

Vaccine Campaign SARS-CoV-2 2020

2018

2018

Contents

1. Background & objectives.....	3
2. Strategy based on Survey.....	5
3. Key messages.....	7
4. Campaign Audience.....	8
5. Campaign Materials.....	9
6. Modes of dissemination.....	12
7. Timeline.....	15
8. Evaluation.....	15
Annex 1:.....	13
Annex 2:.....	17

CONFIDENTIAL

1. Background & objectives

The nearly yearlong corona virus pandemic has brought with it many challenges for the Aruban community. As the cases slowly continues to rise in Aruba for SARS-CoV-2, with total positive cases nearly 5350 with 49 death, the stress of the disease is beginning to take a toll on the community in general. The health care workers have learned how to treat the symptoms of COVID-19, but it seems that it is a never-ending battle. These gloomy days might be over with the new COVID-19 vaccine. As we all know the best way to reach herd immunity is through vaccination.

A vaccine acceptance survey has been conducted in the healthcare sector in Aruba. It remarkable that the HOH nor the IMSAN have not contributed to this survey. It is necessary for them to collaborate in this survey as they are first called to be vaccinated according the "Introductie COVID-19 Vaccinatie" plan 2021. Nevertheless, the preliminary results of the survey are in. A total of 157 health care workers have contributed to the survey. Of these healthcare workers the largest age group where, 27% where between the ages of 55-64, 22% where age group 54-45 and 26% where between the ages of 44-35. A total of 76% has direct contact with COVID-19 patients. 46% of the healthcare workers are uncertain to take the vaccine, 18% is certain and 18% is more than likely to take it, 7% wil most likely not take the vaccine and 17% is certain not to take it. The most common reason to vaccinate are: 20% want to protect the most vulnerable, 17% want to protect themselves against the virus, 11% wants to stay healthy, 9% wants that kids can go to school unhindered and 7% wants that the public measurement against coronavirus are abolished. The most common reason not to vaccinate are: 27% wants more information on the vaccines, 26% thinks more research is needed on the safety of the vaccine, 24% thinks more research is needed on the effectivity of the vaccine, 20% are afraid of severe side effects. Only 4% thinks that the vaccine is not safe, 2% have already contracted COVID and 2% have thinks healthy lifestyle and do not need a vaccine.

There are two vaccine that have been approved mRNA-1273 and BNT162b2. Both these vaccines are mRNA-based vaccine which means that the vaccine contains a molecule

called “messenger RNA” (mRNA) with instructions for producing a protein from SARS CoV-2, the virus that causes COVID-19. These vaccines do not contain the virus itself and cannot cause COVID-19. BNT162b2 also named Comirnaty (Pfizer) has been approved by the European Union and mRNA also named Moderna Covid-19 Vaccine (Moderna) has been approved in the US and Canada. As of date of writing the European Union is also planning to approve the Moderna Covid-19 Vaccine. As part of the Kingdom of the Netherlands, Aruba will be receiving a combination of Comirnaty and Moderna.

The objective of this campaign is to raise awareness by informing the general public on the how the vaccine work, how safe is it and the importance of acquiring the vaccine. This campaign will encourage the general public to vaccinate against SARS-CoV-2 in order to prevent them and others from becoming ill from COVID-19. The vaccines are given by the medical staff of DVG. The focus group will be:

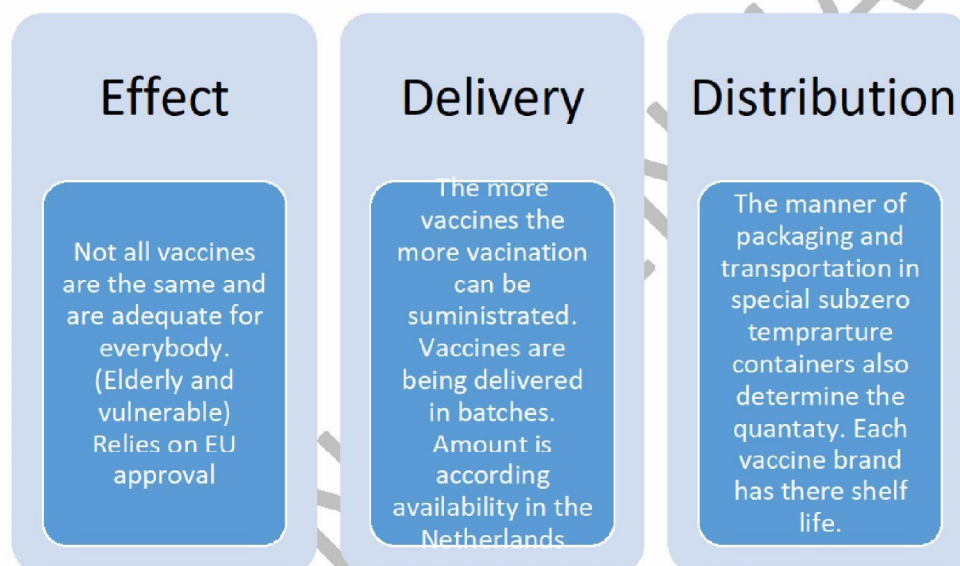
1. Acute health care workers.
2. Clients nursing, elderly care homes, special care homes and rest of health care workers
3. Rest of the population (accordingly to morbidity list provided by HAVA)

