Elizabeth Hart
elizmhart@gmail.com

14 May 2026

Mr Hugh Marks
Managing Director
Australian Broadcasting Corporation
GPO Box 9994
SYDNEY NSW 2001

cc: Mr Kim Williams, Chair, ABC Board

Dear Mr Marks

Re: Failure to correct misleading information – Brendan Murphy interview, ABC *7.30* (3 February 2021)

I write to formally follow up on my correspondence of February and March 2021 concerning the ABC *7.30* interview between then Department of Health Secretary Professor Brendan Murphy and Leigh Sales, broadcast on 3 February 2021.

At that time, I brought to the attention of Mr David Anderson, then Managing Director of the ABC, that Professor Murphy had provided materially misleading information regarding the regulatory status of the COVID-19 vaccine products.

Professor Murphy asserted that the Pfizer and AstraZeneca vaccine products had "gone through the normal, full range of regulatory approvals for our vaccines … we have been able to do the full, safe, regulatory approval … we have not cut any corners", when in fact those products were only provisionally approved by the Therapeutic Goods Administration.

These statements were made in response to a question from Leigh Sales about whether Australians could be confident in the safety of the vaccines and whether the process had been rushed. The regulatory status of the products was therefore directly relevant to the audience's understanding of safety, approval standards, and informed consent.

The difference between full approval and provisional approval was significant. Provisional approval explicitly relied on ongoing clinical trials and post-market data collection, and carried acknowledged uncertainty regarding longer-term safety, duration of protection, and impact on transmission. This information was directly relevant to the ability of individuals to give informed consent for vaccination.

Despite my contemporaneous correspondence to Mr Anderson dated 8 March 2021 and 26 February 2021, which included the email I sent to Professor Murphy on 24 February 2021, as far as I am aware the ABC did not correct the broadcast record, clarify the regulatory status for viewers, or substantively respond to the concerns I raised.

For ease of reference, I attach copies of my contemporaneous correspondence to Professor Murphy and Mr Anderson, together with the ABC *7.30* transcript of 3 February 2021, relevant Therapeutic Goods Administration material concerning the provisional approval status of the Pfizer and AstraZeneca COVID-19 vaccine products, and a copy of my 9 March 2021 submission to then Prime Minister Scott Morrison raising these concerns.

As the taxpayer-funded national broadcaster, the ABC operates under a statutory Charter established by the *Australian Broadcasting Corporation Act 1983*, which requires it to provide innovative and comprehensive broadcasting services of a high standard. The ABC is also subject to the *Public Governance, Performance and Accountability Act 2013*, which sets governance and accountability standards for Commonwealth entities and their officials.

As these issues go directly to the ABC's statutory functions and the Board's responsibility under the *Australian Broadcasting Corporation Act 1983* for the proper and efficient performance of those functions, they warrant Board-level awareness.

I request that the ABC advise:

1. **Why the provisional approval status of COVID-19 vaccine products was not clarified during or after the 3 February 2021 broadcast.**

2. **Why my February–March 2021 correspondence raising this issue did not result in correction or substantive response.**

3. **What editorial safeguards were applied in reviewing factual claims made during that interview.**

4. **Whether the ABC considers that the provisional approval status of COVID-19 vaccine products was adequately conveyed to viewers during the rollout period, and whether any review of relevant broadcasts has been or will be undertaken.**

This is not a matter of retrospective disagreement. It concerns a documented inaccuracy identified at the time of broadcast and left uncorrected, with implications for public understanding and informed consent for vaccination.

I look forward to your response.

