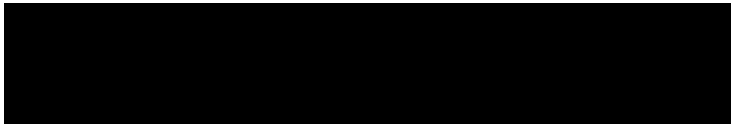


Submission on:

Public Health and Other Legislation (Further Extension of Expiring Provisions) Amendment Bill 2021

Authors Name: Mr Michael Bannister



Preamble

The following submission is made on my own behalf as I have read the proposed amendments and am overly concerned at what the State Government is trying to do.

I would also like to add that I have had many vaccinations throughout my life, mostly within the Army. I have been hospitalised from vaccinations whilst I was in the Army but continued to get injections as required. I also received vaccinations after leaving the Army as I believed they were helping me.

I have strong objections to these injections and proposed course of actions by all levels of government. These are PROVISIONALLY approved around the world and still under clinical trial, basically the human population are being used as 'guinea pigs'. The adverse reactions to date in many countries around the world to me far outweighs the benefits. I also note that people who have been vaccinated are still getting the disease and dying. This begs the question why?

I also consider that the actions being taken by all levels of government regarding lockdowns, masks and detention of healthy people are draconian measures that when statistics (which we all know can be made to lie) prove that there is no real benefit from these measures. The most recent 'cases' in Queensland would seem to support this – we locked down and had people mask up in portions of the State for 3 cases. On Sunday we increased to 5 cases – but the lock down restrictions were eased – and funnily enough the football at Suncorp went ahead. Just questioning the logic??

I also note that not at any time during the 'pandemic' has the CHO or Queensland Health department or come out and recommended/promoted people adopt a healthier lifestyle, including eating better, exercising and when necessary, taking vitamin supplements to improve the bodies immune system. My belief, having said this, is that it is our own personal responsibility to take care of ourselves and it is not up to the government to legislate controls on us – just offer support to improve our health. Ultimately it is my view (formed by reading papers from Immunologists, virologists, epidemiologists and other medical specialists from around the world) that if we had left this 'virus' run its course it would have been long gone by now, and the bulk of the population would have had natural immunity. We have prolonged the pain.

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Much of what I have read in the proposed in the amendment in my mind breaches our civil rights and freedoms that are expressed in the Australian Human Rights Commission Act, 1986, Schedule 2 which is basically the ***International Covenant on Civil and Political Rights***, which Australia is signed up to. The overall public health implications do not warrant the requirement of either the State or Commonwealth Governments to trample the Australian people in this manner.

Finally, it is my understanding that our *Commonwealth of Australia Constitution Act* is the highest law in the land – under Common Law – and cannot be usurped by State laws.

Submission Notes

Item	Statement from Legislation	Submission point
1	Despite overall low numbers of COVID-19 in Queensland and few restrictions now in place on the movement and gathering of people, there is still potential for larger scale outbreaks. The current global epidemiological situation, with sustained growth in new cases and the spread of highly transmissible COVID-19 variants, continues to present a significant risk to the community. (Page 1)	The use of cases to define this current global epidemiological situation is misleading. I believe that if we looked at recovery rates it would be more positive, particularly as the recovery rate as stated by many organisations is over 99.97% for the general population. It is also important to note that other countries are allowing and even recommending the use of alternative prophylactic medicines (Ivermectin and Hydroxy chloroquine, Vitamin D, C, Zinc and other combinations of treatment) to great effect. The doctors using these treatments have had peer reviewed articles published and they have been accepted. These countries are also treating larger numbers of people - more than in Australia.
2	Recent outbreaks in other Australian jurisdictions and continued large-scale transmission around the world serve as a clear reminder of how rapidly COVID-19 can spread and overwhelm health systems. The pandemic continues to be unpredictable, as recently underscored by the sudden state-wide lockdown of Victoria on 28 May 2021 following a widespread outbreak in Greater Melbourne, the three-day lockdown of Greater Brisbane on 29 March 2021 following cases of community transmission, and the changes to the	This is contradictory to the CHO advise as the Astrazeneca injection is not for use in people under 50 (<i>quotes are from the transcript of proceedings ECONOMICS AND GOVERNANCE COMMITTEE dated 5 Jul 21</i>): "Mr STEVENS: I am personally informed by two young doctors that I am familiar who are working in your department in a regional area as frontline workers that they had to have the AstraZeneca vaccine by necessity rather than choice. Given your strong advice to 18-year-

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	<p>recommendations for use of the AstraZeneca vaccine in people under 50 years of age. (Page 1)</p>	<p><i>olds not to have the AstraZeneca vaccine, do you have any concerns for frontline workers under 40 in the department having the AstraZeneca vaccine?</i></p> <p>Dr Young: <i>Yes, I absolutely have concerns. I have made the Pfizer vaccine available to every single healthcare worker for many months now. I do not understand why any individual who is employed in Queensland Health—whether they be a doctor, a nurse, a groundsman, a cleaner, a receptionist or someone who works in the kitchens—has not come forward and had the Pfizer vaccine.</i></p> <p><i>from the same briefing:</i></p> <p>"Dr Young: <i>Everywhere, throughout the entire state. Anyone employed—all 110,000—may have the Pfizer vaccine. Of course, prior to ATAGI coming out—remember ATAGI came out on that Thursday night; the Prime Minister announced it—they could have had AstraZeneca. However, once ATAGI had stood up and said anyone under the age of 50 should preferentially get Pfizer, we immediately enacted that. When ATAGI changed their advice to 60, we immediately enacted that.</i></p> <p><i>Being that the advice is not to mix the injections these people are now at risk from injury due to misinformation.</i></p>
3	<p>As at 31 May 2021, the World Health Organization reported a total of 170,051,718 confirmed positive COVID-19 cases reported globally. Australia has experienced a lesser burden from COVID-19 than other countries. However, as at 31 May 2021, the Australian Government Department of Health reported 30,106 confirmed COVID-19 cases, including 910 deaths in Australia. As at 31 May 2021, there had been 1,618 confirmed cases of COVID-19 in Queensland,</p>	<p>The Federal and State health departments highlight 'cases' - none mention the recovery rates. This is using fear and paranoia to rule people's lives. Using 25,788,215 million (ref Google 6 Jul 21) people as the current population and the reported 30,106 cases (as of 21 May 21) that equates to 0.1167% of the population. How many people have died in 2021: 1!!</p> <p>This could hardly be a major emergency that is destroying people's lives! In comparison 3,074 deaths occurred from</p>

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	including 14 active cases, with seven deaths relating to COVID-19 being Queensland residents. (Page 2)	ischaemic heart disease between January and March 2021 (Ref ABS - Provisional Mortality Statistics Jan - Mar 2021) compared to 1 death to Covid 19 - and we have spent billions trying to stop Covid 19? Does not make much sense to me.
4	The public health emergency for COVID-19 continues to require a significant response from the health system and support from other government departments. It is expected the need for emergency powers will remain until many of the Queensland population has been vaccinated and the risk of widespread outbreaks has subsided. (Page 2)	The Government is not truly focused on preventing Covid 19 or it would allow the use of prophylactics such as those mentioned earlier, as well as promoting healthier lifestyle and improving the immune system. The injections are not the only answer - which is indicated in the product information data from both injections available on the TGA website and supported by the fact that vaccinated people are still getting Covid 19, and whilst they are recovering so are the un-vaccinated people - based on the government's own data - 1 death Australia wide!
5	<p>increase powers for emergency officers and the Chief Health Officer to limit, or respond to, the spread of COVID-19 in Queensland, including by issuing directions to require physical distancing, restrict movement and gatherings, require persons to quarantine or self-isolate and implement other containment measures</p> <p>authorise the sharing of confidential information for contact tracing</p> <p>encourage compliance with quarantine requirements, border restrictions and other public health directions by providing appropriate penalties for contraventions</p> <p>increase the period for which a regulation may extend a declared public health emergency from seven to 90 days</p>	<p>Why is it that public servants and politicians revert to fines and penalties instead of assisting people to get healthy in this case?? Give people support if they are sick instead of destroying their lives and livelihoods. The extending of powers for a 'declared public health emergency' is nothing more than a bid for control over the lives of the people who do not need the imposition.</p> <p>Quarantine appears to be the source of many of our problems - although some of the 'cases' are dubious as the people coming in from other countries are 'apparently' required to be tested negative before getting on the plane to Australia, and in some cases, they are already vaccinated before leaving other countries. Begs the question - if one person on a plane has a deadly Covid 19 variant of some sort then why is it that everyone on the plane does not get it??</p>

