[redacted]

Our democracy was founded on the principles of free speech and free debate.

Australians should have the right to hear all the arguments – the good ones and the bad ones – and decide for ourselves what's true and what's false.

Politicians and unelected bureaucrats have no place interfering in that process.

The so-called 'fact checkers' already get it wrong all the time. How much worse would the situation be if ACMA were given an explicit mandate to control free speech?!

I urge you to STOP with this terrible idea.

A single body being charged and empowered with enforcing their own views as the 'truth' is nothing short of being totalitarian and despotic. The proposal is dangerous, un-Australian and CANNOT be allowed.

You know that democracy relies on free speech and open debate – and that more free speech, NOT censorship, is the best way to handle what you call 'misinformation'.

Australia already has a robust legal framework for dealing with dangerous lies or defamation. We do not need censorship. Focus instead on educating the masses to consider using a range of sources of information and to use their own discernment when deciding what is true or false TO THEM. Leave conversation pathways open. Open and free sharing of information and perspectives is a basic human right. Please, please do not reduce us to a communism country.

I ask you now to stand up for our democracy and reject the proposed Communications Legislation Amendment (Combatting Misinformation and Disinformation) Bill 2023.

I implore you to respect our democracy and commit yourself to this country's founding principles: free speech and free debate.

Stop this authoritarian Bill in its tracks now.

[redacted] 18th August 2023

Communications Legislation Amendment (Combatting Misinformation and Disinformation) Bill 2023.

Freedom of expression and opinion are the foundation stone for a free and democratic society and a necessary condition for the promotion and protection of human rights. The real-world impacts of Covid 19 challenged the Australian Government and sadly the response was at the expense of truth and commonsense. The Australian Government has pledged to protect and promote traditional rights and freedoms, including freedom of speech, opinion, religion, association and movement. And yet over the last 3 ½ years this commitment has been broken. To many Australians this has resulted in a feeling of mistrust and a breakdown in relationship.

February 2021, as the rollout of the Covid 19 vaccine began, former Minister for Health and Aged Care, Greg Hunt stated "We always have to be aware of the capacity of the virus to mutate and we have to look at what is called the longevity of the protection with regards to the antibodies that are developed. The world doesn't know that answer. The world is engaged in the largest clinical trial, the largest global vaccination trial ever, and we will have enormous amounts of data. What's the message to the public, it's safe, it's effective, it will help protect you, but it will also help to protect your mum and dad, your grandparents, your nonna, all of Australia."

Despite Greg Hunt indicating that Australians would be participating in a clinical trial, no control group was identified. A control group is a group of participants in a trial that do not receive the drug or the treatment being studied. The control group plays a fundamental role in clinical trials as they serve as a baseline for determining the effectiveness of the study treatment. A clinical trial cannot be ethically justified unless it can produce scientifically reliable results, which is what a control group helps to do. The effectiveness of the treatment can be validated if the experimental group has a better outcome than the control group. Why was a control group not used???

Throughout 2021, with the rollout of Covid 19 vaccinations, the Australian public was bombarded by the term safe and effective. Words have meaning, the words we choose and the language we use have the power to affect the people and the world around us.

Safe - 1.: free from harm or risk: unhurt. 2. a.: secure from threat of danger, harm, or loss.

Effective - successful in producing a desired or intended result.

Despite repeated assurances that the vaccines were safe and effective it became apparent that for some the vaccine was not free from harm or risk and if the desired or intended result was to protect the vaccinee from infection, severe illness, hospitalisation and death due to Covid 19, well this was not assured. In fact, it became apparent that misinformation was being used to bolster the vaccination program and worst of all this was being propagated by government, healthcare professionals, health bureaucrats and the mainstream media. The public had largely been convinced that if they received the covid 19 vaccine they would not get covid, they would not pass it onto their loved ones, but this was not true.

In the months following the vaccine rollout it slowly started to dawn on the public that not all was well. Everyone has the right to freedom of expression. This right includes freedom to hold opinions and to receive and impart information and ideas without interference by public authority. Vaccine hesitancy was not to be tolerated and so freedom to choose was decimated by the introduction of vaccine mandates.

Harkening back to an earlier statement – words have meaning. In 2021 the following excerpts were available to the public on the Australian Technical Advisory Group website (see attachments for full documents) –

Astra Zeneca Consumer Information

Vaxzevria® (previously COVID-19 Vaccine AstraZeneca) This vaccine has provisional approval in Australia to protect people aged 18 years and older against COVID-19 disease. The approval has been granted on the basis of short-term efficacy and safety data. Evidence of longer term efficacy and safety from ongoing clinical trials and vaccination in the community continues to be gathered and assessed.

5. What should I know about being given VAXZEVRIA?

General

As with any vaccine, VAXZEVRIA may not protect everyone who is vaccinated from COVID-19. It is not yet known how long people who receive the vaccine will be protected for.

Comirnaty Consumer Information

COMIRNATY™ COVID-19 VACCINE

This approval has been granted on the basis of short term safety and efficacy data. Evidence of longer term efficacy and safety from ongoing clinical trials and vaccination in the community continues to be gathered and assessed.

2. What should I know before I am given COMIRNATY?

As with any vaccine, COMIRNATY may not fully protect all those who receive it and it is not known how long you will be protected.

The Australian Government – COVID-19 Vaccination (health.gov.au/covid19-vaccines 2)

Information on Spikevax (Moderna) COVID-19 vaccine

Last updated: 15 September 2021

Vaccination is voluntary.

Benefits of the vaccine

No vaccine is 100 percent effective, so it is possible that you can still get infected and sick from COVID-19 after vaccination. We do not know how long the protection from Moderna will last. We will learn more about this over time. We currently do not know exactly how effective COVID-19 vaccines are at preventing spread of the virus. This means that even vaccinated people could be infected with the virus that causes COVID-19 and even if they have no symptoms or only mild symptoms, they could still pass it on to others. This is why it is important to continue other preventative measures like: • physical distancing • hand washing • wearing a face mask • COVID-19 testing and quarantine/isolation as required by your state/territory. If you have been vaccinated with two doses of Moderna, you should still get a COVID-19 test if you have symptoms that meet testing criteria according to your local health authority (e.g. fever, cough, sore throat).