Yours sincerely

Elizabeth Hart
Independent researcher on medical ethics and vaccination policy
vaccinationispolitical.net

Attachments:

1. Email from Elizabeth Hart to Professor Brendan Murphy – 24 February 2021
2. Email thread from Elizabeth Hart to Mr David Anderson – 8 March 2021 and 26 February 2021
3. ABC *7.30* Transcript – Interview with Professor Brendan Murphy, 3 February 2021
4. TGA provisional approval information – Pfizer COVID-19 vaccine, 25 January 2021
5. TGA provisional approval information – AstraZeneca COVID-19 vaccine, 16 February 2021
6. Submission from Elizabeth Hart to Prime Minister Scott Morrison – 9 March 2021

COVID-19 vaccines are NOT fully approved by the TGA

Elizabeth Hart <elizmhart@gmail.com> Wed, Feb 24, 2021 at 9:20 PM
To: Brendan.Murphy@health.gov.au
Cc: covid19vaccinerfi@health.gov.au, christopher.blyth@uwa.edu.au, Allen Cheng <Allen.Cheng@monash.edu>, chief.scientist@chiefscientist.gov.au, "Marshall, Larry (Executive, Black Mountain)" <larry.marshall@csiro.au>, a.wilson@sydney.edu.au, sue.macleman@mtpconnect.org.au, mark.sullivan@medicinesdevelopment.com, ATAGI Secretariat <atagi.secretariat@health.gov.au>, PBAC <pbac@health.gov.au>

For the attention of:
Professor Brendan Murphy
Secretary of the Australian Department of Health
Chair of the COVID-19 Vaccines and Treatments for Australia - Science and Industry Technical Advisory Group

Professor Murphy

You recently assured Australians that the Pfizer and AstraZeneca vaccine products have ***"gone through the normal, full range of regulatory approvals for our vaccines...we have been able to do the full, safe, regulatory approval...we have not cut any corners"*** and ***"...we decided that to get the confidence of the people in Australia, because we had no community transmission, we were not going to do anything other than our full normal registration process"***, during an interview with Leigh Sales on the ABC's *7.30* program on 3 February 2021. (See copy of transcript attached.)

Your statements were in response to Leigh Sales' questions *"...what is your message to any Australian who might be legitimately worried thinking, "This has happened all pretty quickly. I'm sort of worried.* ***Is it going to be safe to have a vaccine? What is your official advice on that?"*** (My emphasis.)

Professor Murphy, I suggest your 'official advice' on this matter is misleading because **in fact both the Pfizer and and AstraZeneca vaccine products have only been given *'provisional'* approval by the TGA. This has *not* been made clear to the Australian public.**

The TGA provisional approval statement for both the Pfizer COMIRNATY[1] and COVID-19 Vaccine AstraZeneca[2] vaccine products states: (See copies attached.)

> *"**Provisional approval** of this vaccine is valid for two years and means it can now be legally supplied in Australia. The approval is subject to certain strict conditions, such as the requirement for (Pfizer/AstraZeneca) **to continue providing information to the TGA on longer term efficacy and safety from ongoing clinical trials and post market assessment**. (Pfizer COMIRNATY/COVID-19 Vaccine AstraZeneca) has been shown to prevent COVID-19 **however it is not yet known whether it prevents transmission or asymptomatic disease**."* (My emphasis.)

Professor Murphy, I again suggest you have misled Australians about the TGA approval for the Pfizer and AstraZeneca vaccine products.

These vaccine products have ***not*** been fully approved, and it is ***not*** yet known whether they prevent transmission or asymptomatic disease.

The Pfizer and AstraZeneca vaccine products are ***provisionally approved*** for two years, and the TGA will be relying on manufacturer supplied data to judge the longer term efficacy and safety from ongoing clinical trials and **post-market assessment**. 'Post-market assessment' indicates people being vaccinated in the community are now part of the clinical trials assessing these vaccine products - **are people being informed they are part of a vaccine clinical trial? Are these people giving their consent to being involved in a vaccine clinical trial with these *provisionally approved* vaccine products?**

It's on the record I have brought this matter to your attention Professor Murphy, as witnessed by other members of the COVID-19 Vaccines and Treatments for Australia - Science and Industry Technical Advisory Group copied on this email.

This email will be forwarded to Prime Minister Scott Morrison, Health Minister Greg Hunt and other parties.