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	enable fees to be charged for costs associated with the mandatory quarantine of persons in government-provided accommodation.	<p>It also seems that the government, more directly the Queensland Health Department, is more focused on getting money out of people for quarantine than helping people recover from Covid 19.</p> <p><i>"The bill introduces a prepayment framework for quarantine fees, and it authorises the director-general of Queensland Health to require persons who will be required to quarantine in Queensland to pay the prescribed quarantine fees before they arrive. The prepayment requirements will only apply to specific categories, or cohorts, of travellers, though, and these will be prescribed in regulation."</i></p> <p>(Dr Wakefield - (taken from the transcript of proceedings ECONOMICS AND GOVERNANCE COMMITTEE dated 5 Jul 21)</p> <p>Let incoming people self-isolate at home or the location they are heading to.</p>
6	A transitional regulation will expire two years after the COVID-19 legislation expiry day.(Page 4)	<p>Why is this necessary - supposedly we will be 'back to normal'?? Based on what is contained in this document it is proposed that the date for 'Covid 19 legislation expiry day' is being extended to 1 May 2022 - which means this transitional legislation will be until 1 May 2024.</p>
7	<p>Extension of expiring provisions</p> <p>Unless extended, most of the emergency COVID-19 legislative amendments will expire on 30 September 2021. As the health response to COVID-19 is ongoing, it is expected that the declared public health emergency and COVID-19 related amendments to the Public Health Act will need to continue into early 2022 to manage international arrivals in hotel quarantine and respond to any localised outbreaks in Queensland while the vaccine rollout progresses. It is proposed to extend the amendments in the</p>	<p>If the extension applies until early 2022 (1 May 2022) 'to manage international arrivals in hotel quarantine' then it is clear that the government has no faith in the testing being undertaken overseas on passengers destined for Australia. It also begs the question if we are still having 'cases' in quarantine how is it that if the 'virus' is so deadly and transmissible why do not more people contract it on the aircraft?</p> <p>With regards to the 'effectiveness of the vaccine rollout' assessment - if the official TGA trial does not end until Feb</p>

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	Public Health Act until 30 April 2022, which will also allow time for the effectiveness of the vaccine rollout to be assessed.	2023 then that means the full assessment is not complete. Based on current data from the TGA (Database of Adverse Event Notifications -medicines report for the injections from 1 December 2020 to 6 April 2021 – see accompanying document) there has been 37 suspected deaths and overall (including the suspected deaths) 6163 adverse reactions. This bares serious consideration based on the number of Covid deaths Australia wide during that period - 1.
8	<p>Currently, a direction to isolate or quarantine under section 362H of the Public Health Act must be given to a person by an emergency officer in writing. In practice, directions are usually issued electronically, such as by sending a direction to a person's nominated email address. This is particularly important for contact tracing, as the sheer volume of potential close contacts of confirmed COVID-19 cases and the size of the geographical area in which directions must be given makes personal service of orders infeasible in many cases.</p> <p>The Public Health Act does not explicitly deal with the issue of how a quarantine direction notice may be given in writing. Also, the Act does not specify at what point in time a direction issued to a person via email or other electronic communication is deemed to have been received by the person. Clarifying these issues will remove doubt and is considered important given the heavy reliance on electronic communications by Queensland's contact tracing and quarantine systems.</p>	<p>This proposed requirement to issue quarantine 'directions' electronically is in conflict to the Commonwealth Biosecurity Act 2015 - Compilation 10, Section 63, Giving a human biosecurity control order to an individual.</p> <p><i>(1) An officer who imposes a human biosecurity control order on an individual must cause the individual to be given a copy of the order as soon as reasonably practicable.</i></p> <p><i>(2) The officer who imposes the order on the individual must ensure that the contents of the order are read out to the individual.</i></p> <p><i>(3) The order ceases to be in force if:</i></p> <p><i>(a) a copy of the order is not given to the individual within 24 hours of the order beginning to be in force; or</i></p> <p><i>(b) the contents of the order are not read out in accordance with subsection (2).</i></p> <p>In my understanding this is in against the <i>Commonwealth of Australia Constitution Act (The Constitution)</i>, Section 109: <i>Inconsistency of laws</i></p> <p><i>When a law of a State is inconsistent with a law of the Commonwealth, the latter shall prevail, and the former shall, to the extent of the inconsistency, be invalid.</i></p>

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		<p>In my understanding a 'direction' may not be legal - I would be interested to see the legal definition? Also, if a person is to be detained under quarantine, which is a Commonwealth responsibility under <i>Section 51 (IX), of the Constitution</i>, then should that person not be put under a Biosecurity Control Order?</p> <p>It is also very possible that even though a direction is issued a person may not have access to reliable electronic communication device to receive it, unless of course the government is going to issue and pay for electronic communication devices to these people to ensure delivery of directions?</p> <p>It also assumes that the person will in fact be in a location that has reliable internet access.</p>
9	<p>Quarantine fees</p> <p>From 1 July 2020, persons required to undertake hotel quarantine have been required to contribute to the costs of government accommodation by payment of a quarantine fee. As the rollout of COVID-19 vaccines progresses in Australia and overseas, additional demands will be placed on the quarantine system as more people from a broader range of cohorts are permitted to enter Queensland following a period of mandatory quarantine. The entry of particular cohorts, such as critical and skilled workers and persons who support service-related industries such as tourism and education, is critical to the State's economic recovery. To address these challenges, amendments to the Public Health Act are required to improve the State's ability to recoup quarantine-related expenses and ensure that Queensland's quarantine system remains sustainable and responsive to changing public health and economic circumstances. (Page 6)</p>	<p>Whilst I understand what is written in this proposed amendment, in the Biosecurity Act 2015, Section 108 <i>Expenses incurred in complying with human biosecurity control orders</i></p> <p><i>The Commonwealth is liable to pay for reasonable expenses incurred by an individual in complying with a biosecurity measure included in a human biosecurity control order.</i></p> <p>In my understanding this takes us back to Section 51 (IX) and Section 109 of the Constitution.</p> <p>If that is not the case, then could I please receive an explanation?</p>

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10	<p>The COVID-19 emergency continues to require a significant response from the health system and given the continued unpredictability of the pandemic and uncertainties regarding the rollout of the vaccine both nationally and internationally, the extension of these amendments will ensure that public health measures remain in place to allow Queensland to effectively manage overseas arrivals and the risk of local outbreaks, including of highly contagious COVID-19 variants. (Page 6)</p>	<p>According to Medical Definition of Pandemic - Medical Editor: Charles Patrick Davis, MD, PhD, a Pandemic is: Pandemic: An epidemic (a sudden outbreak) that becomes very widespread and affects a whole region, a continent, or the world due to a susceptible population. By definition, a true pandemic causes a high degree of mortality (death).</p> <p>Based on information in the transcript of proceedings, ECONOMICS AND GOVERNANCE COMMITTEE, 5 Jul 2021 Part of Statement by Dr Jeannette YOUNG, Chief Health Officer, Queensland Health on page 4: <i>"Globally, there have now been over 180 million confirmed COVID-19 cases and over 3.9 million deaths."</i></p> <p>Based on various sites on the internet the current world population is approximately 7.9 billion, with this in mind it means (on the figures quoted) that cases (180 million) are 0.2278% of the population, and deaths (3.9 million) are 0.04936% of the population. In Australia (based on information at the beginning of this document) using 25,788,215 million (<i>ref Google 6 Jul 21</i>) people as the current population and the reported 30,106 cases (<i>as of 21 May 21</i>) that equates to 0.1167% of the population. How many people have died in Australia of Covid in 2021: 1!! Based on the definition above it is hard to call this a pandemic, therefore it appears that there is no need extend the legislation.</p>
11	<p>The Bill amends the Public Health Act to clarify that directions given by an emergency officer under section 362H of the Act may, with a person's consent, be provided to a person electronically via a unique email address nominated by the person. (Page 15)</p>	<p>If the person does not give consent for the direction to be emailed (which the person is legally entitled to do), will the direction still be personally delivered and explained as it is possible that the person involved may have poor comprehension of the English language (especially if they are unskilled workers being bought in or people who have</p>

