This document has been created in order to answer specific FOI questions raised by s 11C(1)(a) under FOI 27-3438.

Vaccine	*Number of Batches NOT tested*	*Number of Batches with no OCABR*	*Number of batches tested by the TGA*	*Total Batches Released to date*
Comirnaty	4* (FA4598, FA7338, FA7812, and FC8736)	1	128	132
Spikevax	0	9**	48	48
Totals	4	10**	176	180

* These batches were used in the private market for the Australian Pfizer employee vaccination program only and not distributed to the Australian Public - no samples were received for testing at TGA, these were released under pathway 1.

**Note that OCABR Certification is only possible for batches undergoing some manufacturing in Europe. Some batches of Spikevax CoVID 19 vaccines supplied in Australia were manufactured outside of the EU and did not come with OCABR Certificates. However, these were independently tested by the TGA before being distributed.

Note: No COVID-19 vaccine batches supplied to the Australian public were released under Pathway 1 alone. Although the TGA received OCABR certificates for 170 of the 180 COVID-19 vaccine batches released, it adopted a policy of independently assessing all batches prior to distribution. As a result, all Comirnaty and Spikevax batches supplied through Australia's vaccination program underwent TGA laboratory assessment, including testing, before release.

The only exception was four Comirnaty batches (FA4598, FA7338, FA7812 and FC8736) supplied exclusively for Pfizer's employee vaccination program. These batches were not tested by the TGA because samples were not provided; however, they were assessed through review of the relevant batch documentation and the OCABR certificates issued by a comparable overseas regulatory laboratory. These batches were supplied only to the private Pfizer employee vaccination program and were not distributed to the broader Australian public.

In total, the TGA tested 176 of the 180 COVID-19 vaccine batches released in Australia. Ten batches of Spikevax did not have associated OCABR certificates, as they were manufactured outside the European Network, OCABR certification is only available for products manufactured in Europe. Nevertheless, these batches were also assessed under the TGA's batch release framework prior to release.

Further information

SQ23-002114 – Comirnaty Batch Release Assessment

Senate Committee: Community Affairs Committee

QUESTION ON NOTICE

Supplementary Budget Estimates 2023-2024
Outcome: 1 - Health Policy, Access and Support

PDR Number: SQ23-002051

Question Subject: Detection of plasmid DNA and SV40 sequence

Type of Question: Written

Senator: Alex Antic

Question:

Regarding the detection of plasmid DNA and SV40 sequence

1. Is the TGA aware of international concern regarding the detection of plasmid DNA in the COVID-19 mRNA Pfizer and Moderna “vaccines”? https://osf.io/mjc97/https://www.researchgate.net/publication/369967228_Sequencing_of_bivalent_Moderna_and_Pfizer_mRNA_vaccines_reveals_nanogram_to_microgram_quantities_of_expression_vector_dsDNA_per_dose

2. Has the TGA investigated the possible contamination of Pfizer and Moderna COVID-19 vaccines once it was reported that DNA contamination levels were possible 18-70 times higher than the limits set by the FDA and the European Medicines Agency (EMA)?

3. Did the TGA conduct its own independent analysis to determine the level of contamination of DNA or did it depend on information supplied by the manufacturers?

4. Have any batches of COVID-19 vaccine been released to the public with levels of plasmid DNA considered unsafe by international standards?

5. What plans does the TGA have to alert the public to the potential contamination of the COVID-19 vaccines so they can be fully informed?

6. Did Pfizer alert the drug regulator that the plasmid DNA used to make the mRNA contained the Simian Virus 40 ((SV40) promotor gene sequence?

7. If so, when did the TGA know SV40 was used in the Pfizer manufacturing process?

Answer:

1. The Therapeutic Goods Administration (TGA) is aware of online articles about the presence of DNA in the mRNA COVID-19 vaccines. No conclusions about the levels of DNA in the COVID-19 vaccines can be made from these unverified studies. This is, in large part, because some of the laboratory studies which have been cited in a number of the online articles are not of the standard that the TGA expects of pharmaceutical companies or regulatory laboratories. As an example, some of the testing was conducted on a small number of expired vials of the COVID-19 vaccines with unknown provenance, using an unofficial and potentially unvalidated method.