Sincerely
Elizabeth Hart
Independent person investigating the over-use of vaccine products and conflicts of interest in vaccination policy

References:
1. TGA provisionally approves Pfizer COVID-19 vaccine. 25 January 2021.
2. TGA provisionally approves AstraZeneca's COVID-19 vaccine. 16 February 2021.

3 attachments

Dr Brendan Murphy answers questions about the safety of the COVID vaccine - 7.30.pdf
119K

TGA provisionally approves AstraZeneca's COVID-19 vaccine (TGA).pdf
102K

TGA provisionally approves Pfizer COVID-19 vaccine (TGA).pdf
94K

Re: Misleading information - Brendan Murphy's interview with Leigh Sales, 3 February 2021

Elizabeth Hart <elizmhart@gmail.com> Mon, Mar 8, 2021 at 9:43 PM
To: david.anderson@abc.net.au
Cc: Sales.Leigh@abc.net.au

For the attention of:
Mr David Anderson
ABC Managing Director

Mr Anderson, in my email of 26 February 2021, below, **I brought it to your attention that Professor Brendan Murphy, Australian Secretary of Health, lied to the Australian public during his interview with Leigh Sales on ABC 7.30** on 3 February 2021.

Professor Murphy firmly asserted the Covid-19 vaccine products have **'full'** TGA approval, when in fact they are ***only provisionally approved.***

People being vaccinated in the current vaccine rollout are participating in a massive vaccine trial with the provisionally approved vaccine products. Health Minister Greg Hunt admitted this in his interview with David Speers on ABC Insiders on 21 February 2021, when he said **"The world is engaged in the largest clinical trial, the largest global vaccination trial ever..."**

Are the people being vaccinated giving their informed consent to participate in this experimental vaccine trial? Do the people being vaccinated know that the Morrison government has given the vaccine suppliers indemnity for 'inevitable' side effects, as reported in The Sydney Morning Herald?

The ABC's Code of Practice 2019 states that the ABC belongs to the Australian people, and that **"Earning and retaining their trust is essential to fulfilling the ABC's charter and its responsibilities under the ABC Act to provide innovative and comprehensive services of a high standard to Australian and international audiences"**.

The ABC's Code of Practice notes **"The ABC has a statutory duty to ensure that the gathering and presentation of news and information is accurate according to the recognised standards of objective journalism. Credibility depends on factual accuracy...The ABC requires that reasonable efforts be made to ensure accuracy in all fact-based content"**.

Mr Anderson, the information provided on ABC 7.30 by Professor Brendan Murphy about the regulatory status of the Covid-19 vaccine products was grossly inaccurate and misleading, resulting in the Australian public being misinformed about an experimental medical intervention, i.e. Covid-19 vaccination, and this is obviously relevant to the Pfizer and AstraZeneca vaccine products being rolled out now.

People in Australia are being misinformed about the regulatory status of the vaccine products, a matter which may have great bearing on their decision to be vaccinated, along with considering their personal risk with this virus which isn't serious for most people under the age of 70, and not necessarily a death sentence for those over 70.

I again request you take steps to address this misinformation, and for your response on this matter, see my original email to you below.

It's on the record I have brought this example of misleading information to your attention.

Sincerely
Elizabeth Hart
Independent citizen investigating the over-use of vaccine products and conflicts of interest in vaccination policy

On Fri, Feb 26, 2021 at 3:17 PM Elizabeth Hart <elizmhart@gmail.com> wrote:

> **For the attention of:**
> Mr David Anderson
> ABC Managing Director
>
> Dear Mr Anderson, during a recent interview with Leigh Sales on 7.30, **Australian Secretary of Health Professor Brendan Murphy relayed misleading information about the Covid-19 vaccine products to the Australian population, i.e. that these products have been fully approved by the TGA, when in fact they have only been provisionally approved.**
>
> FYI, please see below my email to Professor Murphy with more details.
>
> Mr Anderson, it's a serious matter that Australians have been misled by the taxpayer-funded ABC, what steps will you take to address this misinformation?
>
> Sincerely
> Elizabeth Hart
> Independent person investigating the over-use of vaccine products and conflicts of interest in vaccination policy
>
> ---------- Forwarded message ---------
> From: **Elizabeth Hart** <elizmhart@gmail.com>