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		<p>left quarantine and then are 'contact traced' to an infected person). This could quite possibly lead to unintentionally breach of the direction.</p> <p>Again, I refer to the Biosecurity Act 2015 which I covered previously with regards to Biosecurity Control orders.</p>
12	<p>Alternative ways of achieving policy objectives There is no alternative method of achieving the policy objective. (Page 16)</p>	<p>I consider that all the changes proposed to be implemented with regards to Quarantine fees are unacceptable as if people coming into the country are unskilled workers going to carry out seasonal work, then this will place a financial burden on them or the businesses (most likely farmers) who employ these workers. These smaller/medium businesses are already under financial pressure, and this is adding to the pressures.</p> <p>As an alternative why not allow the workers to be isolated at the work area and be able to work? If the system is working how it is meant to be then workers coming in should already have a negative Covid 19 test prior to entering Australia, or have already been vaccinated.</p>
13	<p>Estimated cost for government implementation There are no significant costs to the State for implementation of the amendments. Any costs will be met from within existing budget allocations. (Page 16)</p>	<p>If this is the case, then what is going to happen to some existing services that are covered by "existing budget allocations"?</p> <p>The health system is already struggling, and it would seem that more emergency control officers will be employed as well as administrative staff, which begs the question: who will go without?</p>
14	<p>It is expected that the need for quarantine will remain until a large number of the Queensland population has been vaccinated and the risk of widespread outbreaks has subsided. (Page 17)</p>	<p>Two Questions:</p> <ol style="list-style-type: none">1. What is a "large number"?2. Why are we not able to access prophylactics such as Ivermectin which has over 60 peer reviewed studies

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		exulting their performance in reducing the effects and even halting Covid 19 in infected people?
15	Appropriate safeguards are in place to protect the rights of individuals. For example, under section 361 of the Public Health Act, a person may apply, through their lawyer or another nominated person, to a magistrate to order the end of the detention order made by the emergency officer. Given the need to protect the health of the public, the limitations on the rights and liberties of individuals from the extension of the amendments regarding the duration of detention powers are considered appropriately justified. (Page 17)	<p>Questions:</p> <ol style="list-style-type: none"> 1. Is an Emergency Officer medically qualified or trained? If not, how can they make an impartial educated decision on a person's health? 2. If, "Given the need to protect the health of the public, the limitations on the rights and liberties of individuals from the extension of the amendments regarding the duration of detention powers are considered appropriately justified" how does that comply with the <i>Australian Human Rights Commission Act 1986</i>, Schedule 2, Articles 4 and 7? If this is deemed a public health emergency or threat then the data relating to Covid 19 and alternative treatments needs to be made available to all members of the public, especially those in quarantine, and alternative treatments must be offered as an option - not the injection alone.
16	Extending the expiry of the amendments to the Public Health Act may potentially breach this principle as the provisions authorise the Chief Health Officer and emergency officers to issue directions that may interfere with the rights and liberties of individuals by, for example, restricting movement and requiring closure of business premises. (Page 18)	<p>Question:</p> <p>How is this not affecting people's rights, especially small to medium business owners who may be closed for a duration at the discretion of the CHO or Emergency Officer? These people all have a right to earn a living and look after any family they may have and pay their bills without the need to be propped up by any level of Government. If this is a 'justifiable impact' then the data, particularly the mortality and recovery data from Covid 19 needs to be presented to the public at large.</p>
17	The ability to give quarantine directions electronically is critical to effectively responding to a potential outbreak of COVID-19 in the community. Under the amendments,	See comments previously made with regards to electronic communication of directions.

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	electronic service can only be done with the express consent of the recipient, which provides an important safeguard for the rights of individuals. The amendments also align with current practice and established policies governing the issuance of directions by emergency officers. These policies contain robust safeguards, including the requirement that the contents of a quarantine direction are explained to a person and the person is requested to reply and acknowledge receipt of the direction. (Page 20)	
18	<p>The Bill extends the operation of the regulation-making powers and the modification framework under the ER Act to 30 April 2022. This extension represents a potential departure from the fundamental legislative principle requiring legislation to have sufficient regard to the rights and liberties of individuals in the sense that further amendments may:</p> <ul style="list-style-type: none"> • make rights and liberties, or obligations, dependent on administrative power in circumstances where the power may not ordinarily be considered to be sufficiently defined or subject to appropriate review (section 4(3)(a) Legislative Standards Act); • not be consistent with principles of natural justice, and in particular the right to be heard and the right to procedural fairness (section 4(3)(b) Legislative Standards Act); • allow the delegation of administrative power in cases, and to persons, that may not be considered appropriate (section 4(3)(c) Legislative Standards Act), were it not for the state of emergency currently in place in Queensland; and • adversely affect rights and liberties, or impose obligations, retrospectively (section 4(3)(g) Legislative Standards Act). (Page 20) 	<p>The overall intent to of this proposed amendment to extend powers is based on an exceptionally large assumption that Covid 19 will persist until April 2022. How is this known? I find it difficult to understand how health officials can predict with any accuracy that this virus will extend into 2022 when we do not even have a cure for the common cold, seasonal influenzas (which several highly qualified virologists, immunologists and epidemiologists from overseas believe this virus is) cancer which has billions spent on it? <i>Please supply or produce the data that these assumptions are made on.</i></p>

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19	<p>The Bill has the effect of extending amendments in the Disaster Management Act 2003 that provide for a longer period by which a declared disaster situation may be extended. These amendments raise considerations as to whether the legislation has sufficient regard to the rights and liberties of individuals (section 4(2)(a) of the Legislative Standards Act). This includes, for example, whether the legislation makes rights and liberties, or obligations, dependent on administrative power only if the power is sufficiently defined and subject to appropriate review; allows delegation of administrative power only in appropriate cases and to appropriate persons; and confers power to enter premises, and search for or seize documents or other property, only with a warrant issued by a judge or other judicial officer.</p> <p>The declaration of a disaster situation empowers authorised officers to undertake certain actions or compel others to undertake or refrain from certain actions. This includes controlling the movement of persons, entering places, removing or destroying animals, vegetation, vehicles and structures; and closing roads to traffic. The powers of authorised officers are discretionary and, will only be exercised in circumstances associated with the COVID-19 disaster situation, where the powers are necessary for public safety and the protection of life or property. Authorised officers are limited to those with the necessary expertise or experience to exercise the powers, and authorisations may be limited or given on conditions specific to the circumstances of the officer or event. The power to give directions about property includes that, if the property is residential or business premises, directions may only be given with the written approval of the relevant</p>	<p>I find that the empowering '<i>of authorised officers to undertake certain actions or compel others to undertake or refrain from certain actions</i>' is a very broad loose statement. In my mind this gives some 'authorised officer' the ability to abuse the powers, even if a judge must supply a warrant. This power should be only used by Police, and with exceptionally good reason. This is supposed to be dealing with public health – not hardened criminals.</p> <p>To have the power to be '<i>controlling the movement of persons, entering places, removing or destroying animals, vegetation, vehicles and structures; and closing roads to traffic</i>' appears outrageous for a public health issue. It is an extreme amendment that is unnecessary.</p>
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	district disaster coordinator (section 78 of the Disaster Management Act). (Page 25)	
20	The amendment to the Disaster Management Act to set aside the right to compensation raises whether the legislation has sufficient regard to a person's right to fair compensation for compulsory acquisition of property and, that rights and liberties should not be adversely affected, or obligations imposed, retrospectively (sections 4(3)(i) and 4(3)(g) of the Legislative Standards Act). (Page 25)	Based on <i>The Constitution</i> this is not acceptable, <i>Section 51 (xxxi): the acquisition of property on just terms from any State or person for any purpose in respect of which the Parliament has power to make laws.</i> Acquiring property and not compensating people fairly is totally unjustified – especially when we are dealing with a supposed Public Health emergency.
21	The Bill extends the powers provided under the Public Health Act that allow the Chief Health Officer to issue: <ul style="list-style-type: none"> • a direction restricting the movement of persons; • a direction requiring persons to stay at or in a stated place; • a direction requiring persons not to enter or stay at or in a stated place; • a direction restricting contact between persons; • any other direction the Chief Health Officer considers necessary to protect public health. (Page 30) 	I would strongly consider that these powers breach our basic rights and freedom under the <i>Australian Human Rights Commission Act 1986, Schedule 2.</i> The Biosecurity Act 2015 also covers all of the points laid out here by the issuance of a Biosecurity Control Order so once again I refer to <i>The Constitution, Section 109</i>



Australian Government

Department of Health

Therapeutic Goods Administration

Database of Adverse Event Notifications - medicines

Medicine summary

You searched for the following **2 medicines** between **01/12/2020 – 06/04/2021**:

- COMIRNATY COVID-19 vaccine (BNT162b2 (mRNA))
- COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector))

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Important information

The TGA uses adverse event reports to identify when a safety issue may be present. An adverse event report does not mean that the medicine is the cause of the adverse event. If you are experiencing an adverse event, or think you may be experiencing one, please seek advice from a health professional as soon as possible. The TGA strongly advises people taking prescription medicines not to change their medication regime without prior consultation with a health professional.