The campaign will entirely be in Papiamentu. This document is presented in English so that it can be easily shared with international partners.

2. Strategy based on survey

Starting point

As per information received from the Netherlands a very limited amount of vaccine are available and will be delivered in batches. The time frame of logistics between send date and delivery is still not yet known. The strategy of vaccination will have strongly on the information approval of vaccines from EU, type of vaccine approved, effect, distribution and delivery.



Also the vaccination acceptancy of the public should be taken in consideration. The timeline when these vaccine will be injected also rely strongly on this information, therefore a concrete timeline is not possible. Changes in strategy are very real and the strategy relies strongly on advice from RIVM or new developments.

Predisposition to take the vaccine in Healthcare workers

According to the survey 46% of the healthcare workers are uncertain to take the vaccine, 18% is certain and 18% is more than likely to take it. This means that around 36% of the health care predisposed to take the vaccine. From the group not 24% will not take it or most likely not to take it. The most common reason to vaccinate is that health care workers want to protect the most vulnerable and themselves (37%). Only 7% wants that public measurement are abolished. This is obvious since healthcare workers are more disposed and trained in this manner of thinking. A 75% of the health care workers believe that more information is needed, and more research is needed on the safety and effectivity of the vaccines, while 20% of Health care workers are afraid of the side effects of the vaccine.

Healthcare workers are well trained in hygiene and follows strict precautionary protocols. It is usual for protecting others and themselves the results of the survey also shows this type of thinking. What is remarkable to see is that healthcare workers are not very informed on the matter of the COVID vaccine with nearly 75 procent believes they need more information, and more research is needed on the safety and effectivity of the vaccines. Looking at the numbers more closely we believe that around 36 % of the healthcare worker are already certain or leaning towards taking the vaccine. Little effort should be given on this group but could use this group into leveraging our message as they can be used as testimonials group who have successfully taken the vaccine with no or little side effect. However, there is nearly 50% of healthcare workers who have many doubt in taking the vaccine. The reasons as shown in the survey are.

- Lack of information
- Uncertainty
- Fear

More information on general public and from IMSAN and HOH is needed in order to better define our strategy goals in vaccination campaign.

CONFIDENTIAL

3. Key Messages

- COVID-19 Vaccines save lives and protect against the spread of disease.
- COVID-19 Vaccines work to protect people of all ages from potentially dangerous diseases.
- When all eligible individuals are fully vaccinated those, who cannot be vaccinated are also protected through herd immunity.
- Get vaccinated at our community outreach facilities (MFA).
- Immunization keeps us protected together.
- How vaccines work.
- What you need to know about the COVID-19 vaccine.
- Vaccine is safe.

CONFIDENTIAL

4. Campaign audience

- ✓ Healthcare worker:
 - Emergency medical service personnel
 - Nurses and nursing assistant
 - Physicians
 - Dentists, Dentist hygienist, assistant and Technicians

- ✓ People older than 60

- ✓ Frontline workers and Public servant

- ✓ People with non-communicable disease/ underlying conditions

- ✓ Population of > 18 years of age

- ✓ Undocumented people on the island

CONFIDENTIAL

5. Campaign Materials

Information

A complete information on Comirnaty and Moderna COVID-19 Vaccine, will be provide on the website of www.arubacovid.org and on www.dvg.aw. With an Overview of the vaccine, authorization details of the vaccine, product information of the vaccine and assessment history of the vaccine.

