swedish company AstraZeneca to develop and test the AstraZeneca vaccine. This is also a two-dose vaccine, given four to twelve weeks apart in the four trials conducted in the UK, Brazil and South Africa. Over 20,000 participants were enrolled, assigned to the vaccinated and placebo groups. On December 8, 2020, <u>*The Lancet*</u> confirmed that AstraZeneca was well tolerated and that there were no serious safety events confirmed related to the vaccine. The participants were from diverse ethnic and geographic groups who were healthy or had stable underlying medical conditions.

AstraZeneca has already been granted conditional marketing authorization (CMA) or emergency use in 20 countries, spanning four continents including a number of Latin American countries, India, Morocco and the UK. Phase III trial results are being released on a rolling basis. AstraZeneca's COVID-19 vaccine has been recommended for CMA in the European Union (EU) for active immunization to prevent COVID-19 caused by SARS-CoV-2, in individuals 18 years of age and older.<u>https://www.astrazeneca.com/media-centre/press-releases/2021/covid-19-vaccine-astrazeneca-recommended-for-use-in-the-eu.html</u>

Interestingly, a recent primary analysis of the Phase III clinical trials from the UK, Brazil and South Africa, was published as a <u>preprint in *The Lancet*</u> on February 2, 2021 showing that AstraZeneca efficacy after a single standard dose of vaccine from day 22 to day 90 post vaccination was 76%, and that *protection did not wane during this initial 3-month period*. Similarly, *antibody levels were maintained during this period with minimal waning by day 90 day*. Authors concluded that *vaccination programs aimed at vaccinating a large proportion of the population with a single dose, with a second dose given after a 3-month period* is an effective strategy for reducing disease, and may be the optimal for rollout of a pandemic vaccine when supplies are limited in the short term.

<u>Sputnik V:</u> Russia's Sputnik V vaccine demonstrated *efficacy of 91.6% against Covid-19*, according to interim results of Phase 3 trials published Feb. 2, 2021in <u>The Lancet</u>. Nearly 20,000 volunteers were enrolled in the efficacy analysis – 75% received the two-dose vaccine and 25% received the placebo. After 21 days, the vaccine group displayed only 16 cases of symptomatic Covid-19, while 62 cases were found in the placebo group -- equating to an efficacy of 91.6%. The results suggest Sputnik V is among the top performing vaccines, alongside Pfizer and Moderna.

In analyzing efficacy against severe and moderate Covid-19 disease -21 days after the first dose - researchers found no severe or moderate cases in the vaccinated group, while 20 placebo group participants developed severe or moderate illness. Serious adverse events were also rare, reported by less than 0.2% of vaccine recipients. Most side-effects were defined as mild, such as pain at the injection site, flu-like symptoms and low energy levels. Importantly, the trial included 2,144 people over 60, and results revealed the vaccine was well tolerated and had a similar efficacy of 91.8%.

<u>CanSino (Canvidicia)</u>: CanSino is currently in global phase III trials in Argentina, Chile, Mexico, (Aguascalientes, Mexico City, Coahuila, Durango, Guerrero, Oaxaca, Michoacan and Quintana Roo), Pakistan, Russia, and Saudi Arabia with around 40,500 participants using a single dose administration. Half of the participants receive the vaccine and half are in the control group. Participants are healthy adults aged 18 and older. The trial excludes those who are immune-compromised and pregnant. The primary completion date is December 30, 2021, with the full study completion date is January 30, 2022.

In February 2021 data released from an interim analysis of global Phase III trials with 30,000 participants and 101 COVID cases, the vaccine had an efficacy of 65.7% at preventing moderate cases of COVID-19 and 90.98% at preventing severe cases. In the Pakistan trial subset, the vaccine had an efficacy of 74.8% at preventing symptomatic cases and 100% for preventing severe disease. No information has been provided to date on adverse effects.

<u>SinoVac (CoronaVac)</u>: On Feb 2, 2021, SinoVac released preliminary findings from its Phase III trials of the vaccine CoronaVac, which began on July 21, 2020. Trials were conducted with in Brazil, Turkey, Indonesia, and Chile. The findings only report on the results from the trials in Brazil and Turkey. The phase III trials conducted in Brazil and Turkey evaluated the efficacy of the vaccine in healthcare workers who provide treatment to COVID-19 patients. Both trial studies were randomized, double-blind, and placebo-controlled. The two trials shared the same primary endpoint of an efficacy rate 14 days after the vaccination with either vaccine candidate or placebo. As of December 16, 2020, there were 12,396 health workers over 18 years old and under 59 enrolled. A total of 253 positive COViD-19 cases were collected during the observation period. After 14 days following vaccination with 2 doses of the vaccine following a 0, 14 day schedule, the efficacy rate against diseases caused by COVID-19 was 50.65% for all cases, 83.70% for cases requiring medical treatment, and 100.00% for hospitalized, severe, and fatal cases. No information has been provided on the incidence of adverse effects.

The Cold Chain and the approved vaccines

The *Cold Chain* refers to the chain of different cold storage devices (cold containers, refrigerators, ice chests, thermoses, vials, etc.) that are critically needed to maintain a vaccine at its required temperature as it moves on its journey from the manufacturer to the moment it is injected into people's arms.