The Australian Government – COVID-19 Vaccination (health.gov.au/covid19-vaccines 2)

Information on COVID-19 Comirnaty (Pfizer) vaccine

Last updated: 15 September 2021

Vaccination is voluntary and free.

Benefits of the vaccine

No vaccine is 100 per cent effective, so it is possible that you can still get sick from COVID-19 after vaccination. SARS-CoV-2 could potentially still infect a vaccinated person. Even if they have no symptoms or only mild symptoms, they could still pass it on to others. However, the COVID-19 vaccines currently used in Australia is effective in reducing the likelihood of a vaccinated person transmitting the virus to close contacts if the person is infected. This is why after vaccination it is important to continue other preventative measures like: • physical distancing • hand washing • wearing a face mask • COVID-19 testing and quarantine/isolation as required by your state/territory. If you have been vaccinated with two doses of Pfizer, you should still get a COVID-19 test if you have symptoms that meet testing criteria according to your local health authority (e.g. fever, cough, sore throat).

An experimental vaccination was offered to the public and touted as being safe and effective. If further information or evidence received is contrary to what is being promoted, it is the obligation of the promoter to validate the information and not to suppress or conceal this information or evidence. If the citizens of Australia cannot rely on the government, healthcare professionals, health bureaucrats and mainstream media to expose the harm done to individuals, then they should not be exempt from the requirements of this Bill, and in fact should be held to a higher requirement.

If one of the aims of the Communications Legislation Amendment Bill 2023 is to prevent harm to the individual, then it must take into consideration the breach of human rights. In 2021 we saw the introduction of vaccine mandates. How many people took this vaccine to keep their job? How many people took the vaccine because they believed that it was safe and effective? How many people took the vaccine because they believed it would stop them getting covid and spreading it to their loved ones? How many people took the vaccine without knowing the risks and benefits? How many took the vaccine because they were scared that they would be mistreated by healthcare workers if they got sick? Keeping in mind that the vaccines were experimental with no medium- or long-term safety data, we only need look to the requirements to obtain informed consent to highlight that no Australian was afforded informed consent. The Australian Immunisation Handbook states –

> **Valid consent is the voluntary agreement by an individual to a proposed procedure, which is given after sufficient, appropriate and reliable information about the procedure, including the potential risks and benefits, has been conveyed to that individual.**
>
> **As part of the consent procedure, people receiving vaccines and/or their parents or carers should be given sufficient information (preferably written) about the risks and benefits of each vaccine. This includes:**
>
> - **what adverse events are possible**
> - **how common they are**
> - **what they should do about them**
>
> **For consent to be legally valid, the following elements must be present:**

1. **It must be given by a person with legal capacity, and of sufficient intellectual capacity to understand the implications of receiving a vaccine.**
2. **It must be given voluntarily in the absence of undue pressure, coercion or manipulation.**
3. **It must cover the specific procedure that is to be performed.**
4. **It can only be given after the potential risks and benefits of the relevant vaccine, the risks of not having it, and any alternative options have been explained to the person.**

The person must have the opportunity to seek more details or explanations about the vaccine or its administration.

The information must be provided in a language or by other means that the person can understand. Where appropriate, involve an interpreter or cultural support person.

Obtain consent before each vaccination, after establishing that there are no medical condition(s) that contraindicate vaccination. Consent can be verbal or written.

In 2021 the citizens of Australia were placed under undue pressure, they were coerced and manipulated and if they did not submit to taking the Covid 19 vaccine they were threatened with termination of their employment. How many had their employment terminated? How many were forced to resign their position? How many still to this day have not been able to return to their chosen professions? Why did this occur? It occurred due to misinformation. The outcome was the serious harm of individuals who did not, for a variety of reasons, want to undergo an experimental procedure. People have suffered terribly because of this one decision. Misinformation and disinformation have had destructive consequences and the people who have perpetrated this against their fellowman have remained committed to suppressing the truth. Despite the growing evidence that the vaccines have harmed, injured and caused deaths, the government, healthcare professionals, health bureaucrats and mainstream media have cruelly deprived their fellowman of the right to be seen and heard and believed. This Bill should not encroach on freedom of expression. People should have the right to express their opinions and they should have the ability to tell their story. The real concern lies with people in positions of authority, who hide behind their credentials in promoting misinformation and disinformation. If this Bill has no power to arbitrate for truth, then it should not be amended to impose penalties on digital platforms who may be providing a voice to those who have been ignored or forgotten. The suppression of information risks silencing protected speech and has enormous consequences for public debate.

Vaxzevria® (previously COVID-19 Vaccine AstraZeneca)

This vaccine has **provisional approval** in Australia to protect people aged 18 years and older against COVID-19 disease. The approval has been granted on the basis of short-term efficacy and safety data. Evidence of longer term efficacy and safety from ongoing clinical trials and vaccination in the community continues to be gathered and assessed.

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this vaccine, speak to your healthcare provider (e.g. doctor, nurse or pharmacist).

▼ This vaccine is new. Please report side effects. See the full CMI for further details.

1. Why am I being given VAXZEVRIA?

VAXZEVRIA contains the active ingredient ChAdOx1-S. This vaccine is used to protect people aged 18 years and older against COVID-19. For more information, see Section 1. Why am I being given VAXZEVRIA? in the full CMI.

2. What should I know before I am given VAXZEVRIA?

You should not receive VAXZEVRIA if you have ever had an allergic reaction to VAXZEVRIA or any of the ingredients listed at the end of the CMI, have had a major blood clot occurring at the same time as having low levels of platelets (thrombocytopenia) after receiving any COVID-19 vaccine or have had capillary leak syndrome (a condition causing fluid leakage from small blood vessels).