A specific FAQ on Comirnaty

Also on the website mentioned above a specific frequently asked questions and answers on Comirnaty will appear (See Appendix)

Information for general public

Main idea:

We are restricted in doing many things that are part of our normal live! By taking vaccine we can get our freedom back.

- Video will be shown in cinemas as well as on social media
- A radiospot.
- Mediatour
- Daily facebook "bo tabata sa?" on Comirnaty/ Moderna(?)
- Testimonial videos
- Infographic on billboards
- Life Facebook sessions with doctors?

No ads have been developed yet.

Radio spot script:

We will make use of the <http://coronavaccinatie.nl/> to get al the communication material for the campaign. Aruba will adapt the information to the Aruban context. But will make sure that the information stays the same for the public.

Audio:

- We all desire a time were we are completely free from Coronavirus measures.
- Every approved vaccine has been tested on more than 10,000 people.

- In this manner we can be sure that it is safe and effective to be used while being protected from the virus.
- Every shot of the vaccine against Coronavirus is one step closer to regaining our freedom back.
- It is perfectly understandable if you have more question
- For answers please visit www.dvg.aw and www.arubacovid19.org

Duration: 33 seconds

Video spot script:

We will make use of the <http://coronavaccinatie.nl/> to get al the communication material for the campaign. Aruba will adapt the information to the Aruban context. But will make sure that the information stays the same for the public.

Duration: 1 minute (for online media), 30 seconds (for movies)

Audio:

- To protect yourself and others around you against Coronavirus is vaccination the most important step.
- So let's together roll-up our sleeves.
- If we let us get vaccinated, we will get little by little our freedom back.
- Every approved vaccine has been tested on more than 10,000 people.
- In this manner we can be sure that it is safe and effective to be used while being protected from the virus.
- It is perfectly understandable if you have more question
- For answers please visit www.dvg.aw and www.arubacovid19.org

Visual:

- Things you do on a daily basis: people going to supermarket, gym
- Hobbys and sport: going to the beach, group training
- A person with NCD rolling up there sleeves
- People social distancing in restaurant
- An elderly person taking shot while supported by family member
- The drama should be present where the new normal with mask and social distance and together we are all working to getting our freedom back.

Duration: 30 seconds

6. Modes of dissemination

Social media

- Ads and Videos will be boosted on Facebook and Instagram (Directie Volksgezondheid)
- Video can be put on DVG's Youtube channel
- Factsheets

Movie Theater

- Multiplex Caribbean Cinemas located at Palm Beach Plaza Aruba for two months before each movie appearance. Starting 2nd week of January 2021.
- Seaport cinemas Located at the Renaissance Mall and Paseo Herencia for two months before each movie appearance. Starting 2nd week of January 2021.

Magazine

- AZV's magazine Pulso.

Printed posters

A very limited amount of ads will be printed (poster size) and hung in the frames at DVG, HOH, IMSAM, Multifunctional facilities, Wit Gele Kruis, Supermarkets to showcase the on-going campaign and its material.

DVG will print folders to be handed at all households in Aruba. This is especially important for the elderly and/or people that do not have access to digital platforms.

Road signs

Posters will be put at the bus stations on different locations on the island. Especially those that are most used by the locals.

Mediatour

PR PLAN NEWSPAPER & SOCIAL MEDIA
CORONA VACCINE -JAN 2021-




PR Topic	Date	Remarks
Announcement Aruba preparing to get the vaccines	Jan 11th	PR send after the press conference
Vaccine what are the benefits of it? Why vaccinate against COVID-19? Explanation about the Rna vaccine.	Jan 13th	5.1.2e interview
Explaining the Vaccination strategy	Jan 15th	5.1.2e interview
Explaining the process of vaccination (GP, Downloading the Aruba Health and registration process before and after getting vaccinated)	Jan 21 st	5.1.2e interview
When the vaccines arrived	Mid feb	DVG
First person receiving the vaccine	Mid feb	DVG

CONFIDENTIAL

Radio tour:

CONFIDENTIAL

MEDIA TOUR INTERVIEWS RADIO & TELEVISION					 <small>DIRECTIE VOLKSGEZONDHEID</small>	
CORONA VACCINE -JAN 2021-						
MEDIA	CHANNEL	PROGRAM	DATE	HOUR	SPEAKER	
Television	TeleAruba	Programa Special	Jan 18th	7.30pm	5.1.2e	
		Serca Dika	Jan 13th	11am		
		Nos Mainta	Jan 14th	9.15am		
		Al Caso	Jan 15th	11am		
		Primera Plana (Spanish Program)	Jan 18th	8am - 9am		
		Canal 22	Programa Special	Jan 19th		7.30pm
		Canal 90 FM	Noon News - Enfoka 90	Jan 12th		1.30pm
Radio	Magic FM	Morning News with Erin Croes	Jan 12th	8.15am		
		Power FM	Morning Program with Ruben Garcia	Jan 13th		10.30am
			Bo Guia FM	Afternoon program with Mimi Carion		Jan 13th
		HIT 100FM	Morning News	Jan 14th		7.30am
			Top FM	Noon News		Jan 14th
		Caliente FM	Noon News	Jan 15th		10am
			Hit 94 FM	Noon News		Jan 15th

7. Timeline

Campaign will start by the second week of January 2021 till September 2021 (tentatively). There will be an evaluation after 6 months to evaluate if the campaign must be further extended.

8. Evaluation

Social media analytics

Numbers regarding likes, reach, shares will be tracked and the analytics on Facebook will also be followed closely.

Surveys

After 3 months and after 6 months DVG will send a survey to determine the willingness to take vaccine. The main idea is to get an idea why people are hesitant to vaccinate. This is important to focus the campaign to further motivate the population to get themselves vaccinated.

DBZ

Internal feedback and feedback on the working field is crucial to improving the campaign and if necessary, strategy change.

General Practitioners

Information will be gathered through the general practitioners to get an idea about the fears, anxiety of those who still needs to get vaccinated.

CONFIDENTIAL

Annex 1:

The NEW ENGLAND JOURNAL of MEDICINE

RESEARCH SUMMARY

Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine

F.P. Polack, et al. DOI: 10.1056/NEJMoa2034577

CLINICAL PROBLEM

Safe and effective vaccines to prevent severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and Covid-19 are urgently needed. No vaccines that protect against betacoronaviruses are currently available, and mRNA-based vaccines have not been widely tested.

CLINICAL TRIAL

A randomized, double-blind study of an mRNA vaccine encoding the SARS-CoV-2 spike protein.

43,548 participants ≥ 16 years old were assigned to receive the vaccine or placebo by intramuscular injection on day 0 and day 21. Participants were followed for safety and for the development of symptomatic Covid-19 for a median of 2 months.

RESULTS

Safety:

Vaccine recipients had local reactions (pain, erythema, swelling) and systemic reactions (e.g., fever, headache, myalgias) at higher rates than placebo recipients, with more reactions following the second dose. Most were mild to moderate and resolved rapidly.

Efficacy:

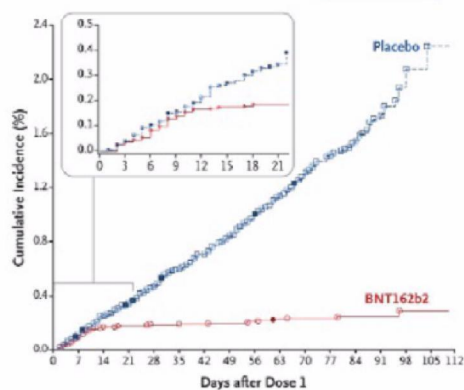
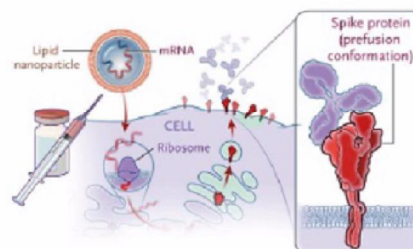
The vaccine showed some early protection 12 days after the first dose; 7 days after the second dose, 95% efficacy was observed.

LIMITATIONS AND REMAINING QUESTIONS

Further study is required to understand the following:

- Safety and efficacy beyond 2 months and in groups not included in this trial (e.g., children, pregnant women, and immunocompromised persons).
- Whether the vaccine protects against asymptomatic infection and transmission to unvaccinated persons.
- How to deal with those who miss the second vaccine dose.

Links: Full article | NEJM QuickTake | Editorial



	BNT162b2 Vaccine	Placebo
Symptomatic Covid-19	8	162
	N=18198	N=18125
Severe Covid-19	1	9
	N=21669	N=21686

Vaccine efficacy of 95% (95% credible interval, 90.3–97.6%)

CONCLUSIONS

Two doses of an mRNA-based vaccine were safe over a median of two months and provided 95% protection against symptomatic Covid-19 in persons 16 years of age or older.