Approved COVID-19 vaccines are being flown to Mexico from the manufacturer at critically defined temperatures, then moved quickly to their destinations. If at any point during the chain (air-cargo, trucking, hospital storage, transfer to remote clinics, etc.) the vaccine deviates from its required temperature, the vaccine will expire and cannot be used. As you can imagine, unintentional breaks in the chain could happen any place along the journey from the manufacturing plant to your arm. Breaks in the Cold Chain result every year to in a loss of many different types of vaccines. Although this can happen anywhere, in any country, the cold chain is especially challenging in countries like Mexico, with scarce resources and disperse rural communities.

Having said that, however, with assistance from the WHO, the Pan-American Health Organization and UNICEF, developing countries often have more experience than developed countries in mounting large-scale vaccination campaigns. The brigade concept being put into practice by the Mexican government for the vaccination of the elderly is an example of that.

<u>The Pfizer vaccine</u> is especially tricky since it must be kept at a continuous -94F (-70C) from the manufacturer to the place where it will be stored – usually a hospital that is capable of storing vaccines at extremely low temperatures. The State of Guanajuato has said it is confident it will be able to ensure the cold-chain for the Pfizer vaccine. The Policy states that the Pfizer vaccine will be kept at -70C in super-freezers and thawed before use, e ach vial of five doses to be applied in less than six hours so that the vaccine stays intact.

<u>The AstraZeneca vaccine</u> cold chain will also be easier to handle as long as there is refrigeration. The AstraZeneca vaccine for Covid-19 is more rugged than the mRNA vaccines from Pfizer. DNA is not as fragile as RNA, and the adenovirus's tough protein coat helps protect the genetic material inside. As a result, the AstraZeneca vaccine doesn't have to stay frozen. The vaccine is *expected to last for at least six months when refrigerated between two and eight degrees C (38–46°F)*.

<u>The Sputnik V vaccine can be formulated as frozen and freeze-dried forms</u>. The first formulation was developed for large-scale use. It is cheaper than other vaccines, is easier to manufacture and will be easy to handle as long as there is refrigeration.

<u>The CanSino:</u> vaccine has a normal refrigerator storage requirement (2°to 8°C) that could make it a favorable option for many countries, including Mexico.

<u>The SinoVac vaccine</u> also does not need to be frozen, and both the vaccine and raw material for formulating the new doses could be transported and refrigerated at 2–8 °C (36–46 °F), temperatures at which flu vaccines are kept. CoronaVac could remain stable for up to three years in storage, which might offer some advantage in vaccine distribution to regions where cold chains are not developed.

Private and illegal sources of vaccines

The Federalist Alliance and National Action – State Governors not authorized to purchase

The Guanajuato State Governor, Diego Sinhue Rodriguez Vallejo stated in an interview with the press that the governors of Mexico who had been previously authorized to purchase vaccines against COVID-19 by the Mexican President will *not be able to exercise that right until the end of the year or early 2022* because the production of biologicals authorized by COFEPRIS is insufficient for the great demand that it exists.

He said that both the state governors of the Federalist Alliance and those of National Action are making the effort to buy vaccine and make it available for sale by the end of this year or the beginning of the coming year. "We are

waiting for other options, we can work with those that COFEPRIS is authorizing, which until yesterday were AstraZéneca and Pfizer. Now they are looking at the Russian vaccine and we will be exploring the options."

He assured that the resource for the acquisition is ready so "now what we need is availability, let's remember that all countries have fallen short in the expectation of vaccines because no vaccines are already authorized but producing them takes months. Hopefully soon we can have vaccines for everyone "he said.

COFEPRIS warnings against illegal private sales of COVID-19 vaccines:

- February 17, 2021 warning against the illegal private sale of Pfizer vaccine
- 3 de February 2021, COFEPRIS warns against the illegal private sale of the AstraZeneca vaccine
- January 22, 2021, COFEPRIS warns against the illegal private sale of the Moderna vaccine

Warning regarding criminal vaccine sales

Interpol issued a <u>global alert</u> to law enforcement last December warning of the potential falsification, theft, and illegal advertising of COVID-19 and flu vaccines. "Criminal networks will also be targeting unsuspecting members of the public via fake websites and false cures, which could pose a significant risk to their health, even their lives," said Interpol's Secretary General, Jürgen Stock. Interpol also reported a rise in COVID-related fraud. Last year its Cyber Security Unit revealed that, of 3,000 websites associated with online pharmacies suspected of selling illicit medicines and medical devices, around 1,700 contained cyber threats.

Last week, Raúl Sapién Santos, presidente del Consejo Nacional de Seguridad Privada (CNSP) de México. warned *that criminal organizations are already advertising online fake vaccination campaigns and counterfeit vaccines*. He told the news agency EFE that the Consejo had detected more than 400 fake websites that advertise COVID-19 vaccines. He said that these false domains also offer medical equipment for sales, such as masks, rapid tests and oxygen.

That is one reason why the government prefers not to open vaccination to private purchase and sale. Restricting vaccination to public distribution and free application, prevents possible entry into the market for criminal organizations.

And that's it for now! I hope this has been useful.