Talk to your healthcare provider if you have or have had any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.
VAXZEVRIA should not be given to children under 18 years.
For more information, see Section 2. What should I know before I am given VAXZEVRIA? in the full CMI.

3. What if I am taking, have recently taken or might take other medicines or vaccines?

Medicines (including other vaccines) that may impact whether you should be given this vaccine or not are listed in Section 3. What if I am taking, have recently taken or might take other medicines or vaccines? in the full CMI.

4. How am I given VAXZEVRIA?

VAXZEVRIA will be given to you by a healthcare provider. It is injected into a muscle (usually in the upper arm). You will receive 2 (0.5 mL per dose) injections. The second injection can be given between 4 and 12 weeks after the first injection. More instructions can be found in Section 4. How am I given VAXZEVRIA? in the full CMI.

5. What should I know about being given VAXZEVRIA?

General	As with any vaccine, VAXZEVRIA may not protect everyone who is vaccinated from COVID-19. It is not yet known how long people who receive the vaccine will be protected for.
Driving or using machines	VAXZEVRIA has no known effect on the ability to drive and use machines. However, side effects listed in section 6 may impact your ability to drive and use machines. If you feel unwell, do not drive or use machines.

For more information, see Section 5. What should I know about being given VAXZEVRIA? in the full CMI.

6. Are there any side effects?

Most side effects are mild to moderate in nature and resolve within a few days. Fewer side effects were reported after the second dose. These include tenderness, pain, warmth, redness, itching or swelling where the injection is given; Generally feeling unwell; Feeling tired (fatigue); Flu like symptoms such as fever/feeling feverish (high temperatures), sore throat, runny nose, cough and/or chills; Headache; Feeling sick (nausea), being sick (vomiting) or diarrhoea; Muscle pain/ache, joint pain, pain in legs or arms.

Some very rare serious side effects, such as major blood clots in combination with low levels of blood platelets (thrombocytopenia), capillary leak syndrome or allergic reactions, may require urgent medical attention or hospitalisation.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

▼ This vaccine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor or other healthcare provider, or directly at www.tga.gov.au/reporting-problems.

VAXZEVRIA® (previously COVID-19 Vaccine AstraZeneca)

Active ingredient: *ChAdOx1-S*

This vaccine has **provisional approval** in Australia to protect people aged 18 years and older against COVID-19 disease. This approval has been granted on the basis of short term efficacy and safety data. Evidence of longer term efficacy and safety from ongoing clinical trials and vaccination in the community continues to be gathered and assessed.

Consumer Medicine Information (CMI)

This leaflet provides important information about VAXZEVRIA. **You should also speak to your healthcare provider (e.g. doctor, nurse or pharmacist) if you would like further information or if you have any concerns or questions about using VAXZEVRIA.**

Where to find information in this leaflet:

1. Why am I being given VAXZEVRIA?

VAXZEVRIA contains the active ingredient ChAdOx1-S. This vaccine is used to protect people aged 18 years and older against COVID-19.

COVID-19 is caused by a virus called coronavirus (SARS-CoV-2).

VAXZEVRIA stimulates the body's natural defences (immune system). It causes the body to produce its own protection (antibodies) against the virus. This will help to protect you against COVID-19 in the future. None of the ingredients in this vaccine can cause COVID-19.

2. What should I know before I am given VAXZEVRIA

Warnings

You should not receive VAXZEVRIA if you:

- Are allergic to this vaccine or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this vaccine.
- Have had a major blood clot occurring at the same time as having low levels of platelets (thrombocytopenia) after receiving any COVID-19 vaccine.
- Have had capillary leak syndrome (CLS; a condition causing fluid leakage from small blood vessels).

Check with your healthcare provider before vaccination if:

- You have ever had a severe allergic reaction after any other vaccine injection or after you were given VAXZEVRIA in the past;
- Your immune system does not work properly (immunodeficiency) or are taking medicines that weaken the immune system (such as high-dose corticosteroids, immunosuppressants or cancer medicines);
- You currently have a severe infection with a high temperature (over 38°C);
- You have ever had a blood clot in the past or if you have an autoimmune disorder (illness where the body's immune system attacks its own cells) including immune thrombocytopenia (ITP; previously known as idiopathic thrombocytopenic purpura);
- You have ever had a serious medical condition (heparin induced thrombocytopenia; HIT) where your blood platelet levels became very low (thrombocytopenia) after taking heparin (a blood thinning medicine)
- You have a problem with bleeding or bruising, or if you are taking a blood thinning medicine (anticoagulant);
- You have ever had capillary leak syndrome (CLS; a condition causing fluid leakage from small blood vessels)
- You have any other medical conditions
- You take any medicines for any other condition including any recent or planned vaccines
- You have ever fainted or felt stressed (eg dizziness, increased heart rate, difficulty in breathing, sweating, tingling feeling and/or feeling anxious) when you have been given an injection including other vaccines.

Very rare cases of blood clots with low levels of blood platelets have been observed following vaccination with VAXZEVRIA. The majority of these cases occurred within the first 21 days following vaccination but have also been reported after this period. Some had a fatal outcome. Seek urgent medical attention if from a few days following vaccination you:

- Experience a severe or persistent headache, blurred vision, confusion or seizures (fits)
- Develop shortness of breath, chest pain, leg swelling, leg pain or persistent abdominal pain
- Notice unusual skin bruising or pinpoint round spots beyond the site of vaccination

After vaccination you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your healthcare provider if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby. There are limited data on the use of VAXZEVRIA in pregnant or breastfeeding women. Your healthcare provider will discuss with you whether you can be given the vaccine.

Children and adolescents

No data are currently available on the use of VAXZEVRIA in children and adolescents younger than 18 years of age.