Annex 2: Frequently Asked Questions

- How does a vaccine work?
 - ❖ COVID-19 vaccines help our bodies develop immunity to the virus that causes COVID-19 without us having to get the illness. Different types of vaccines work in different ways to offer protection, but with all types of vaccines, the body is left with a supply of “memory” T-lymphocytes as well as B-lymphocytes that will remember how to fight that virus in the future.
 - ❖ It typically takes a few weeks for the body to produce T-lymphocytes and B-lymphocytes after vaccination. Therefore, it is possible that a person could be infected with the virus that causes COVID-19 just before or just after vaccination and then get sick because the vaccine did not have enough time to provide protection.
 - ❖ Sometimes after vaccination, the process of building immunity can cause symptoms, such as fever. These symptoms are normal and are a sign that the body is building immunity.
- What are the types of Vaccines on COVID-19?
 - ❖ Currently, there are three main types of COVID-19 vaccines that are or soon will be undergoing large-scale (Phase 3) clinical trials in the or have been already approved. Below is a description of how each type of vaccine prompts our bodies to recognize and protect us from the virus that causes COVID-19. None of these vaccines can give you COVID-19.
 - ❖ mRNA vaccines contain material from the virus that causes COVID-19 that gives our cells instructions for how to make a harmless protein that is unique to the virus. After our cells make copies of the protein, they destroy the genetic material from the vaccine. Our bodies recognize that the protein should not be there and build T-lymphocytes and B-lymphocytes that will remember how to fight the virus that causes COVID-19 if we are infected in the future.
 - ❖ Protein subunit vaccines include harmless pieces (proteins) of the virus that cause COVID-19 instead of the entire germ. Once vaccinated, our immune system recognizes that the proteins don't belong in the body and begins making T-lymphocytes and antibodies. If we are ever infected in the future, memory cells will recognize and fight the virus.
 - ❖ Vector vaccines contain a weakened version of a live virus—a different virus than the one that causes COVID-19—that has genetic material from the virus that causes COVID-19 inserted in it (this is called a viral vector). Once the viral vector is inside our cells, the genetic material gives cells instructions to make a protein that is unique to the virus that causes COVID-19. Using these instructions, our cells make copies of the protein. This prompts our bodies to build T-lymphocytes and B-lymphocytes that will remember how to fight that virus if we are infected in the future.
- What are the world wide authorized and approved vaccines?

❖ As of 23 of December 2020:

Name	Vaccine Type	Primary Developers	Country of Origin	Authorization and Approval
BNT162b2	mRNA-based vaccine	Pfizer, BioNTech; Fosun Pharma	Multinational	UK, Bahrain, Canada, Mexico, US, Singapore, Oman, Saudi Arabia, Kuwait, EU
mRNA-1273	mRNA-based vaccine	Moderna, BARDA, NIAID	USA	USA, Canada
CoronaVac	Inactivated vaccine (formalin with alum adjuvant)	Sinovac	China	China
No name announced	Inactivated vaccine	Wuhan Institute of Biological Products; China National Pharmaceutical Group (Sinopharm)	China	China
Sputnik V	Non-replicating viral vector	Gamaleya Research Institute, Acellena Contract Drug Research and Development	Russia	Russia
BBIBP-CorV	Inactivated vaccine	Beijing Institute of Biological Products; China National Pharmaceutical Group (Sinopharm)	China	China and Saudi Arabia
EpiVacCorona	Peptide vaccine	Federal Budgetary Research Institution State Research Center of Virology and Biotechnology	Russia	Russia

- How is Comirnaty used?
 - ❖ Comirnaty is given as two injections, usually into the muscle of the upper arm, at least 21 days apart.
 - ❖ Arrangements for the supply of the vaccine will be the responsibility of national authorities. For more information about using Comirnaty, see the package leaflet or consult a healthcare professional.
- How does Comirnaty work?
 - ❖ Comirnaty works by preparing the body to defend itself against COVID-19. It contains a molecule called mRNA which has instructions for making the spike protein. This is a protein on the surface of the SARS-CoV-2 virus which the virus needs to enter the body's cells.
 - ❖ When a person is given the vaccine, some of their cells will read the mRNA instructions and temporarily produce the spike protein. The person's immune system will then

recognise this protein as foreign and produce antibodies and activate T cells (white blood cells) to attack it.