About the Database of Adverse Event Notifications (DAEN) - medicines

- The DAEN - medicines contains information from reports of adverse events that the TGA has received in relation to medicines including vaccines used in Australia.
- The DAEN - medicines does not contain all known safety information about a particular medicine. Please do not make an assessment about the safety of a medicine based on the information in the DAEN - medicines.

The TGA medicine safety monitoring program

More information about the DAEN - medicines and the TGA medicines safety monitoring program is available at:

- About the DAEN - medicines <<http://www.tga.gov.au/safety/daen-about.htm>>
- Medicines safety <<http://www.tga.gov.au/safety/information-medicines.htm>>

You are encouraged to report an adverse event suspected of being related to a medicine used in Australia. Reports of adverse events in relation to medicines and vaccines can be reported using the 'blue card' reporting form, by phone and online <<http://www.tga.gov.au/safety/problem.htm>>.

Other useful sources of information on Australian medicines

More information about a medicine is available from the Product Information (PI)

<<http://www.tga.gov.au/hp/information-medicines-pi.htm>> and Consumer Medicine Information (CMI)

<<http://www.tga.gov.au/consumers/information-medicines-cmi.htm>> leaflet or the labelling of the medicine. Australian Public Assessment Report for Prescription Medicines (AusPARs) <<http://www.tga.gov.au/industry/pm-auspar.htm>> for some prescription medicines, are also available from the TGA website. <<http://www.tga.gov.au>>

Your health professional can also provide help and assistance on how to use medicines.

Information on medicines used in Australia is available from NPS MedicineWise <<http://www.nps.org.au/>>.

About the release of this information

While reasonable care is taken to ensure that the information is an accurate record of the adverse events reported to the TGA, the TGA does not guarantee or warrant the accuracy, reliability, completeness or currency of the information or its usefulness in achieving any purpose.

To the fullest extent permitted by law, including but not limited to section 61A of the Therapeutic Goods Act 1989, the TGA will not be liable for any loss, damage, cost or expense incurred in or arising by reason of any person relying on this information.

Copyright restrictions apply to the DAEN - medicines <<http://www.tga.gov.au/about/website-copyright.htm>>.

Results

Number of reports (cases): 6163

(Multiple adverse events have been reported for some patients)

Number of cases with a single suspected medicine: 6148

(The TGA thinks there is a possibility that the medicine caused the adverse event)

Number of cases where death was a reported outcome: 37

(These reports of death may or may not have been a result of taking a medicine)

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Nervous system disorders	Headache	2782	2775	0
General disorders and administration site conditions	Pyrexia	2194	2187	1
Musculoskeletal and connective tissue disorders	Myalgia	2186	2180	0
General disorders and administration site conditions	Chills	1520	1517	0
General disorders and administration site conditions	Fatigue	1375	1373	0
Gastrointestinal disorders	Nausea	1252	1250	1
Musculoskeletal and connective tissue disorders	Arthralgia	1163	1160	0
General disorders and administration site conditions	Injection site reaction	1127	1123	2
Nervous system disorders	Lethargy	766	765	0
Nervous system disorders	Dizziness	723	723	0
General disorders and administration site conditions	Injection site pain	433	432	0
Gastrointestinal disorders	Vomiting	388	388	7
General disorders and administration site conditions	Pain	269	267	0
Nervous system disorders	Paraesthesia	245	244	0
Gastrointestinal disorders	Diarrhoea	245	245	1
General disorders and administration site conditions	Malaise	240	240	2
Skin and subcutaneous tissue disorders	Hyperhidrosis	238	236	0
Respiratory, thoracic and mediastinal disorders	Dyspnoea	217	217	5
Skin and subcutaneous tissue disorders	Rash	213	212	1
Gastrointestinal disorders	Abdominal pain	207	207	0
Cardiac disorders	Tachycardia	189	189	0

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Medicine summary

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Musculoskeletal and connective tissue disorders	Pain in extremity	187	187	0
Blood and lymphatic system disorders	Lymphadenopathy	175	175	0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	163	163	0
Psychiatric disorders	Insomnia	153	152	0
Nervous system disorders	Presyncope	153	153	0
Respiratory, thoracic and mediastinal disorders	Cough	152	150	0
Skin and subcutaneous tissue disorders	Pruritus	130	130	0
Metabolism and nutrition disorders	Decreased appetite	130	130	2
Vascular disorders	Hypertension	115	115	0
General disorders and administration site conditions	Chest pain	109	109	1
General disorders and administration site conditions	Influenza like illness	104	104	1
General disorders and administration site conditions	Chest discomfort	100	100	0
Nervous system disorders	Syncope	97	97	0
General disorders and administration site conditions	Injection site swelling	93	93	0
Nervous system disorders	Tremor	82	82	0
Immune system disorders	Anaphylactic reaction	81	81	0
Cardiac disorders	Palpitations	79	79	0
Vascular disorders	Flushing	75	75	0
Nervous system disorders	Migraine	74	72	0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	72	72	0
Musculoskeletal and connective tissue disorders	Back pain	72	72	0
Nervous system disorders	Hypoaesthesia	71	71	0
Gastrointestinal disorders	Paraesthesia oral	70	70	0
Skin and subcutaneous tissue disorders	Urticaria	68	68	0
General disorders and administration site conditions	Asthenia	62	62	0
Respiratory, thoracic and mediastinal disorders	Throat irritation	60	60	0
Vascular disorders	Hot flush	58	58	0

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Medicine summary

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
General disorders and administration site conditions	Feeling hot	57	57	0
Respiratory, thoracic and mediastinal disorders	Throat tightness	55	55	0
Musculoskeletal and connective tissue disorders	Neck pain	54	54	0
Nervous system disorders	Dysgeusia	51	51	0
Skin and subcutaneous tissue disorders	Erythema	50	50	0
Eye disorders	Vision blurred	50	49	0
Skin and subcutaneous tissue disorders	Cold sweat	44	44	0
Musculoskeletal and connective tissue disorders	Muscle spasms	44	44	0
General disorders and administration site conditions	Feeling abnormal	44	43	0
Ear and labyrinth disorders	Vertigo	42	42	0
Musculoskeletal and connective tissue disorders	Musculoskeletal stiffness	41	41	0
Psychiatric disorders	Anxiety	40	40	0
General disorders and administration site conditions	Swelling	39	39	0
General disorders and administration site conditions	Injection site discomfort	39	39	0
Vascular disorders	Hypotension	38	38	0
Eye disorders	Photophobia	38	38	0
General disorders and administration site conditions	Injection site erythema	37	37	0
Investigations	Heart rate increased	34	34	0
Respiratory, thoracic and mediastinal disorders	Nasal congestion	34	34	0
Investigations	Blood pressure increased	33	33	0
Gastrointestinal disorders	Abdominal pain upper	32	32	0
Immune system disorders	Hypersensitivity	30	29	0
General disorders and administration site conditions	Injection site pruritus	29	29	0
General disorders and administration site conditions	Injection site hypersensitivity	28	28	0
Eye disorders	Eye pain	27	27	0
Skin and subcutaneous tissue disorders	Rash pruritic	27	27	0