2. The COVID-19 mRNA vaccines are not contaminated. All batches of mRNA vaccines supplied in Australia have met the established acceptable limits of residual DNA. This is confirmed as part of the vaccine batch release process, prior to the release of the batch. As outlined above, the information referenced in the article has significant flaws in its scientific robustness, and the TGA's assessment is that there are no indications of DNA contamination of any of the COVID-19 mRNA vaccines. Residual DNA is a manufacturing impurity found in very low levels in many biotechnology medicines and vaccines, including mRNA vaccines. The safe use of biological medicines in millions of patients for over 40 years demonstrates that this technology is safe, and that residual DNA presents a low safety risk. All mRNA vaccines registered in Australia comply with the established acceptable limits of residual DNA. The World Health Organization, European Pharmacopeia, and regulators including the United States Food and Drug Administration, and the TGA have provided guidance on the acceptable limits of total residual DNA. All mRNA vaccines registered in Australia comply with these limits.

3. The TGA's Laboratories have independently tested batches of COVID-19 mRNA vaccines for residual DNA. All batches of COVID-19 vaccine tested to date have met the approved requirements for residual DNA.

4. All batches of mRNA vaccines supplied in Australia have met the established acceptable limits of residual DNA.

5. As noted in the response to question 2, the mRNA vaccines are not contaminated and there is no need, therefore, for public notifications. The TGA Laboratories will continue to monitor the quality of COVID-19 vaccines through the batch release process. The TGA continues to inform the public of COVID-19 vaccine batch release testing outcomes by publishing information on the TGA website. If a safety issue is identified, the TGA will commence standard safety product alert or recall processes.

6. Pfizer provided the sequence of the plasmid used. They did not specifically label the SV40 promoter sequence in the plasmid. The TGA identified the promoter through sequence alignment. The DNA template used to manufacture the mRNA does contain smaller promoter sequences such as the SV40 promoter. These are commonly used in the manufacture of biotechnology-based medicines. In line with the internationally recognised guidance, residual plasmid DNA is considered lower risk as it is fully characterised, is not from a human cell line, and contains no oncogenes.

7. The TGA performed the sequence alignment in October 2023 and does not consider the presence of the SV40 promoter to be a safety concern. The SV40 promoter sequence is considered safe and is a common sequence used in biotechnology-based medicines. Please see the response to question 6.

Senate Committee: Community Affairs Committee

QUESTION ON NOTICE

Supplementary Budget Estimates 2023-2024
Outcome: 1 - Health Policy, Access and Support

PDR Number: SQ23-002114

Question Subject: COMIRNATY - batch release assessment

Type of Question: Written

Senator: Ralph Babet

Question:

1. According to TGA Batch release assessment of COVID-19 vaccines, multiple batches entered Australia without TGA laboratory assessment.
2. Batch FF0884*, FA4598*, FE3064*, FA7338*, FA7812*, FC8736* and FC3558* of COMIRNATY are listed as not being tested for composition, strength, purity, integrity, identity or endotoxins. The stated reason is “limited batch quantity allocated for use in Pfizer Australia employee vaccination program”. Please confirm why these batches were not tested by the TGA laboratories?
3. Were all other batches of COMIRNATY tested by TGA laboratories for composition, strength, purity, integrity, identity or endotoxins?
4. Did the manufacturing process of batches FF0884*, FA4598*, FE3064*, FA7338*, FA7812*, FC8736* and FC3558* vary in any way from other batches of COMIRNATY released in Australia?
5. Did the sponsor follow the same manufacturing protocol for all batches of COMIRNATY released in Australia?

Answer:

1. No batches of the COVID-19 vaccines entered Australia without being carefully assessed by the Therapeutic Goods Administration (TGA) Laboratories. Documentation relating to four batches in the Pfizer employee vaccination program were assessed by the TGA Laboratories, and the batches were independently tested by a comparable overseas regulatory laboratory.
2. Four of the batches (FA4598, FA7338, FA7812, and FC8736) were assessed by the TGA Laboratories by reviewing the relevant documentation and the European Official Control Authority Batch Release (OCABR) certificates issued by the comparable overseas regulatory laboratory. Three batches (FF0884, FE3064, and FC3558) used in Pfizer's employee vaccination program and also distributed as part of the public vaccination program, were tested in the TGA laboratory facilities. The search tool on the TGA website displays all entries for each batch, including those that were used in both programs.
3. Yes. All other batches of Pfizer's Comirnaty vaccine (excluding the batches used in the Pfizer employee vaccination program outlined above) and all other COVID-19 vaccines supplied in Australia were tested by the TGA laboratories. Some batches may have been supplied in multiple shipments. In these situations, the first shipment of the batch is tested, and subsequent shipments utilise this testing along with document assessment to determine the additional shipment batch is suitable for release. This is indicated on the TGA website as an additional shipment.
4. No. There was no variation in manufacturing processes between the batches for Pfizer employees and those supplied in the public vaccination program.
5. Yes. The same manufacturing protocol was followed for the batches used for the Pfizer employee vaccination program and the batches supplied in the public vaccination program. Three of the batches were used in both programs.