3. What if I am taking, have recently taken or might take other medicines or vaccines?

Tell your healthcare provider if you are taking, have recently taken, or might take, any other vaccines or medicines including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Medicines (including other vaccines) that may impact whether you should be given this vaccine or not include the following (see also Section 2 above):

- medicines that weaken the immune system (such as high-dose corticosteroids, immunosuppressants or cancer medicines);
- blood thinning medicines (anticoagulant)
- any other vaccine including any other COVID-19 vaccines

Check with your healthcare provider if you are not sure about what vaccines, medicines, vitamins or supplements you are taking or have recently taken and if these may affect VAXZEVRIA.

4. How am I given VAXZEVRIA?

How VAXZEVRIA is given

VAXZEVRIA will be given to you by a healthcare provider. It is injected into a muscle (usually in the upper arm).

You will receive 2 (0.5 mL per dose) injections. You will be told when you need to return for your second injection of VAXZEVRIA.

The second injection can be given between 4 and 12 weeks after the first injection.

When VAXZEVRIA is given for the first injection, VAXZEVRIA (and not another vaccine against COVID-19) should be given for the second injection to complete vaccination course.

If you forget to get your second injection

If you forget to go back at the scheduled time, ask your healthcare provider for advice. It is important that you return for your second injection of VAXZEVRIA. If you miss a scheduled second injection you may not achieve maximum protection.

If you use too much VAXZEVRIA

As VAXZEVRIA is given under the close supervision of a healthcare provider it is unlikely that you will be given too much.

If you are concerned that you have been given too much VAXZEVRIA, tell your healthcare provider immediately.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know about being given VAXZEVRIA?

As with any vaccine, VAXZEVRIA may not protect everyone who is vaccinated from COVID-19. It is not yet known how long people who receive the vaccine will be protected for.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how this vaccine affects you.

VAXZEVRIA has no known effect on the ability to drive and use machines. However, side effects listed in section 6 may impact your ability to drive and use machines. If you feel unwell, do not drive or use machines.

Looking after your vaccine

Your healthcare provider is responsible for storing this vaccine and disposing of any unused product correctly.

6. Are there any side effects?

All vaccines can have side effects. If you do experience any side effects, most of them are mild to moderate in nature and resolve within a few days. Fewer side effects were reported after the second dose However, some side effects may need medical attention.

After vaccination, you may have more than one side effect at the same time (for example, muscle pain/ache, joint pain, headaches, chills and generally feeling unwell).

See the information below and, if you need to, ask your healthcare provider if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• Tenderness, pain, warmth, redness, itching or swelling where the injection is given • Generally feeling unwell • Feeling tired (fatigue) • Flu like symptoms such as fever/feeling feverish (high temperatures), sore throat, runny nose, cough and/or chills • Headache • Feeling sick (nausea), being sick (vomiting) or diarrhoea • Muscle pain/ache, joint pain, pain in legs or arms	**Speak to your healthcare provider if you have any of these less serious side effects and they worry you.** **Medicines containing paracetamol can be taken if you need relief from side effects such as pain and/or fever.**

Serious side effects

Serious side effects	What to do
Low levels of blood platelets (thrombocytopenia) with or without major blood clots have been observed very rarely.	**Tell your healthcare provider straight away, or go straight to the Emergency**

Serious side effects	What to do
Get medical attention immediately if from a few days following vaccination you get any of the following symptoms: • experience a severe or persistent headache, blurred vision, confusion or seizures (fits) • develop shortness of breath, chest pain, leg swelling, leg pain or persistent abdominal pain • notice unusual skin bruising or pinpoint round spots beyond the site of vaccination	**Department at your nearest hospital if you notice any of these serious side effects.** You may need urgent medical attention or hospitalisation.
Very rare cases of capillary leak syndrome (CLS) have been reported. Get medical attention immediately if you get any of the following symptoms in the days following vaccination: • rapid swelling of the arms and legs, • sudden weight gain, and • feeling faint (low blood pressure)	**Tell your healthcare provider straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.** You may need urgent medical attention or hospitalisation.
Very rare cases of Guillain-Barré syndrome (GBS) have been reported. GBS is a rare immune disorder that causes nerve inflammation. Get medical attention immediately if you get any of the following symptoms: Pain, numbness, muscle weakness in the arms and legs, which may progress to the chest and face.	**Tell your healthcare provider straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.** You may need urgent medical attention or hospitalisation.
All injectable vaccines have the potential for an allergic reaction after you are injected. Some of the symptoms of an allergic reaction may include: • swelling of the face, lips, tongue, mouth, throat and/or other parts of the body • shortness of breath, wheezing or difficulty breathing • fainting, dizziness, feeling lightheaded (due to a drop in blood pressure) • changes in your heartbeat • rash, itching or hives on the skin	**Tell your healthcare provider straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.** You may need urgent medical attention or hospitalisation.

Tell your healthcare provider if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems and include the vaccine name (VAXZEVRIA) and batch/lot number if available. By reporting side effects, you can help provide more information on the safety of this vaccine.

7. Product details

This vaccine is only available with a doctor's prescription.

What VAXZEVRIA contains

Active ingredient (main ingredient)	One dose (0.5 mL) contains: ChAdOx1-S* $5x10^{10}$ viral particles (vp) [corresponding to not less than 2.5×10^{8} infectious units (Inf.U)]
Other ingredients (inactive ingredients)	histidine, histidine hydrochloride monohydrate, sodium chloride, magnesium chloride hexahydrate, disodium edetate, sucrose, ethanol absolute, polysorbate 80 and water for injections.

* Recombinant, replication-deficient chimpanzee adenovirus vector encoding the SARS-CoV-2 Spike glycoprotein. The vaccine is manufactured using material originally sourced from a human embryo (Human Embryo Kidney cells: HEK293).

Do not take this vaccine if you are allergic to any of these ingredients.