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Medicine summary

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Musculoskeletal and connective tissue disorders	Limb discomfort	26	26	0
Respiratory, thoracic and mediastinal disorders	Wheezing	26	25	0
Nervous system disorders	Somnolence	25	25	1
General disorders and administration site conditions	Feeling cold	25	25	0
Vascular disorders	Pallor	25	25	0
Injury, poisoning and procedural complications	Contusion	24	24	0
Skin and subcutaneous tissue disorders	Night sweats	22	22	0
General disorders and administration site conditions	Peripheral swelling	22	22	0
General disorders and administration site conditions	Feeling of body temperature change	21	21	0
Respiratory, thoracic and mediastinal disorders	Dysphonia	21	21	0
Gastrointestinal disorders	Dry mouth	20	20	0
Gastrointestinal disorders	Swollen tongue	20	20	0
Musculoskeletal and connective tissue disorders	Muscular weakness	20	20	0
Psychiatric disorders	Confusional state	20	20	0
Respiratory, thoracic and mediastinal disorders	Epistaxis	20	20	0
General disorders and administration site conditions	Injected limb mobility decreased	19	19	0
Gastrointestinal disorders	Lip swelling	19	19	0
General disorders and administration site conditions	Local reaction	19	19	0
Ear and labyrinth disorders	Tinnitus	18	17	0
Nervous system disorders	Taste disorder	18	18	0
Gastrointestinal disorders	Dysphagia	18	18	2
Eye disorders	Ocular hyperaemia	17	17	0
General disorders and administration site conditions	Thirst	17	17	0
General disorders and administration site conditions	Swelling face	16	16	0
Skin and subcutaneous tissue disorders	Swelling face	16	16	0
General disorders and administration site conditions	Injection site rash	15	15	0

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Medicine summary

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Infections and infestations	Cellulitis	15	15	0
Investigations	Body temperature increased	15	15	0
Ear and labyrinth disorders	Ear pain	14	14	0
Nervous system disorders	Seizure	14	14	0
Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	14	14	2
Respiratory, thoracic and mediastinal disorders	Asthma	14	14	0
Skin and subcutaneous tissue disorders	Rash erythematous	14	14	0
Gastrointestinal disorders	Hypoaesthesia oral	14	14	0
Psychiatric disorders	Disorientation	13	13	0
General disorders and administration site conditions	Injection site bruising	13	13	0
Nervous system disorders	Balance disorder	12	12	0
Gastrointestinal disorders	Abdominal discomfort	12	12	0
Gastrointestinal disorders	Retching	12	12	0
Psychiatric disorders	Restlessness	12	12	0
Skin and subcutaneous tissue disorders	Angioedema	12	12	0
Nervous system disorders	Ageusia	11	11	0
Infections and infestations	Nasopharyngitis	11	11	0
Infections and infestations	Oral herpes	11	10	0
General disorders and administration site conditions	Gait disturbance	10	10	0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal discomfort	10	10	0
Musculoskeletal and connective tissue disorders	Bone pain	10	10	0
Nervous system disorders	Burning sensation	10	10	0
Vascular disorders	Deep vein thrombosis	10	10	0
Skin and subcutaneous tissue disorders	Skin sensitisation	10	10	0
Nervous system disorders	Head discomfort	10	10	0
Gastrointestinal disorders	Mouth ulceration	10	10	0
General disorders and administration site conditions	Injection site inflammation	10	10	0
Skin and subcutaneous tissue disorders	Sensitive skin	10	10	0
Psychiatric disorders	Sleep disorder	10	10	0

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Medicine summary

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Musculoskeletal and connective tissue disorders	Muscle tightness	9	9	0
Nervous system disorders	Loss of consciousness	9	9	2
Nervous system disorders	Disturbance in attention	9	9	0
Injury, poisoning and procedural complications	Vaccination error	9	8	0
Renal and urinary disorders	Pollakiuria	9	9	0
Gastrointestinal disorders	Abdominal distension	9	9	0
Eye disorders	Visual impairment	9	9	0
Respiratory, thoracic and mediastinal disorders	Pharyngeal swelling	9	9	0
Nervous system disorders	Restless legs syndrome	8	8	0
Cardiac disorders	Bradycardia	8	8	0
Respiratory, thoracic and mediastinal disorders	Pharyngeal paraesthesia	8	8	0
General disorders and administration site conditions	Extensive swelling of vaccinated limb	8	8	0
Eye disorders	Eye pruritus	7	7	0
General disorders and administration site conditions	Injection site warmth	7	7	0
Respiratory, thoracic and mediastinal disorders	Sneezing	7	7	0
Respiratory, thoracic and mediastinal disorders	Productive cough	7	7	0
Eye disorders	Eye irritation	7	7	0
Psychiatric disorders	Abnormal dreams	7	7	0
Investigations	Oxygen saturation decreased	7	7	0
General disorders and administration site conditions	Axillary pain	7	7	0
General disorders and administration site conditions	Non-cardiac chest pain	7	7	0
Respiratory, thoracic and mediastinal disorders	Dry throat	7	7	0
Respiratory, thoracic and mediastinal disorders	Tachypnoea	7	7	1
Musculoskeletal and connective tissue disorders	Pain in jaw	7	7	0
General disorders and administration site conditions	Concomitant disease aggravated	7	7	0
Psychiatric disorders	Delirium	7	7	0
Investigations	Blood pressure abnormal	6	6	0

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Medicine summary

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Metabolism and nutrition disorders	Dehydration	6	6	0
General disorders and administration site conditions	Injection site mass	6	6	0
Respiratory, thoracic and mediastinal disorders	Sinus congestion	6	6	0
Blood and lymphatic system disorders	Lymph node pain	6	6	0
Psychiatric disorders	Hallucination	6	6	0
Skin and subcutaneous tissue disorders	Skin irritation	6	6	0
Gastrointestinal disorders	Dyspepsia	6	6	0
Nervous system disorders	Dysarthria	6	6	0
Eye disorders	Lacrimation increased	6	6	0
Infections and infestations	Injection site cellulitis	6	6	0
Infections and infestations	Pneumonia	6	6	4
Psychiatric disorders	Nervousness	6	6	0
Infections and infestations	Rhinitis	6	6	0
Musculoskeletal and connective tissue disorders	Muscle twitching	6	6	0
General disorders and administration site conditions	Facial pain	5	5	0
General disorders and administration site conditions	Injection site nodule	5	5	0
Nervous system disorders	Aphasia	5	5	0
Renal and urinary disorders	Haematuria	5	5	0
Nervous system disorders	Unresponsive to stimuli	5	4	3
Skin and subcutaneous tissue disorders	Pain of skin	5	5	0
Infections and infestations	Herpes zoster	5	5	0
Investigations	Blood pressure decreased	5	5	0
General disorders and administration site conditions	Tenderness	5	5	0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	5	5	0
Nervous system disorders	Neuralgia	5	5	0
Infections and infestations	Tonsillitis	4	4	0
Metabolism and nutrition disorders	Hypoglycaemia	4	4	0
General disorders and administration site conditions	Injection site hypoaesthesia	4	4	0
Infections and infestations	Conjunctivitis	4	4	0

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Medicine summary

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Skin and subcutaneous tissue disorders	Rash macular	4	4	0
Injury, poisoning and procedural complications	Adverse event following immunisation	4	4	4
Reproductive system and breast disorders	Breast pain	4	4	0
Nervous system disorders	Cognitive disorder	4	4	0
Eye disorders	Periorbital swelling	4	4	0
Infections and infestations	Injection site infection	4	4	0
Nervous system disorders	Cerebrovascular accident	4	4	2
Vascular disorders	Orthostatic hypotension	4	4	0
Injury, poisoning and procedural complications	Fall	4	4	0
Musculoskeletal and connective tissue disorders	Joint stiffness	4	4	0
Eye disorders	Diplopia	4	4	0
Gastrointestinal disorders	Constipation	4	4	0
Nervous system disorders	Facial paralysis	4	4	0
General disorders and administration site conditions	Injection site paraesthesia	4	4	0
Nervous system disorders	Tension headache	4	4	0
Musculoskeletal and connective tissue disorders	Musculoskeletal discomfort	4	4	0
Gastrointestinal disorders	Eructation	4	4	0
Investigations	Heart rate irregular	4	4	0
General disorders and administration site conditions	Condition aggravated	3	3	0
Investigations	Urine output increased	3	3	0
Vascular disorders	Blood pressure fluctuation	3	3	0
Infections and infestations	Pharyngitis	3	3	0
Nervous system disorders	Anosmia	3	3	0
Psychiatric disorders	Poor quality sleep	3	3	0
Cardiac disorders	Cyanosis	3	3	0
General disorders and administration site conditions	Ulcer	3	3	0
Respiratory, thoracic and mediastinal disorders	Haemoptysis	3	3	0
Respiratory, thoracic and mediastinal disorders	Sinus pain	3	3	0
Ear and labyrinth disorders	Deafness	3	3	0