Senate Committee: Community Affairs Committee

QUESTION ON NOTICE

Supplementary Budget Estimates 2023-2024
Outcome: 1 - Health Policy, Access and Support

PDR Number: SQ23-002232

Question Subject: SV40 promoter in production of vaccine

Type of Question: Written

Senator: Gerard Rennick

Question:

71. Was the SV40 promoter used in the production of the Pfizer vaccines? Was it eliminated completely from the final batches? What testing did the TGA do to verify this and can it be provided?

Answer:

Please refer to the response provided in SQ23-002051.

Senate Committee: Community Affairs Committee

QUESTION ON NOTICE

Additional Estimates 2023-2024
Outcome: 1 - Health Policy, Access and Support

PDR Number: SQ24-000206

Question Subject: Presence of SV40 and other genes being in the DNA plasmid templates that were used to make the Pfizer Covid-19 vaccine

Type of Question: Written

Senator: Gerard Rennick

Question:

18. Pfizer lied to the FDA about the presence of SV40 and other genes being in the DNA plasmid templates that were used to make the Covid vaccine. Will the TGA sue Pfizer for fraud over their deception? If not, why not?

Answer:

18. The Therapeutic Goods Administration (TGA) was aware of the plasmid DNA sequences used in the Pfizer manufacturing process when the data was submitted and the TGA assessed this information and found the sequences contained within the plasmids to be safe for use in the manufacturing process.

Any alleged false representations or statements made by Pfizer to the United States Food and Drug Administration (US FDA) is a matter for the US FDA to pursue if it so wishes. The TGA has no jurisdiction in relation to conduct of a US company where that conduct occurs in the US.

Senate Committee: Community Affairs Committee

QUESTION ON NOTICE

Supplementary Budget Estimates 2024-2025
Outcome: 1 - Health Policy, Access and Support

PDR Number: SQ24-003080

Question Subject: Plasmid DNA and SV-40 Codon

Type of Question: Spoken, Hansard page 125, 07 November 2024

Senator: Gerard Rennick

Question:

Senator RENNICK: Can you take it on notice, please? Can I get the entire sequence of the plasmids that were used in process 2, please.

Dr Kerr: We can take that on notice.

Senator RENNICK: Thank you.

Prof. Lawler: I would highlight that we may not be in the position to provide entire sequences of substances, but we will take that on notice.

Senator RENNICK: But, given this is related to the safety of the vaccine, I would have thought it was very important that this question was answered.

Prof. Lawler: We'll take the question on notice.

Answer:

The Therapeutic Goods Administration (TGA) does not consider the presence of the SV40 promoter to be a safety concern either before or after the product is subjected to DNA digestion and purification.

The TGA is unable to provide the sequences requested as they are commercial in confidence.

Senate Committee: Community Affairs Committee

QUESTION ON NOTICE

Supplementary Budget Estimates 2023-2024
Outcome: 1 - Health Policy, Access and Support

PDR Number: SQ23-002145

Question Subject: Batch testing of COVID-19 vaccine

Type of Question: Written

Senator: Ralph Babet

Question:

15. Did the Laboratories branch of the TGA test every single batch of Covid-19 vaccine before they were released for supply in Australia?

16. Evidence relied upon to inform their decision (safe and effective) did they equally explore evidence that there were adverse effects (VAERS)

17. The TGA advises that every Covid 19 vaccine batch is tested in Australia. Evidence from the TGA website suggests that Pfizer Employee vaccines were not tested by the TGA. Is this correct?

346290	COMIRNATY (tozinameran) COVID-19 VACCINE 30 micrograms/0.3 mL concentrated suspension for injection vial	FF0884*	12/08/2021	Not tested - see remarks	Not tested - see remarks	Not tested - see remarks	Not tested - see remarks	OCABR Reviewed. Limited batch quantity allocated for use in Pfizer Australia employee vaccination program
346290	COMIRNATY (tozinameran) COVID-19 VACCINE 30 micrograms/0.3 mL concentrated suspension for injection vial	FA4598*	30/07/2021	Not tested - see remarks	Not tested - see remarks	Not tested - see remarks	Not tested - see remarks	OCABR Reviewed. Limited batch quantity allocated for use in Pfizer Australia employee vaccination program

https://www.tga.gov.au/products/covid-19/covid-19-vaccines/batch-release-assessment-covid-19-vaccines

18. What Covid-19 vaccine batches were tested in Australia, by TGA staff within TGA laboratories?

19. Did ANY Covid-19 vaccines batches supplied to Australia fail the batch release test?

20. For all Covid-19 batches please provide a list of batches tested by Pathway 1 and Pathway 2?

Answer:

15. Refer to the response provided in SQ23-002114.

16. Refer to the response provided in SQ21-000668, published 24 August 2021.

17. Refer to the response provided in SQ23-002114.

18. As outlined in the response to SQ23-002114, all but four batches of COVID-19 vaccines were tested by Therapeutic Goods Administration (TGA) staff in the TGA Laboratories.