Date: Wed, Feb 24, 2021 at 9:20 PM
Subject: COVID-19 vaccines are NOT fully approved by the TGA
To: <Brendan.Murphy@health.gov.au>
Cc: <covid19vaccinerfi@health.gov.au>, <christopher.blyth@uwa.edu.au>, Allen Cheng <Allen.Cheng@monash.edu>, <chief.scientist@chiefscientist.gov.au>, Marshall, Larry (Executive, Black Mountain) <larry.marshall@csiro.au>, <a.wilson@sydney.edu.au>, <sue.macleman@mtpconnect.org.au>, <mark.sullivan@medicinesdevelopment.com>, ATAGI Secretariat <atagi.secretariat@health.gov.au>, PBAC <pbac@health.gov.au>

For the attention of:
Professor Brendan Murphy
Secretary of the Australian Department of Health
Chair of the COVID-19 Vaccines and Treatments for Australia - Science and Industry Technical Advisory Group

Professor Murphy

You recently assured Australians that the Pfizer and AstraZeneca vaccine products have ***"gone through the normal, full range of regulatory approvals for our vaccines...we have been able to do the full, safe, regulatory approval...we have not cut any corners"*** and ***"...we decided that to get the confidence of the people in Australia, because we had no community transmission, we were not going to do anything other than our full normal registration process"***, during an interview with Leigh Sales on the ABC's *7.30* program on 3 February 2021. (See copy of transcript attached.)

Your statements were in response to Leigh Sales' questions *"...what is your message to any Australian who might be legitimately worried thinking, "This has happened all pretty quickly. I'm sort of worried.* ***Is it going to be safe to have a vaccine? What is your official advice on that?"*** (My emphasis.)

Professor Murphy, I suggest your 'official advice' on this matter is misleading because **in fact both the Pfizer and and AstraZeneca vaccine products have only been given *'provisional'* approval by the TGA. This has *not* been made clear to the Australian public.**

The TGA provisional approval statement for both the Pfizer COMIRNATY[1] and COVID-19 Vaccine AstraZeneca[2] vaccine products states: (See copies attached.)

> *"**Provisional approval** of this vaccine is valid for two years and means it can now be legally supplied in Australia. The approval is subject to certain strict conditions, such as the requirement for (Pfizer/AstraZeneca) **to continue providing information to the TGA on longer term efficacy and safety from ongoing clinical trials and post market assessment**. (Pfizer COMIRNATY/COVID-19 Vaccine AstraZeneca) has been shown to prevent COVID-19 **however it is not yet known whether it prevents transmission or asymptomatic disease**."* (My emphasis.)

Professor Murphy, I again suggest you have misled Australians about the TGA approval for the Pfizer and AstraZeneca vaccine products.

These vaccine products have ***not*** been fully approved, and it is ***not*** yet known whether they prevent transmission or asymptomatic disease.

The Pfizer and AstraZeneca vaccine products are ***provisionally approved*** for two years, and the TGA will be relying on manufacturer supplied data to judge the longer term efficacy and safety from ongoing clinical trials and **post-market assessment**. 'Post-market assessment' indicates people being vaccinated in the community are now part of the clinical trials assessing these vaccine products - **are people being informed they are part of a vaccine clinical trial? Are these people giving their consent to being involved in a vaccine clinical trial with these *provisionally approved* vaccine products?**

It's on the record I have brought this matter to your attention Professor Murphy, as witnessed by other members of the COVID-19 Vaccines and Treatments for Australia - Science and Industry Technical Advisory Group copied on this email.

This email will be forwarded to Prime Minister Scott Morrison, Health Minister Greg Hunt and other parties.