- ❖ If, later on, the person comes into contact with SARS-CoV-2 virus, their immune system will recognize it and be ready to defend the body against it.
 - ❖ The mRNA from the vaccine does not stay in the body but is broken down shortly after vaccination.
- What benefits of Comirnaty has been shown in the study?
 - ❖ A very large clinical trial showed that Comirnaty was effective at preventing COVID-19 in people from 16 years of age.
 - ❖ The trial involved around 44,000 people in total. Half received the vaccine and half were given a dummy injection. People did not know whether they received the vaccine or the dummy injection.
 - ❖ Efficacy was calculated in over 36,000 people from 16 years of age (including people over 75 years of age) who had no sign of previous infection. The study showed a 95% reduction in the number of symptomatic COVID-19 cases in the people who received the vaccine (8 cases out of 18,198 got COVID-19 symptoms) compared with people who received a dummy injection (162 cases out of 18,325 got COVID-19 symptoms). This means that the vaccine demonstrated a 95% efficacy in the trial.
 - ❖ The trial also showed around 95% efficacy in the participants at risk of severe COVID-19, including those with asthma, chronic lung disease, diabetes, high blood pressure or a body mass index ≥ 30 kg/m².
 - Can people who have already had Covid-19 be vaccinated with Comirnaty?
 - ❖ There were no additional side effects in the 545 people who received Comirnaty in the trial and had previously had COVID-19.
 - ❖ There were not enough data from the trial to conclude on how well Comirnaty works for people who have already had COVID-19.
 - Can Comirnaty reduce the transmission of the virus from one person to another?
 - ❖ The impact of vaccination with Comirnaty on the spread of the SARS-CoV-2 virus in the community is not yet known. It is not yet known how much vaccinated people may still be able to carry and spread the virus.
 - How long does protection of Comirnaty last?
 - ❖ It is not currently known how long protection given by Comirnaty lasts. The people vaccinated in the clinical trial will continue to be followed for 2 years to gather more information on the duration of protection.

- Can children be vaccinated with Comirnaty?
 - ❖ Comirnaty is not currently recommended for children below 16 years of age. There is an agreement with the company on a plan to trial the vaccine in children at a later stage.
- Can immunocompromised people be vaccinated with Comirnaty?
 - ❖ There are limited data on immunocompromised people (people with weakened immune systems). Although immunocompromised people may not respond as well to the vaccine, there are no particular safety concerns. Immunocompromised people can still be vaccinated as they may be at higher risk from COVID-19.
- Can pregnant or breastfeeding woman be vaccinated with Comirnaty?
 - ❖ Animal studies do not show any harmful effects in pregnancy, however data on the use of Comirnaty during pregnancy are very limited. Although there are no studies on breast-feeding, no risk for breast-feeding is expected.
 - ❖ The decision on whether to use the vaccine in pregnant women should be made in close consultation with a healthcare professional after considering the benefits and risks.
- Can people with allergies be vaccinated with Comirnaty?
 - ❖ People who already know they have an allergy to one of the components of the vaccine listed in section 6 of the package leaflet should not receive the vaccine.
 - ❖ Allergic reactions (hypersensitivity) have been seen in people receiving the vaccine. A very small number of cases of anaphylaxis (severe allergic reaction) have occurred since the vaccine started being used in vaccination campaigns. Therefore, as for all vaccines, Comirnaty should be given under close medical supervision, with the appropriate medical treatment available. People who have a severe allergic reaction when they are given the first dose of Comirnaty should not receive the second dose.
- How well does Comirnaty work with people with different ethnicities and genders?
 - ❖ The main trial included people of different ethnicities and genders. Efficacy of around 95% was maintained across genders, racial and ethnic groups.
- What are the risks associated with Comirnaty?
 - ❖ The most common side effects with Comirnaty in the trial were usually mild or moderate and got better within a few days after vaccination. These included pain and swelling at the injection site, tiredness, headache, muscle and joint pain, chills and fever. They affected more than 1 in 10 people.
 - ❖ Redness at the injection site and nausea occurred in less than 1 in 10 people. Itching at the injection site, pain in the limb, enlarged lymph nodes, difficulty sleeping and feeling unwell were uncommon side effects (affecting less than 1 in 100 people). Weakness in

muscles on one side of face (acute peripheral facial paralysis or palsy) occurred rarely in less than 1 in 1,000 people.