This product contains genetically modified organisms (GMOs).

VAXZEVRIA does not contain any preservatives and the vial stopper is not made with natural rubber latex.

What this vaccine looks like

VAXZEVRIA is approved^ for the following multidose vial packs (Aust R 349072):

- 4mL (8 dose) vial in packs of 10 vials
- 5mL (10 dose) vial in packs of 10 vials.

^not all pack sizes may be available in Australia

Sponsor

AstraZeneca Pty Ltd
ABN 54 009 682 311
66 Talavera Road
MACQUARIE PARK NSW 2113

For VAXZEVRIA enquiries contact 1800 343 949

This leaflet was prepared on 20 August 2021

Vaxzevria is a registered trade mark of the AstraZeneca group of companies.

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COMIRNATY™ COVID-19 VACCINE

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about receiving this vaccine, speak to your doctor or pharmacist.

▼ This vaccine is new or being used differently. Please report side effects. See the full CMI for further details.

1. Why am I being given COMIRNATY?

COMIRNATY is a vaccine given to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in adults and adolescents from 12 years of age and older. COMIRNATY contains the active ingredient BNT162b2 [mRNA]. For more information, see Section 1. Why am I being given COMIRNATY? in the full CMI.

2. What should I know before I am given COMIRNATY?

You should not be given COMIRNATY if you have had an allergic reaction to any of the ingredients in COMIRNATY. See list at the end of the CMI.

Check with your doctor if you have had: a severe allergic reaction or breathing problems after any other vaccine or after being given COMIRNATY in the past; fainted following any needle injection; a severe illness or infection with high fever; a weakened immune system or are on a medicine that affects your immune system; a bleeding disorder, bruise easily or are on a blood thinning medicine.

As with any vaccine, COMIRNATY may not fully protect all those who receive it and it is not known how long you will be protected.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

COMIRNATY should not be given to children under 12 years. For more information, see Section 2. What should I know before I am given COMIRNATY? in the full CMI.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription. Tell your doctor or pharmacist if you have recently received any other vaccine. For more information, see Section 3. What if I am taking other medicines? in the full CMI.

4. How will I be given COMIRNATY?

COMIRNATY will be given as an injection into the muscle of your upper arm by a doctor, nurse or pharmacist. You will be given one dose followed by a second dose at least 21 days later. It is very important that you receive your second dose. A doctor, nurse or pharmacist will observe you for at least 15 minutes after being given COMIRNATY. For more information, see Section 4. How will I be given COMIRNATY? in the full CMI.

5. What should I know while being given COMIRNATY?

Things you should know	• If you receive one dose of COMIRNATY, you should receive a second dose of the same vaccine 21 days later to complete the vaccination schedule. • You may not be protected against COVID-19 disease until at least seven days after your second dose. • You may not be protected if you only receive one dose, so a second dose is important.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how COMIRNATY affects you. Some of the side effects of COMIRNATY may temporarily affect your ability to drive or use machines.

For more information, see Section 5. What should I know while being given COMIRNATY? in the full CMI.

6. Are there any side effects?

Very common side effects of COMIRNATY include pain/swelling at injection site, tiredness, headache, muscle pain, chills, joint pain and fever. For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

▼ This vaccine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

COMIRNATY™ COVID-19 VACCINE

Active ingredient: *BNT162b2 [mRNA]*

This vaccine has **provisional approval** in Australia to prevent COVID-19 disease caused by SARS-CoV-2 virus in adults and adolescents from 12 years of age and older. This approval has been granted on the basis of short term safety and efficacy data. Evidence of longer term efficacy and safety from ongoing clinical trials and vaccination in the community continues to be gathered and assessed.

Consumer Medicine Information (CMI)

This leaflet provides important information about using COMIRNATY. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about receiving COMIRNATY.**

Where to find information in this leaflet:

1. Why am I being given COMIRNATY?

COMIRNATY contains the active ingredient BNT162b2 [mRNA]. COMIRNATY is an mRNA (messenger ribonucleic acid) vaccine.

COMIRNATY is a vaccine given to prevent COVID-19 disease caused by SARS-CoV-2 virus in adults and adolescents from 12 years of age and older.

COMIRNATY works by triggering your immune system to produce antibodies and blood cells that work against the virus, to protect against COVID-19 disease.

2. What should I know before I am given COMIRNATY?

Warnings

COMIRNATY should not be given:

1. if you are allergic to BNT162b2 [mRNA] or any of the ingredients listed at the end of this leaflet.

Check with your doctor if you have:

- had a severe allergic reaction or breathing problems after any other vaccine or after being given COMIRNATY in the past.
- fainted following any needle injection.
- a severe illness or infection with high fever. However, you can have your vaccination if you have a mild fever or upper airway infection like a cold.
- a weakened immune system, such as due to HIV infection or are on a medicine that affects your immune system.
- a bleeding disorder, bruise easily or are on a blood thinning medicine.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Very rare cases of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have been reported after vaccination with COMIRNATY. The cases have mostly occurred within two weeks following vaccination, more often after the second vaccination, and more often occurred in younger men. Following vaccination, you should be alert to signs of myocarditis and pericarditis, such as breathlessness, palpitations and chest pain, and seek immediate medical attention should these occur.

You may develop a temporary, stress-related response associated with the process of receiving your injection. This may include dizziness, fainting, sweating, increased heart rate and/or anxiety. If you start to feel faint at any time during the process of receiving your injection, let your doctor, nurse or pharmacist know and take actions to avoid falling and injuring yourself, such as sitting or lying down.

As with any vaccine, COMIRNATY may not fully protect all those who receive it and it is not known how long you will be protected.

Pregnancy and breastfeeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before you receive this vaccine.

Children and adolescents

COMIRNATY should not be given to children under 12 years.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Tell your doctor or pharmacist if you have recently received any other vaccine.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect, or are affected by, COMIRNATY.