Sincerely
Elizabeth Hart
Independent person investigating the over-use of vaccine products and conflicts of interest in vaccination policy

References:
1. TGA provisionally approves Pfizer COVID-19 vaccine. 25 January 2021.
2. TGA provisionally approves AstraZeneca's COVID-19 vaccine. 16 February 2021.

Image:

7.30 Report

Dr Brendan Murphy answers questions about the safety of the COVID vaccine

Posted Wed 3 Feb 2021, 8:27pm
Updated Wed 3 Feb 2021, 11:31pm
Expires: Thursday 1 January 4759 8:27pm

Dr Brendan Murphy is the former Chief Medical Officer, now Secretary of the Department of Health. He joins Leigh Sales to answer questions about the vaccine rollout and to dispel some of the myths that have been circling about the vaccine.

Transcript

plusminus

LEIGH SALES, PRESENTER: Dr Murphy, thanks for your time today

DR BRENDAN MURPHY, DEPARTMENT OF HEALTH SECRETARY: Pleasure.

LEIGH SALES: Just to get it out of the way, vaccine misinformation, can you briefly answer with yes or no kind of answers and dispense with some of this nonsense for us.

Is hydroxychloroquine the answer to stopping the coronavirus pandemic?

BRENDAN MURPHY: There is no current evidence that supports a role for hydroxychloroquine and stopping the coronavirus pandemic.

LEIGH SALES: Are any of the vaccines dangerous or going to kill you?

BRENDAN MURPHY: There is no evidence at all that any of the vaccines are dangerous or would kill you. They are all very, very carefully tested by our TGA, which is one of the best regulatory authorities in the world.

LEIGH SALES: Is the health risk of side effects from any of the vaccines greater than the health risks to the community of COVID?

BRENDAN MURPHY: There is no evidence to support that and we now have quite good evidence of the vaccine rollout in a number of countries where they've needed to do it in an emergency situation, and the evidence suggests that whilst there are some minor side effects, serious side effects are very, very limited and the risk is much greater of the disease than being vaccinated - much, much, much greater.

LEIGH SALES: Have you ever raised with the Prime Minister concerns about politicians like Craig Kelly spreading misinformation?

BRENDAN MURPHY: No, I haven't personally raised concerns with the Prime Minister.

I'm on the record in parliamentary committees saying that I think everyone should follow the expert medical advice and their views.

LEIGH SALES: And just to wrap up, what is your message to any Australian who might be legitimately worried thinking, "This has happened all pretty quickly. I'm sort of worried. Is it going to be safe to have a vaccine?" What is your official advice on that?

BRENDAN MURPHY: My official advice is that we have deliberately gone through the normal, full range of regulatory approvals for our vaccines, because we are in such a good place in this country with no community transmission, we have been able to do the full, safe, regulatory approval.

The Pfizer vaccine is approved and we hope the TGA (Therapeutic Goods Administration) will approve the AstraZeneca vaccine in coming weeks, but we have not cut any corners and we will not register a vaccine unless we're confident about its safety.

LEIGH SALES: Okay, so that aside, is Australia going to get to herd immunity using the AstraZeneca vaccine, given that some of the other leading vaccines have greater efficacy?

BRENDAN MURPHY: We don't know whether any of the vaccines will give us herd immunity. That's our goal.

All we know at the moment is that the vaccines are very good, all of them, at protecting against clinical COVID disease.

There is less data on the AstraZeneca vaccine in the phase 3 trials, but there is more data coming, and the data coming just recently out of the UK suggests that they are getting a very good benefit from that vaccine.

We are confident that both the Pfizer vaccine, the AstraZeneca vaccine and later the Novavax vaccine are all good at preventing clinical disease.

We will only know over time whether they prevent transmission of the virus and give us herd immunity.

We don't know how long that immunisation will last for and we don't know what any of them will do on the transmission of the virus. That information will come in time.

Our strategy at the moment is to protect our population against COVID disease, and both vaccines are very good at that.

I'm going to have the AstraZeneca vaccine. I will be very pleased to have it.