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Medicine summary

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
General disorders and administration site conditions	Sensation of foreign body	3	3	0
Infections and infestations	Ear infection	3	3	0
Nervous system disorders	Hemiparesis	3	3	0
Reproductive system and breast disorders	Vaginal haemorrhage	3	3	0
Infections and infestations	Respiratory tract infection	3	3	0
Musculoskeletal and connective tissue disorders	Flank pain	3	3	0
Nervous system disorders	Bell's palsy	3	3	0
Psychiatric disorders	Agitation	3	3	0
Reproductive system and breast disorders	Breast tenderness	3	3	0
Nervous system disorders	Depressed level of consciousness	3	3	2
Psychiatric disorders	Irritability	3	3	0
Skin and subcutaneous tissue disorders	Petechiae	3	3	0
Ear and labyrinth disorders	Deafness unilateral	3	3	0
Respiratory, thoracic and mediastinal disorders	Aphonia	3	3	0
Skin and subcutaneous tissue disorders	Photosensitivity reaction	3	3	0
Vascular disorders	Cyanosis	3	3	0
Ear and labyrinth disorders	Hypoacusis	3	3	0
Eye disorders	Eye swelling	3	3	0
Reproductive system and breast disorders	Menstruation irregular	3	3	0
Skin and subcutaneous tissue disorders	Dry skin	3	3	0
Eye disorders	Conjunctival haemorrhage	3	3	0
Injury, poisoning and procedural complications	Product administered to patient of inappropriate age	3	3	0
Skin and subcutaneous tissue disorders	Rash vesicular	3	3	0
Musculoskeletal and connective tissue disorders	Joint swelling	3	3	0
Vascular disorders	Peripheral coldness	3	3	0
Nervous system disorders	Poor quality sleep	3	3	0
Vascular disorders	Thrombophlebitis	3	3	0
Eye disorders	Swelling of eyelid	3	3	0

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Medicine summary

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Gastrointestinal disorders	Haematemesis	3	3	0
Gastrointestinal disorders	Oral discomfort	3	3	0
Renal and urinary disorders	Polyuria	3	3	0
Respiratory, thoracic and mediastinal disorders	Bronchospasm	3	2	0
Eye disorders	Eye disorder	2	2	0
Eye disorders	Pupil fixed	2	2	0
Gastrointestinal disorders	Salivary hypersecretion	2	2	0
General disorders and administration site conditions	General physical health deterioration	2	2	2
General disorders and administration site conditions	Injection site urticaria	2	2	0
Investigations	Fibrin D dimer increased	2	2	0
Investigations	White blood cell count increased	2	2	0
Metabolism and nutrition disorders	Hyperglycaemia	2	2	0
Musculoskeletal and connective tissue disorders	Axillary mass	2	1	0
Nervous system disorders	Sensory disturbance	2	2	0
Renal and urinary disorders	Micturition urgency	2	2	0
Respiratory, thoracic and mediastinal disorders	Pleuritic pain	2	1	0
Gastrointestinal disorders	Abdominal pain lower	2	2	0
Gastrointestinal disorders	Tongue ulceration	2	2	0
General disorders and administration site conditions	Crying	2	2	0
General disorders and administration site conditions	Inflammation	2	2	0
Metabolism and nutrition disorders	Diabetes mellitus	2	2	0
Nervous system disorders	Neuropathy peripheral	2	2	0
Blood and lymphatic system disorders	Thrombocytopenia	2	2	0
Gastrointestinal disorders	Abdominal tenderness	2	2	0
General disorders and administration site conditions	Application site pain	2	2	0
Nervous system disorders	Neurological symptom	2	2	0
Psychiatric disorders	Thinking abnormal	2	2	0
Ear and labyrinth disorders	Motion sickness	2	2	0
Gastrointestinal disorders	Toothache	2	2	0
General disorders and administration site conditions	Application site reaction	2	2	0

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MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Musculoskeletal and connective tissue disorders	Trismus	2	2	0
Nervous system disorders	Dizziness postural	2	2	0
Nervous system disorders	Hyperaesthesia	2	2	0
Nervous system disorders	Monoplegia	2	2	0
Nervous system disorders	Paralysis	2	2	0
Skin and subcutaneous tissue disorders	Keratosis pilaris	2	2	0
Skin and subcutaneous tissue disorders	Skin burning sensation	2	2	0
Cardiac disorders	Cardiac arrest	2	2	2
Gastrointestinal disorders	Gingival pain	2	2	0
General disorders and administration site conditions	Hangover	2	2	0
Investigations	Weight decreased	2	2	1
Respiratory, thoracic and mediastinal disorders	Pharyngeal hypoaesthesia	2	2	0
Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	2	2	0
Skin and subcutaneous tissue disorders	Dermatitis allergic	2	2	0
Vascular disorders	Venous thrombosis	2	2	0
Infections and infestations	Herpes simplex	2	2	0
Infections and infestations	Influenza	2	2	0
Infections and infestations	Sepsis	2	2	1
Investigations	Respiratory rate increased	2	2	1
Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	2	2	0
Nervous system disorders	Nervous system disorder	2	2	0
Nervous system disorders	Seizure like phenomena	2	2	0
Psychiatric disorders	Depression	2	2	0
Renal and urinary disorders	Dysuria	2	2	0
Respiratory, thoracic and mediastinal disorders	Stridor	2	2	0
Ear and labyrinth disorders	Ear discomfort	2	2	0
Gastrointestinal disorders	Teething	2	2	0
General disorders and administration site conditions	Injection site vesicles	2	2	0
General disorders and administration site conditions	Oedema peripheral	2	2	0

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MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Musculoskeletal and connective tissue disorders	Costochondritis	2	2	0
Musculoskeletal and connective tissue disorders	Fibromyalgia	2	2	0
Nervous system disorders	Ataxia	2	2	0
Eye disorders	Asthenopia	2	2	0
Gastrointestinal disorders	Gastrointestinal disorder	2	2	0
Gastrointestinal disorders	Oral pruritus	2	2	0
Infections and infestations	Injection site abscess	2	2	0
Nervous system disorders	Electric shock sensation	2	2	0
Nervous system disorders	Tonic convulsion	2	2	0
Psychiatric disorders	Mood altered	2	2	0
Psychiatric disorders	Panic reaction	2	2	0
Respiratory, thoracic and mediastinal disorders	Respiratory failure	2	2	2
Injury, poisoning and procedural complications	Exposure via breast milk	2	2	0
Investigations	Blood glucose abnormal	2	2	0
Investigations	Blood glucose increased	2	2	0
Investigations	Lymph node palpable	2	2	0
Investigations	Temperature difference of extremities	2	2	0
Nervous system disorders	Memory impairment	2	2	0
Skin and subcutaneous tissue disorders	Blister	2	2	0
Cardiac disorders	Arrhythmia	2	2	0
Immune system disorders	Seasonal allergy	2	2	0
Investigations	Platelet count decreased	2	2	0
Nervous system disorders	Migraine with aura	2	2	0
Nervous system disorders	Multiple sclerosis	2	2	0
Nervous system disorders	Parosmia	2	2	0
Gastrointestinal disorders	Mouth haemorrhage	2	2	0
Musculoskeletal and connective tissue disorders	Spinal pain	2	2	0
Nervous system disorders	Demyelination	2	2	0
Nervous system disorders	Sensory loss	2	2	0
Nervous system disorders	Transient ischaemic attack	2	2	0
Psychiatric disorders	Depressed mood	2	2	0