- ❖ Allergic reactions have occurred with Comirnaty, including a very small number of cases of severe allergic reactions (anaphylaxis) which have occurred when Comirnaty has been used in vaccination campaigns. As for all vaccines, Comirnaty should be given under close supervision with appropriate medical treatment available.
- Why is Comirnaty authorized in the European Union and what does this mean for Aruba?
 - ❖ Comirnaty offers a high level of protection against COVID-19 which is a critical need in the current pandemic. The main trial showed that the vaccine has a 95% efficacy. Most side effects are mild to moderate in severity and are gone within a few days.
 - ❖ The Agency therefore decided that Comirnaty's benefits are greater than its risks and that it can be authorised for use in the EU.
 - ❖ Comirnaty has been granted a conditional marketing authorisation. This means that there is more evidence to come about the vaccine (see below), which the company is required to provide. The Agency will review any new information that becomes available and this overview will be updated as necessary.
 - ❖ Aruba is part of The Kingdom of the Netherlands and Aruba will receive vaccine from the Netherlands.
- What information is still awaited for Comirnaty?
 - ❖ As Comirnaty received a conditional marketing authorisation, the company that markets Comirnaty will continue to provide results from the main trial, which is ongoing for 2 years. This trial and additional studies will provide information on how long protection lasts, how well the vaccine prevents severe COVID-19, how well it protects immunocompromised people, children and pregnant women, and whether it prevents asymptomatic cases.
 - ❖ In addition, independent studies of COVID-19 vaccines coordinated by EU authorities will also give more information on the vaccine's long-term safety and benefit in the general population.
 - ❖ The company will also carry out studies to provide additional assurance on the pharmaceutical quality of the vaccine as the manufacturing continues to be scaled up.
- What measures are being taken to ensure safe and effective use of Comirnaty?
 - ❖ Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Comirnaty have been included in the summary of product characteristics and the package leaflet.

- ❖ A risk management plan (RMP) for Comirnaty is also in place and contains important information about the vaccine's safety, how to collect further information and how to minimise any potential risks.
 - ❖ Safety measures will be implemented for Comirnaty in line with the EU safety monitoring plan for COVID-19 vaccines to ensure that new safety information is rapidly collected and analysed. The company that markets Comirnaty will provide monthly safety reports.
 - ❖ As for all medicines, data on the use of Comirnaty are continuously monitored. Suspected side effects reported with Comirnaty are carefully evaluated and any necessary action taken to protect patients.
- Other information about Comirnaty
 - ❖ Comirnaty received a conditional marketing authorisation valid throughout the EU on 21 December 2020.

Supporting documents:

Risk management document of Comirnaty

- [Comirnaty, INN-COVID-19 mRNA Vaccine \(nucleoside-modified\) \(europa.eu\)](https://european-council.europa.eu/media/eu-press-room/2020/12/23/EN_IPR_2020_1223_01.pdf)

EU Safety Monitoring plan of Comirnaty

- [Pharmacovigilance Plan of the EU Regulatory Network for COVID-19 Vaccines \(europa.eu\)](https://european-council.europa.eu/media/eu-press-room/2020/12/23/EN_IPR_2020_1223_01.pdf)

Summary of Product Information Comirnaty

- [Comirnaty, INN-COVID-19 mRNA Vaccine \(nucleoside-modified\) \(europa.eu\)](https://european-council.europa.eu/media/eu-press-room/2020/12/23/EN_IPR_2020_1223_01.pdf)

Safety and Efficacy Comirnaty

- [Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine | NEJM](https://www.nejm.org/doi/full/10.1056/NEJMoa2020326)

Summary of Product Information Moderna COVID-19 Vaccine

- [Moderna COVID-19 Vaccine EUA Fact Sheet for Recipients and Caregivers \(fda.gov\)](https://www.fda.gov/oc/2020/12/23/moderna-covid-19-vaccine-eua-fact-sheet-for-recipients-and-caregivers)

Article on trial test Moderna COVID-19 Vaccine

- [‘Absolutely remarkable’: No one who got Moderna’s vaccine in trial developed severe COVID-19 | Science | AAAS \(sciencemag.org\)](https://www.sciencemag.org/news/2020/12/23/absolutely-remarkable-no-one-who-got-modernas-vaccine-in-trial-developed-severe-covid-19)

Vaccine tracker

- [COVID-19 vaccine tracker | RAPS](https://www.raps.org/COVID-19-vaccine-tracker)

CONFIDENTIAL