LEIGH SALES: Novavax has had better results than AstraZeneca, but we aren't producing it locally. Why not?

BRENDAN MURPHY: At the moment, CSL who is our only local manufacturing plant, have been focused on producing AstraZeneca and as I said, it is a vaccine that there have been billions of doses of AstraZeneca ordered around the world in many, many countries. It is a very good vaccine.

Novavax has some preliminary data, too, but all of the vaccines have only got phase 3 trial data. We will get more and more data - big data coming out of a US trial on AstraZeneca soon. So Novavax has on its preliminary phase 3 data good results but I think AstraZeneca is a very strong and good vaccine.

LEIGH SALES: A couple of weeks ago you were asked why Australia isn't getting any of the Moderna vaccine and you implied there was an issue in negotiations. Why haven't we able to get supply from them?

BRENDAN MURPHY: All of our vaccine purchases have been guided a scientific and technical expert advisory group which I chair. That group made a decision before any of the phase 3 data was out to make a strategic investment in Pfizer, which we did.

We continue to review our vaccine portfolio and we're continuing to have discussions with several major vaccine companies, and we also have access to a number of vaccines through the COVAX Facility.

So at the moment we've got three times population coverage with the vaccines we've got. We know those vaccines are good, but we will continue to explore our vaccine portfolio and may make additional purchases in the future, but we can't detail the commercial-in-confidence discussions with all the vaccine companies.

LEIGH SALES: So to be clear, are we currently involved in negotiations to try to secure more doses of vaccine from any of the leading candidates?

BRENDAN MURPHY: We are continuing to discuss with a number of companies and we will continue to get advice from our Scientific and Technical Advisory Group to see whether, despite the fact that we've got very good population coverage, as extra insurance, we may get some more doses of some vaccines, but we can't, I can't detail anything more than that other than to say we are continuing those discussions and continuing to get advice from the Scientific and Technical Advisory Committee.

LEIGH SALES: Why are we slower at rollout than, say, Israel? It has already administered 5 million doses to its 9 million residents, and they are not even manufacturing locally?

BRENDAN MURPHY: The decision we made, unlike a lot of other countries, including Israel, who have community transmission and have an urgent need to get going early, we decided that to get the confidence of the people in Australia, because we had no community transmission, we were not going to do anything other than our full normal registration process.

That has been the major reason why we are starting later than some countries. We have not had that burning platform.

LEIGH SALES: Dr Murphy, thank you very much.

BRENDAN MURPHY: Pleasure, Leigh.

Australian Government
Department of Health
Therapeutic Goods Administration

TGA provisionally approves Pfizer COVID-19 vaccine

25 January 2021

The Therapeutic Goods Administration (TGA) has granted provisional approval to Pfizer Australia Pty Ltd for its COVID-19 vaccine, COMIRNATY (//www.tga.gov.au/covid-19-vaccine-pfizer-australia-comirnaty-bnt162b2-mrna), making it the first COVID-19 vaccine to receive regulatory approval in Australia.

Following a thorough and independent review of Pfizer's submission, the TGA has decided that this vaccine meets the high safety, efficacy and quality standards required for use in Australia.

COMIRNATY is provisionally approved and included in the Australian Register of Therapeutic Goods (ARTG) for active immunisation to prevent coronavirus disease 2019 (COVID-19), caused by SARS-CoV-2, in individuals 16 years of age and older.

Provisional approval of this vaccine is valid for two years and means it can now be legally supplied in Australia. The approval is subject to certain strict conditions, such as the requirement for Pfizer to continue providing information to the TGA on longer term efficacy and safety from ongoing clinical trials and post-market assessment. COMIRNATY has been shown to prevent COVID-19 however it is not yet known whether it prevents transmission or asymptomatic disease.

Australians can be confident that the TGA's review process of this vaccine was rigorous and of the highest standard. The decision to provisionally approve the vaccine was also informed by expert advice from the Advisory Committee on Vaccines (ACV) (//www.tga.gov.au/committee/advisory-committee-vaccines-acv), an independent committee with expertise in scientific, medical and clinical fields including consumer representation.