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Medicine summary

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Ear and labyrinth disorders	Ear congestion	2	2	0
General disorders and administration site conditions	Hypothermia	2	2	0
Infections and infestations	Candida infection	2	2	0
Infections and infestations	Lower respiratory tract infection	2	2	0
Investigations	Heparin-induced thrombocytopenia test positive	2	2	0
Nervous system disorders	Ischaemic stroke	2	2	1
Psychiatric disorders	Nightmare	2	2	0
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	2	2	0
Respiratory, thoracic and mediastinal disorders	Hypoxia	2	2	0
Skin and subcutaneous tissue disorders	Blood blister	2	2	0
Skin and subcutaneous tissue disorders	Skin exfoliation	2	2	0
Cardiac disorders	Cardiac flutter	1	1	0
Eye disorders	Eye oedema	1	1	0
Eye disorders	Eyelid oedema	1	1	0
Eye disorders	Periorbital oedema	1	1	0
Gastrointestinal disorders	Epigastric discomfort	1	1	0
General disorders and administration site conditions	Adverse reaction	1	1	0
General disorders and administration site conditions	Injection site oedema	1	1	0
General disorders and administration site conditions	Localised oedema	1	1	0
Hepatobiliary disorders	Portal vein thrombosis	1	1	0
Injury, poisoning and procedural complications	Underdose	1	1	0
Investigations	Blood glucagon increased	1	1	0
Investigations	Blood pressure ambulatory decreased	1	1	0
Metabolism and nutrition disorders	Fluid retention	1	1	0
Musculoskeletal and connective tissue disorders	Systemic lupus erythematosus	1	1	0
Nervous system disorders	Head titubation	1	1	0
Nervous system disorders	Trigeminal neuralgia	1	1	0
Renal and urinary disorders	Renal colic	1	1	0

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Medicine summary

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Reproductive system and breast disorders	Vulval disorder	1	1	0
Respiratory, thoracic and mediastinal disorders	Aspiration	1	1	1
Respiratory, thoracic and mediastinal disorders	Respiratory symptom	1	1	0
Skin and subcutaneous tissue disorders	Erythema multiforme	1	1	0
Skin and subcutaneous tissue disorders	Nail bed tenderness	1	1	0
Social circumstances	Impaired driving ability	1	1	0
Blood and lymphatic system disorders	Splenic vein thrombosis	1	1	0
Endocrine disorders	Adrenocortical insufficiency acute	1	1	0
Gastrointestinal disorders	Glossodynia	1	1	0
Gastrointestinal disorders	Intestinal ischaemia	1	1	1
Gastrointestinal disorders	Mesenteric vein thrombosis	1	1	0
Gastrointestinal disorders	Oesophagitis	1	1	0
General disorders and administration site conditions	Creptations	1	1	0
General disorders and administration site conditions	Foaming at mouth	1	1	0
General disorders and administration site conditions	Oedema	1	1	0
Infections and infestations	Infection	1	1	0
Injury, poisoning and procedural complications	Inappropriate schedule of product administration	1	1	0
Injury, poisoning and procedural complications	Nerve injury	1	1	0
Nervous system disorders	Carotid artery occlusion	1	1	0
Nervous system disorders	Meningism	1	1	0
Nervous system disorders	Optic neuritis	1	1	0
Psychiatric disorders	Euphoric mood	1	1	0
Respiratory, thoracic and mediastinal disorders	Choking sensation	1	1	0
Respiratory, thoracic and mediastinal disorders	Respiratory tract irritation	1	1	0
Eye disorders	Retinal artery occlusion	1	1	0
Eye disorders	Vitreous floaters	1	1	0
Gastrointestinal disorders	Anaesthesia oral	1	1	0
Gastrointestinal disorders	Gastroesophageal reflux disease	1	1	0

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MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Gastrointestinal disorders	Oral discharge	1	1	0
Gastrointestinal disorders	Tongue discomfort	1	1	0
Infections and infestations	Pneumonia viral	1	1	1
Infections and infestations	Upper respiratory tract infection	1	1	0
Injury, poisoning and procedural complications	Product use issue	1	1	0
Injury, poisoning and procedural complications	Wrong technique in product usage process	1	1	0
Nervous system disorders	Clumsiness	1	1	0
Nervous system disorders	Orthostatic tremor	1	1	0
Respiratory, thoracic and mediastinal disorders	Yawning	1	1	0
Skin and subcutaneous tissue disorders	Acne	1	1	0
Vascular disorders	Vascular pain	1	1	0
Vascular disorders	Vasoconstriction	1	1	0
Blood and lymphatic system disorders	Immune thrombocytopenia	1	1	0
Blood and lymphatic system disorders	Lymphopenia	1	1	0
Cardiac disorders	Postural orthostatic tachycardia syndrome	1	1	0
Eye disorders	Dry eye	1	1	0
Eye disorders	Mydriasis	1	1	1
Gastrointestinal disorders	Aphthous ulcer	1	1	0
Gastrointestinal disorders	Haematochezia	1	1	0
Gastrointestinal disorders	Tongue erythema	1	1	0
General disorders and administration site conditions	Feeling drunk	1	1	0
General disorders and administration site conditions	Injection site haematoma	1	1	0
General disorders and administration site conditions	Injection site irritation	1	1	0
General disorders and administration site conditions	Multiple organ dysfunction syndrome	1	1	0
General disorders and administration site conditions	No adverse event	1	1	0
Infections and infestations	Bronchitis	1	1	0
Infections and infestations	Urosepsis	1	1	1
Injury, poisoning and procedural complications	Foreign body in eye	1	1	0

Database of Adverse Event Notifications - medicines

Medicine summary

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Injury, poisoning and procedural complications	Incorrect route of product administration	1	1	0
Investigations	Blood pressure ambulatory increased	1	1	0
Investigations	Blood urine present	1	1	0
Investigations	Epinephrine abnormal	1	1	0
Investigations	Human rhinovirus test positive	1	1	0
Musculoskeletal and connective tissue disorders	Synovitis	1	1	0
Nervous system disorders	Amnesia	1	1	0
Vascular disorders	Lymphoedema	1	1	0
Vascular disorders	Peripheral circulatory failure	1	1	0
Infections and infestations	Folliculitis	1	1	0
Investigations	Body temperature fluctuation	1	1	0
Investigations	C-reactive protein increased	1	1	0
Nervous system disorders	Facial paresis	1	1	0
Reproductive system and breast disorders	Vulvovaginal pain	1	1	0
Respiratory, thoracic and mediastinal disorders	Pulmonary pain	1	1	0
Skin and subcutaneous tissue disorders	Purpura	1	1	0
Vascular disorders	Raynaud's phenomenon	1	1	0
Eye disorders	Photopsia	1	1	0
Gastrointestinal disorders	Abdominal symptom	1	1	0
Gastrointestinal disorders	Gastrointestinal haemorrhage	1	1	0
Gastrointestinal disorders	Odynophagia	1	1	0
Investigations	Activated partial thromboplastin time prolonged	1	1	0
Investigations	Blood glucose decreased	1	1	0
Investigations	International normalised ratio increased	1	1	0
Nervous system disorders	Multiple sclerosis relapse	1	1	0
Nervous system disorders	Sinus headache	1	1	0
Nervous system disorders	Tunnel vision	1	1	0
Psychiatric disorders	Tic	1	1	0
Reproductive system and breast disorders	Pelvic pain	1	1	0
Reproductive system and breast disorders	Polymenorrhoea	1	1	0

Database of Adverse Event Notifications - medicines

Medicine summary

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Respiratory, thoracic and mediastinal disorders	Tonsillar inflammation	1	1	0
Social circumstances	Bedridden	1	1	0
Cardiac disorders	Heart alternation	1	1	0
Cardiac disorders	Sinus tachycardia	1	1	0
Ear and labyrinth disorders	Paraesthesia ear	1	1	0
Eye disorders	Ocular discomfort	1	1	0
General disorders and administration site conditions	Face oedema	1	1	0
Immune system disorders	Anaphylactic shock	1	1	0
Infections and infestations	Rhinovirus infection	1	1	0
Injury, poisoning and procedural complications	Injection related reaction	1	1	0
Investigations	Blood carbon monoxide decreased	1	1	0
Investigations	Glomerular filtration rate decreased	1	1	0
Investigations	Intraocular pressure increased	1	1	0
Investigations	White blood cell count decreased	1	1	0
Musculoskeletal and connective tissue disorders	Mobility decreased	1	1	0
Nervous system disorders	Haemorrhagic stroke	1	1	0
Nervous system disorders	Myoclonus	1	1	0
Psychiatric disorders	Anger	1	1	0
Psychiatric disorders	Delirium febrile	1	1	0
Psychiatric disorders	Fear	1	1	0
Psychiatric disorders	Panic attack	1	1	0
Psychiatric disorders	Sleep terror	1	1	0
Renal and urinary disorders	Renal pain	1	1	0
Respiratory, thoracic and mediastinal disorders	Cough decreased	1	1	0
Respiratory, thoracic and mediastinal disorders	Rales	1	1	0
Respiratory, thoracic and mediastinal disorders	Respiratory arrest	1	1	0
Skin and subcutaneous tissue disorders	Dermatitis atopic	1	1	0
Skin and subcutaneous tissue disorders	Rash papular	1	1	0
Cardiac disorders	Myocardial infarction	1	1	0
Eye disorders	Exophthalmos	1	1	0