4. How will I be given COMIRNATY?

- COMIRNATY will be given as an injection into the muscle of your upper arm by a doctor, nurse or pharmacist.
- You will be given one dose followed by a second dose at least 21 days later. If you miss the second dose, ask your doctor for advice.
- A doctor, nurse or pharmacist will observe you for at least 15 minutes after being given COMIRNATY.

5. What should I know while being given COMIRNATY?

Things you should know

- If you receive one dose of COMIRNATY, you should receive a second dose of the same vaccine at least 21 days later to complete the vaccination schedule.
- You may not be protected against COVID-19 disease until at least seven days after your second dose.
- You may not be protected if you only receive one dose, so a second dose is important.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how COMIRNATY affects you.

Some of the side effects of COMIRNATY may temporarily affect your ability to drive or use machines.

Storage of the vaccine

COMIRNATY is stored at -90°C to -60°C. It must be kept in the original package in order to protect from light.

A doctor, nurse or pharmacist will prepare the injection for you before you are given it.

Getting rid of any unwanted vaccine

A doctor, nurse or pharmacist will dispose of any unused vaccine.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Very common side effects

Very common side effects	What to do
• pain/swelling at injection site • tiredness • headache • muscle pain • chills • joint pain • fever	**Speak to your doctor if you have any of these very common side effects and they worry you.**

Common side effects

Common side effects	What to do
• redness at injection site • nausea	**Speak to your doctor if you have any of these common side effects and they worry you.**

Uncommon side effects

Uncommon side effects	What to do
• enlarged lymph nodes • feeling unwell • arm pain • insomnia • decreased appetite • excessive sweating • night sweats • physical weakness and/or lack of energy	**Speak to your doctor if you have any of these side effects and they worry you.**

Rare side effects

Rare side effects	What to do
• temporary one-sided facial drooping	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice this side effect.**

Other side effects (frequency unknown)

Other side effects (frequency unknown)	What to do
• severe allergic reaction • allergic reactions such as rash, itching, hives or swelling of the face • inflammation of the heart muscle (myocarditis) or inflammation of the lining outside the heart (pericarditis) which can result in chest pain, breathlessness and/or palpitations	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**
• diarrhoea • vomiting • pain in arm	**Speak to your doctor if you have any of these side effects and they worry you.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this vaccine.

7. Product details

What COMIRNATY contains

Active ingredient **(main ingredient)**	• BNT162b2 [mRNA]
Other ingredients **(inactive ingredients)**	• ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315) • 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159) • Distearoylphosphatidylcholine (DSPC) • Cholesterol • Potassium chloride • Monobasic potassium phosphate • Sodium chloride • Dibasic sodium phosphate dihydrate • Sucrose • Water for injections

Do not receive this vaccine if you are allergic to any of these ingredients.

What COMIRNATY looks like

COMIRNATY is a white to off-white suspension provided in a multidose clear glass vial.

After dilution, each vial contains 6 doses of vaccine.

AUST R 346290.

Who distributes COMIRNATY

Pfizer Australia Pty Ltd

Sydney NSW

www.pfizer.com.au

Medical Information www.pfizermedinfo.com.au or

Toll Free Number: 1800 675 229

This leaflet was prepared in September 2021.

Australian Government

COVID-19 VACCINATION

Information on Spikevax (Moderna) COVID-19 vaccine

Last updated: 15 September 2021

About the vaccine

Moderna is a vaccine that can prevent people from becoming ill from COVID-19. Two doses are required, usually given 4-6 weeks apart (in special circumstances the interval may be longer). The Moderna COVID-19 vaccine does not contain any live virus, and it cannot give you COVID-19. It contains the genetic code for an important part of the SARS-CoV-2 virus called the spike protein. After getting the vaccine, your body makes copies of the spike protein. Your immune system will then learn to recognise and fight against the SARS-CoV-2 virus, which causes COVID-19. The genetic code is broken down quickly by the body.

To prevent COVID-19, everyone who is eligible for a COVID-19 vaccine should get vaccinated, with a few exceptions specified in this information sheet. Vaccination is voluntary. You can discuss any concerns or questions you have about COVID-19 vaccination with your immunisation provider and/or your GP before you receive the vaccine.

Benefits of the vaccine

Very large clinical trials have shown that Moderna is effective in preventing COVID-19 in people aged ≥12 years and older. Adults who had two doses of Moderna were about 94 percent less likely to become ill from COVID-19 than people who did not get the vaccine. The vaccine was also effective in people aged over 65 years (86%) and in adolescents aged 12-17 years.

Protection against COVID-19 starts from about two weeks after the first dose. While one dose may give some protection, it may only last for the short-term. Two doses will give optimal protection. No vaccine is 100 percent effective, so it is possible that you can still get infected and sick from COVID-19 after vaccination. We do not know how long the protection from Moderna will last. We will learn more about this over time. We currently do not know exactly how effective COVID-19 vaccines are at preventing spread of the virus. This means that even vaccinated people could be infected with the virus that causes COVID-19 and even if they have no symptoms or only mild symptoms, they could still pass it on to others.

This is why it is important to continue other preventative measures like:

- physical distancing
- hand washing
- wearing a face mask
- COVID-19 testing and quarantine/isolation as required by your state/territory.

If you have been vaccinated with two doses of Moderna, you should still get a COVID-19 test if you have symptoms that meet testing criteria according to your local health authority (e.g. fever, cough, sore throat).

Who can receive this vaccine

The Therapeutic Goods Administration (TGA) has granted provisional approval for use of Spikevax (Moderna) in people aged ≥ 12 years.