The TGA will continue to actively monitor the safety of the Pfizer vaccine both in Australia and overseas and will not hesitate to take action if safety concerns are identified. As an extra check, the TGA laboratories will undertake batch assessment (//www.tga.gov.au/batch-release-assessment-covid-19-vaccines) of each batch of the vaccine before it can be supplied in Australia.

The TGA has published a series of regulatory documents that relate to this decision, including the Australian Public Assessment Report (AusPAR) (//www.tga.gov.au/auspar/auspar-bnt162b2-mrna-comirnaty) and the decision summary (//www.tga.gov.au/apm-summary/comirnaty), which provide

details about the evidence that the TGA reviewed to support the provisional approval of the vaccine. The Product Information, FAQs and information on labelling and batch testing are also available on the COVID-19 vaccines hub (//www.tga.gov.au/covid-19-vaccines).

Further information on the COVID-19 vaccine rollout is available on the Department of Health website (https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines).

Category: Prescription medicines
Tags: vaccines
URL: https://www.tga.gov.au/node/936166 (https://www.tga.gov.au/node/936166)

Australian Government
Department of Health
Therapeutic Goods Administration

TGA provisionally approves AstraZeneca's COVID-19 vaccine

16 February 2021

The Therapeutic Goods Administration (TGA) has granted provisional approval to AstraZeneca Pty Ltd for its COVID-19 vaccine (//www.tga.gov.au/covid-19-vaccine-astrazeneca-chadox1-s), making it the second COVID-19 vaccine to receive regulatory approval in Australia.

COVID-19 Vaccine AstraZeneca is provisionally approved and included in the Australian Register of Therapeutic Goods (ARTG) for the active immunisation of individuals 18 years and older for the prevention of coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2. The use of this vaccine should be in accordance with official recommendations and given in two separate doses. "TGA's regulatory approval allows the second dose to be administered from 4 to 12 weeks after the first. The Australian Technical Advisory Group on Immunisation has recommended that the interval between first and second dose is 12 weeks. However if this interval is not possible, for example because of imminent travel, cancer chemotherapy, major elective surgery, a minimum interval of 4 weeks between doses can be used.

Provisional approval of this vaccine is valid for two years and means it can now be legally supplied in Australia. The approval is subject to certain strict conditions, such as the requirement for AstraZeneca to continue providing information to the TGA on longer term efficacy and safety from ongoing clinical trials and post-market assessment. COVID-19 Vaccine AstraZeneca has been shown to prevent COVID-19 however it is not yet known whether it prevents transmission or asymptomatic disease.

Elderly patients over 65 years of age demonstrated a strong immune response (high seroconversion rates) to the vaccine in clinical trials, however there were an insufficient number of participants infected by COVID-19 to conclusively determine the efficacy in this subgroup. In this sub-population, efficacy has been inferred from immunogenicity data and efficacy demonstrated in the general population. Reassuringly, there were no safety concerns in this age group in the clinical studies, nor in the large numbers of elderly people who have been vaccinated to date in overseas rollouts. The decision to immunise an elderly patient should be decided on a case-by-case basis with consideration of age, co-morbidities and their environment taking into account the benefits of vaccination and potential risks. Further information from ongoing clinical trials and post-market

monitoring is expected in coming months. Additional details can be found in the Product Information and Australian Public Assessment Report (AusPAR) (//www.tga.gov.au/auspar/auspar-chadox1-s).

Initial supply of this vaccine will be imported into Australia from overseas, however it is anticipated that ongoing supply will be manufactured in Australia. Prior to supply of vaccines manufactured onshore, AstraZeneca will submit further information and data to the TGA to confirm that onshore manufacturing will meet strict quality standards.

Australians can be confident that the TGA's review process of this vaccine was rigorous and of the highest standard. The decision to provisionally approve the vaccine was also informed by expert advice from the Advisory Committee on Vaccines (ACV) (//www.tga.gov.au/committee/advisory-committee-vaccines-acv), an independent committee with expertise in scientific, medical and clinical fields including consumer representation.