Database of Adverse Event Notifications - medicines

Medicine summary

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Eye disorders	Metamorphopsia	1	1	0
Gastrointestinal disorders	Lip ulceration	1	1	0
Gastrointestinal disorders	Rectal haemorrhage	1	1	0
Gastrointestinal disorders	Visceral venous thrombosis	1	1	0
General disorders and administration site conditions	Feeling jittery	1	1	0
General disorders and administration site conditions	Illness	1	1	0
General disorders and administration site conditions	Soft tissue inflammation	1	1	0
General disorders and administration site conditions	Vaccination site movement impairment	1	1	0
Investigations	Blood creatine phosphokinase increased	1	1	0
Investigations	Liver function test increased	1	1	0
Metabolism and nutrition disorders	Diabetic ketoacidosis	1	1	1
Musculoskeletal and connective tissue disorders	Joint effusion	1	1	0
Musculoskeletal and connective tissue disorders	Muscle fatigue	1	1	0
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	1	1	0
Musculoskeletal and connective tissue disorders	Weight bearing difficulty	1	1	0
Nervous system disorders	Dyskinesia	1	1	0
Nervous system disorders	Dysstasia	1	1	0
Nervous system disorders	Fine motor skill dysfunction	1	1	0
Nervous system disorders	Occipital neuralgia	1	1	0
Psychiatric disorders	Somatic symptom disorder	1	1	0
Reproductive system and breast disorders	Intermenstrual bleeding	1	1	0
Reproductive system and breast disorders	Menstrual disorder	1	1	0
Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	1	1	0
Respiratory, thoracic and mediastinal disorders	Pleural effusion	1	1	0
Respiratory, thoracic and mediastinal disorders	Pulmonary oedema	1	1	0
Skin and subcutaneous tissue disorders	Miliaria	1	1	0
Surgical and medical procedures	Lymphadenectomy	1	1	0

Database of Adverse Event Notifications - medicines

Medicine summary

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Cardiac disorders	Myocardial ischaemia	1	1	0
Ear and labyrinth disorders	Hyperacusis	1	1	0
Gastrointestinal disorders	Frequent bowel movements	1	1	0
Gastrointestinal disorders	Lip dry	1	1	0
Gastrointestinal disorders	Lip pruritus	1	1	0
General disorders and administration site conditions	Cyst	1	0	0
General disorders and administration site conditions	Injection site abscess sterile	1	1	0
Musculoskeletal and connective tissue disorders	Rhabdomyolysis	1	1	0
Nervous system disorders	Altered state of consciousness	1	1	0
Nervous system disorders	Clonic convulsion	1	1	0
Nervous system disorders	Febrile convulsion	1	1	0
Nervous system disorders	Nystagmus	1	1	0
Psychiatric disorders	Emotional distress	1	1	0
Renal and urinary disorders	Haemorrhage urinary tract	1	1	0
Renal and urinary disorders	Incontinence	1	1	0
Renal and urinary disorders	Urinary retention	1	1	0
Skin and subcutaneous tissue disorders	Piloerection	1	1	0
Skin and subcutaneous tissue disorders	Pityriasis rosea	1	1	0
Skin and subcutaneous tissue disorders	Rash maculo-papular	1	1	0
Surgical and medical procedures	Trendelenburg position	1	1	0
Ear and labyrinth disorders	Ear haemorrhage	1	1	0
Eye disorders	Eye discharge	1	1	0
Eye disorders	Retinal exudates	1	1	0
Gastrointestinal disorders	Erosive oesophagitis	1	1	1
Gastrointestinal disorders	Intussusception	1	1	0
Gastrointestinal disorders	Pancreatitis	1	1	0
Injury, poisoning and procedural complications	Eye contusion	1	1	0
Injury, poisoning and procedural complications	Scar	1	1	0
Investigations	Enterovirus test positive	1	1	0
Metabolism and nutrition disorders	Food refusal	1	1	0
Nervous system disorders	Cerebral venous thrombosis	1	1	1

Database of Adverse Event Notifications - medicines

Medicine summary

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Nervous system disorders	Hemianopia homonymous	1	1	0
Nervous system disorders	Muscle tension dysphonia	1	1	0
Pregnancy, puerperium and perinatal conditions	Shoulder dystocia	1	1	0
Reproductive system and breast disorders	Priapism	1	1	0
Respiratory, thoracic and mediastinal disorders	Pulmonary fibrosis	1	1	0
Respiratory, thoracic and mediastinal disorders	Sinus disorder	1	1	0
Skin and subcutaneous tissue disorders	Dermatitis	1	1	0
Skin and subcutaneous tissue disorders	Nail bed inflammation	1	1	0
Skin and subcutaneous tissue disorders	Skin swelling	1	1	0
Vascular disorders	Thrombophlebitis superficial	1	1	0
Blood and lymphatic system disorders	Neutropenia	1	1	0
Cardiac disorders	Atrial fibrillation	1	1	1
Eye disorders	Blindness transient	1	1	0
Gastrointestinal disorders	Oral mucosal blistering	1	1	0
Gastrointestinal disorders	Tongue oedema	1	1	0
Gastrointestinal disorders	Upper gastrointestinal haemorrhage	1	1	0
General disorders and administration site conditions	Injection site discolouration	1	1	0
Infections and infestations	Appendicitis	1	1	0
Injury, poisoning and procedural complications	Parasympathetic nerve injury	1	1	0
Investigations	Blood pressure systolic decreased	1	1	0
Investigations	Blood pressure systolic increased	1	1	0
Investigations	Heart rate abnormal	1	1	0
Musculoskeletal and connective tissue disorders	Groin pain	1	1	0
Musculoskeletal and connective tissue disorders	Muscle rigidity	1	1	0
Nervous system disorders	Aura	1	1	0
Nervous system disorders	Cerebral haemorrhage	1	1	1
Nervous system disorders	Dysaesthesia	1	1	0
Psychiatric disorders	Affect lability	1	1	0

Database of Adverse Event Notifications - medicines

Medicine summary

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Psychiatric disorders	Stress	1	1	0
Reproductive system and breast disorders	Premenstrual dysphoric disorder	1	1	0
Reproductive system and breast disorders	Testicular pain	1	1	0
Skin and subcutaneous tissue disorders	Pemphigus	1	1	0
Skin and subcutaneous tissue disorders	Skin reaction	1	1	0
Skin and subcutaneous tissue disorders	Skin warm	1	1	0
Gastrointestinal disorders	Gingival swelling	1	1	0
Gastrointestinal disorders	Glossitis	1	1	0
Gastrointestinal disorders	Mouth swelling	1	1	0
Gastrointestinal disorders	Stomatitis	1	1	0
General disorders and administration site conditions	Discomfort	1	1	0
Hepatobiliary disorders	Gallbladder mass	1	1	1
Infections and infestations	Laryngitis	1	1	0
Infections and infestations	Sinusitis	1	1	0
Nervous system disorders	Akathisia	1	1	0
Nervous system disorders	Allodynia	1	1	0
Nervous system disorders	Hemianopia	1	1	0
Nervous system disorders	Partial seizures	1	1	0
Nervous system disorders	Speech disorder	1	1	0
Nervous system disorders	Tonic clonic movements	1	1	0
Psychiatric disorders	Hallucination, tactile	1	1	0
Psychiatric disorders	Mood swings	1	1	0
Respiratory, thoracic and mediastinal disorders	Apnoea	1	1	0
Respiratory, thoracic and mediastinal disorders	Pleurisy	1	1	0

Footnotes

ⁱ A description of what, in general terms, was affected by the adverse event, as described by the Medical Dictionary for Regulatory Activities MedDRA (for example 'cardiac disorders')

ⁱⁱ A description of the adverse event as defined by MedDRA; these adverse events are grouped by system organ class. You can use the MedlinePlus medical dictionary <<http://www.nlm.nih.gov/medlineplus/mplusdictionary.html>> to look up terms.

- iii The number of cases for which each type of adverse event was reported
- iv Results show where a medicine is the only medicine suspected to be related to the adverse event
- v These reports of death may or may not have been the result of taking a medicine