Who should not receive this vaccine

You should not receive this vaccine if you have had:

- anaphylaxis (a type of severe allergic reaction) to a previous dose of an mRNA COVID-19 vaccine (i.e. Moderna or Comirnaty (Pfizer))
- anaphylaxis after exposure to any component of the vaccine, including polyethylene glycol (PEG)
- myocarditis and/or pericarditis attributed to a previous dose of an mRNA COVID-19 vaccine (i.e. Moderna or Pfizer)
- any other serious adverse event, that following review by an experienced immunisation provider or medical specialist was attributed to a previous dose of an mRNA COVID-19 vaccine (i.e. Moderna or Pfizer) and without another cause identified.

Precautions for vaccination

People with certain conditions may need additional precautions such as staying for 30 minutes of observation after having their vaccine or consulting an allergy specialist. Tell your immunisation provider if you have had:

- an **allergic reaction to a previous dose** or to an ingredient of an mRNA COVID-19 vaccine (i.e. Moderna or Pfizer)
- **anaphylaxis to other vaccines or to other medicines**. Your provider can check to ensure there are no common ingredients with the COVID-19 vaccine you are receiving
- confirmed mastocytosis with recurrent anaphylaxis that requires treatment

If **you have a bleeding disorder** or you are **taking a blood-thinning medication** (anticoagulant), tell your immunisation provider. Your immunisation provider can help determine whether it is safe for you to have an intramuscular injection, and help decide the best timing for injection.

Special circumstances to discuss before vaccination

People with precautionary conditions for Moderna

People with a history of any of the following conditions can receive Moderna but advice should be sought from a GP, immunisation specialist or cardiologist about the best timing of vaccination and whether any additional precautions are recommended:

- Recent (i.e. within the past 6 months) or current inflammatory cardiac illness e.g., myocarditis, pericarditis, endocarditis

- Acute rheumatic fever (i.e., with active myocardial inflammation) or acute rheumatic heart disease
- Acute decompensated heart failure

People with weakened immune systems (immunocompromise)

People with immunocompromise includes those who have a medical condition that weakens their immune system. It also includes those who may be taking medications that suppress their immune system.

The Australian Government strongly recommends people with immunocompromise receive COVID-19 vaccination. Moderna is not a live vaccine. It is safe in people with immunocompromise.

People with immunocompromise, including those living with HIV, have a higher risk of severe illness from COVID-19, including a higher risk of death.

Clinical trials for Moderna did not include people with immunocompromise, except for a small group of people with stable HIV. We do not know if Moderna is as effective in people with immunocompromise compared to the rest of the population. It is possible that Moderna might not be as effective in people with immunocompromise as it is in the general population. It is important to continue other preventative measures such as physical distancing after vaccination.

Women who are pregnant or breastfeeding

Pregnant women and adolescents should be routinely offered one of the mRNA-based COVID-19 vaccines, Pfizer or Moderna, at any stage of pregnancy. If you are trying to become pregnant you do not need to delay vaccination or avoid becoming pregnant after vaccination.

Pregnant women with COVID-19 have an increased risk of severe illness and adverse pregnancy outcomes. Real-world evidence has shown that Moderna is safe for pregnant women and breastfeeding women. You can discuss the decision in relation to timing of vaccination with your health professional.

If you are breastfeeding, you can have Moderna. You do not need to stop breastfeeding after vaccination.

People with a history of COVID-19

If you have had COVID-19 in the past, tell your immunisation provider. Your provider may advise you to wait for up to six months after recovery before having a COVID-19 vaccine. If you have ongoing illness from COVID-19, discuss the best timing of vaccination with your treating doctor.

Moderna and children

Moderna has been provisionally approved for use in people aged ≥ 12 years or older, and cannot be given to younger people.

Ensuring the safety of Moderna

Moderna and other COVID-19 vaccines have been developed quickly due to increased funding for vaccine research, and access to very large numbers of volunteers for research studies. A large clinical trial involving around 30,000 people confirmed Moderna to be safe and effective.

The TGA assesses all vaccines in Australia. This ensures that, in order for a vaccine to be approved, it is safe, effective and manufactured to a very high quality standard. A description of the process for approval of COVID-19 vaccines is available on the TGA website.

The safety of COVID-19 vaccines will be monitored continuously throughout the COVID-19 vaccination program.

There are reports of a very rare side effect involving blood clotting with low blood platelet count after receiving the Vaxzevria (AstraZeneca) vaccine. The AstraZeneca vaccine is made in a different way from Moderna. There is no evidence of this condition being linked to the Moderna COVID-19 vaccine.

You can report suspected side effects to your vaccination provider or other healthcare professional. They will then make a formal report on your behalf to your state or territory health department or directly to the TGA.

If you would prefer to report it yourself, please visit the TGA website for information on how to report suspected side effects associated with COVID-19 vaccines.

Australian Government

COVID-19 VACCINATION

Information on COVID-19 Comirnaty (Pfizer) vaccine

Last updated: 15 September 2021

About the vaccine

Pfizer is a vaccine that can prevent people from becoming ill from COVID-19. Two doses are required, usually given 3-6 weeks apart. In special circumstances the interval may be longer. The Pfizer COVID-19 vaccine does not contain any live virus, and it cannot give you COVID-19. It contains the genetic code for an important part of the SARS-CoV-2 virus called the spike protein. After getting the vaccine, your body makes copies of the spike protein. Your immune system will then learn to recognise and fight against the SARS-CoV-2 virus, which causes COVID-19. The body breaks down the genetic code quickly.

Vaccination is voluntary and free. You can discuss any concerns or questions you have about COVID-19 vaccination with your immunisation provider or your GP before you receive the vaccine.

Benefits of the vaccine

A very large clinical trial showed that Pfizer is effective in preventing COVID-19 in people aged 12 years and older. People who had two doses of Pfizer were about 95 per cent less likely to get symptomatic COVID-19 than people who did not get the vaccine. It was equally effective in people over the age of 65 years, as well as people with some stable pre-existing medical conditions.

Protection against COVID-19 starts from about 2–3 weeks after the first dose. While one dose may give some protection, it may only last for the short-term. Two doses will give optimal protection. No vaccine is 100 per cent effective, so it is possible that you can still get sick from COVID-19 after vaccination.