As with all vaccine approvals, the TGA will:

- Continue to actively monitor the vaccine in Australia and overseas (//www.tga.gov.au/covid-19-vaccine-safety-monitoring-and-reporting) and will not hesitate to take action if safety concerns are identified.
- Undertake laboratory batch assessment (//www.tga.gov.au/batch-release-assessment-covid-19-vaccines) of each batch of the vaccine before it can be supplied in Australia.

The TGA has published a series of regulatory documents that relate to this decision, including the Australian Public Assessment Report (AusPAR) (//www.tga.gov.au/auspar/auspar-chadox1-s) and the decision summary (//www.tga.gov.au/apm-summary/covid-19-vaccine-astrazeneca), which provide details about the evidence that the TGA reviewed to support the provisional approval of the vaccine. The Product Information, FAQs and information on labelling and batch testing are also available on the COVID-19 vaccines hub (//www.tga.gov.au/covid-19-vaccines).

Further information on the COVID-19 vaccine rollout is available on the Department of Health website (https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines).

Category: Prescription medicines
Tags: COVID-19 vaccines, vaccines
URL: https://www.tga.gov.au/node/936567 (https://www.tga.gov.au/node/936567)

From: **Prime Minister of Australia via Prime Minister of Australia** <webservices@pmc.gov.au>
Date: Tue, Mar 9, 2021 at 11:09 PM
Subject: Your message to the Prime Minister
To: <elizmhart@gmail.com>

Thank you for your message to the Prime Minister at pm.gov.au. For your records, a copy of your message is set out at the bottom of this email.

If your message relates to COVID-19, the Australian Government has established https://www.australia.gov.au for up to date advice on how you can protect yourself and your family. Information includes an online symptom checker, travel bans and restrictions, guidance for receiving financial support, health and prevention information and key updates from the Prime Minister and the National Cabinet.

All items of correspondence are read and carefully considered, however not all items will receive a response. When responses are sent, these items will be sent via the same method in which they are received; via email or Australia Post

In some cases, where appropriate, your correspondence will be referred to other Federal Ministers or state/territory governments for their consideration. This will occur when the issue raised falls within their responsibilities.

This is an automatically generated email. Please do not reply to this email as this address is not monitored.

If you have any problems with this service please contact the Web Administrator through the site feedback service at https://www.pm.gov.au/site-feedback

Submitted on Tuesday, 9 March, 2021 - 23:39

Title: Ms
First name: Elizabeth
Family name: Hart
Email address: elizmhart@gmail.com
Phone:
Your address:
Subject: Misleading information about COVID-19 vaccine products from Australian Health Secretary Brendan Murphy
Comment:
Mr Morrison, Health Secretary Professor Brendan Murphy lied to Australians when he said the COVID-19 vaccine products have 'full' TGA approval on the ABC 7.30 program, when in fact they are only provisionally approved.
It's a very serious matter that Australians are being deliberately misled about the regulatory status of these experimental medical interventions, which are being fast-tracked around the world.
Australian Health Minister Greg Hunt has also admitted "The world is engaged in the largest clinical trial, the largest global vaccination trial ever..." in an interview with David Speers, on ABC Insiders.
The Pfizer and AstraZeneca experimental vaccine products are being rolled out in Australia now, with much pressure on people of all ages to have these vaccine products, regardless of their personal risk.
I raised the matter of Brendan Murphy giving misleading information on the ABC 7.30 program with ABC Managing Director David Anderson, in an email dated 26 February 2021, but have received no response.
FYI, please see attached my follow-up email to Mr Anderson, requesting his response on the misinformation spread via 'our' ABC.
What is the situation in other countries - are people being properly informed about these vaccine products not being fully approved, are they giving their informed consent to participating in this massive vaccine trial?
Sincerely
Elizabeth Hart
Independent person investigating the over-use of vaccine products and conflicts of interest in vaccination policy