SARS-CoV-2 could potentially still infect a vaccinated person. Even if they have no symptoms or only mild symptoms, they could still pass it on to others. However, the COVID-19 vaccines currently used in Australia is effective in reducing the likelihood of a vaccinated person transmitting the virus to close contacts if the person is infected.

This is why after vaccination it is important to continue other preventative measures like:

- physical distancing
- hand washing
- wearing a face mask
- COVID-19 testing and quarantine/isolation as required by your state/territory.

If you have been vaccinated with two doses of Pfizer, you should still get a COVID-19 test if you have symptoms that meet testing criteria according to your local health authority (e.g. fever, cough, sore throat).

Who can receive this vaccine

People aged ≥12 years and older can receive Pfizer vaccine.

Who should not receive this vaccine

You should not receive this vaccine if you have had:

- **anaphylaxis** (a type of severe allergic reaction) to a previous dose of an mRNA COVID-19 vaccine (i.e., Pfizer or Spikevax (Moderna))
- **anaphylaxis after exposure to any component of the vaccine**, including polyethylene glycol (PEG)
- **myocarditis and/or** pericarditis attributed to a previous dose of an mRNA COVID-19 vaccine (i.e., Pfizer or Moderna)
- **any other serious adverse event**, that following review by an experienced immunisation provider or medical specialist was attributed to a previous dose of an mRNA COVID-19 vaccine (i.e., Pfizer or Moderna) and without another cause identified

Precautions for vaccination

People with certain conditions may need additional precautions such as staying for 30 minutes of observation after having their vaccine or consulting an allergy specialist. Tell your immunisation provider if you have had:

- an **allergic reaction to a previous dose** or to an ingredient of an mRNA COVID-19 vaccine (i.e Pfizer or Moderna)
- **anaphylaxis to other vaccines or to other medicines**. Your provider can check to ensure there are no common ingredients with the COVID-19 vaccine you are receiving
- confirmed mastocytosis with recurrent anaphylaxis that requires treatment.

If **you have a bleeding disorder** or you are **taking a blood-thinning medication** (anticoagulant), tell your immunisation provider. Your immunisation provider can help determine whether it is safe for you to have an intramuscular injection, and help decide the best timing for injection.

Special circumstances to discuss before vaccination

People with precautionary conditions for Pfizer

People with a history of any of the following conditions can receive Pfizer but advice should be sought from a GP, immunisation specialist or cardiologist about the best timing of vaccination and whether any additional precautions are recommended:

- Recent (i.e., within the past 6 months) inflammatory cardiac illness. For example myocarditis, pericarditis, endocarditis
- Acute rheumatic fever (i.e., with active myocardial inflammation) or acute rheumatic heart disease
- Acute decompensated heart failure.

People with weakened immune systems (immunocompromise)

People with immunocompromise includes those who have a medical condition that weakens their immune system. It also includes those who may be taking medications that suppress their immune system.

The Australian Government strongly recommends people with immunocompromise receive COVID-19 vaccination. Pfizer is not a live vaccine. It is safe in people with immunocompromise.

People with immunocompromise, including those living with HIV, have a higher risk of severe illness from COVID-19, including a higher risk of death.

Clinical trials for Pfizer did not include people with immunocompromise, except for a small group of people with stable HIV. We do not know if Pfizer is as effective in people with immunocompromise compared to the rest of the population. It is possible that Pfizer might not be as effective in people with immunocompromise as it is in the general population. It is important to continue other preventative measures such as physical distancing after vaccination.

Women who are pregnant or breastfeeding

Women and adolescents who are pregnant should be routinely offered Pfizer or Moderna at any stage of pregnancy. If you are trying to become pregnant you do not need to delay vaccination or avoid becoming pregnant after vaccination.

Pregnant women with COVID-19 have an increased risk of severe illness and adverse pregnancy outcomes. Real-world evidence has shown that Pfizer is safe for pregnant women and breastfeeding women.

If you are breastfeeding, you can have Pfizer. You do not need to stop breastfeeding after vaccination.

People with a history of COVID-19

If you have had COVID-19 in the past, tell your immunisation provider. COVID-19 vaccination can be deferred for up to six months after the acute illness in those who have had confirmed SARSCoV-2 infection, as evidence suggests that past infection reduces the risk of reinfection for at least 6 months. However, vaccination can start when they have recovered from the symptomatic infection. It is reasonable to be vaccinated earlier than 6 months following infection for some people. Discuss with your doctor or immunisation provider. If you have ongoing illness from COVID-19, discuss the best timing of vaccination with your treating doctor.

Pfizer and children

Pfizer has been provisionally approved for use in people aged 12 years or older, and cannot be given to younger people.

Ensuring the safety of Pfizer

Pfizer and other COVID-19 vaccines have been developed quickly due to increased funding for vaccine research, and access to very large numbers of volunteers for research studies. A large clinical trial involving around 44,000 people confirmed Pfizer to be safe and effective.

The Therapeutic Goods Administration assesses all vaccines in Australia. This ensures that, in order for a vaccine to be approved, it is safe, effective and manufactured to a very high quality standard. A description of the process for approval of COVID-19 vaccines is available on the TGA website.

The safety of COVID-19 vaccines will be monitored continuously throughout the COVID-19 vaccination program.

There are reports of a very rare side effect involving blood clotting with low blood platelet count after receiving the COVID-19 Vaccine AstraZeneca. The COVID-19 Vaccine AstraZeneca vaccine is made in a different way. There is no evidence of this condition being linked to the Pfizer COVID-19 vaccine.

You can report suspected side effects to your vaccination provider or other healthcare professional. They will then make a formal report on your behalf to your state or territory health department or directly to the TGA.

If you would prefer to report it yourself, please visit the TGA website for information on how to report suspected side effects associated with COVID-19 vaccines.