19. No. All batches of COVID-19 vaccines released in Australia have passed batch release testing.

20. The provision of an Official Control Authority Batch Release (OCABR) (or equivalent certificate) through pathway 1 is dependent on variables such as the country of manufacture, and the global distribution of that batch; for example, batches of Vaxzevria manufactured in Australia and released in Australia would not have an OCABR certificate.

As outlined in the response to SQ23-002114, the TGA Laboratories have performed testing on all but four batches irrespective of which pathway was used for release. There have been over 420 batches of COVID-19 vaccines released in Australia to date. Of those:

- for Comirnaty, 150 of 151 batches were released through pathway 1 and one batch through pathway 2
- for Spikevax, 44 of 53 batches were released through pathway 1 and nine batches through pathway 2
- for Vaxzevria 3, 206 batches were released through pathway 1 and 203 batches through pathway 2
- for Nuvaxovid, none of the 11 batches were released through pathway 1 and 11 batches through pathway 2.

Senate Committee: Community Affairs Committee

QUESTION ON NOTICE

Additional Estimates 2023-2024
Outcome: 0 - Whole of Portfolio

PDR Number: SQ24-001464

Question Subject: Batch release assessment of COVID-19 vaccines

Type of Question: Written

Senator: Ralph Babet

Question:

1. A safe manufacturing process for any substance used in humans for a therapeutic purpose is critical to the protection human health and falls within the responsibility of the Therapeutic Goods Administration (TGA). With respect to answers previously provided to Senator Babet through senate estimates questions on notice the TGA relied upon Official Contral Authority Batch Release testing of 150 imported batches of The Pfizer-BioNTech COVID-19 mRNA vaccine (Comirnaty) via pathway 1 for supply within Australia.

a. For each of the 150 batches of The Pfizer-BioNTech COVID-19 mRNA vaccine (Comirnaty) that were approved under pathway 1 for supply within Australia SPECIFICALLY:

i. Were each of the batches accompanied by a EU official control authority batch release certificate?

ii. If the answer to 1. is no what type of certificate was provided with each batch?

iii. Was the laboratory registered or recognised as an Official Medicines Control Laboratories within the auspices of the European Directorate for the Quality of Medicines and HealthCare (EDQM)?

iv. What is the name, geographical location (country) and certification/registration number of the laboratory that performed the physical sample testing for potency, identity and appearance that informed certification results?

v. Was the TGA provided with information about how the testing is performed or testing guidelines used by the laboratory to ensure consistent testing and accuracy of results provided within the certification?

b. For each of the 44 batches of Moderna COVID-19 mRNA vaccine (Spikevax) that were approved under pathway 1 for supply within Australia SPECIFICALLY:

i. Were each of the batches accompanied by a EU official control authority batch release certificate?

ii. If the answer to 1. is no what type of certificate was provided with each batch?

iii. Was the laboratory registered or recognised as an Official Medicines Control Laboratories within the auspices of the European Directorate for the Quality of Medicines and HealthCare (EDQM)?

iv. What is the name, geographical location (country) and certification/registration number of the laboratory that performed the physical sample testing for potency, identity and appearance that informed certification results?

v. Was the TGA provided with information about how the testing is performed or testing guidelines used by the laboratory to ensure consistent testing and accuracy of results provided within the certification?

Answer:

1a (i)

Yes, all Comirnaty batches released under pathway one, were supplied with an Official Control Authority Batch Release (OCABR) Certificate from a European member country.

1a (ii)

All batches were supplied with an OCABR certificate.

1a (iii - iv)

Yes, the testing of these batches was undertaken at either the Belgium National Control Laboratory (Sciensano) or the National Control Laboratory of Germany (Paul Erhlich Institute). Both of which are recognised as Official Medicines Control Laboratories (OMCL) within the EDQM. It is unclear what the Senator refers to regarding certificate/registration. All OMCL laboratories, as well as the TGA Laboratories, hold accreditation to the international standard ISO/IEC 17025 *General requirements for the competence of testing and calibration laboratories*.

1a (v)

Yes, the methods used for testing were supplied to TGA by the Sponsor.

1b (i)

Yes, for Spikevax all batches supplied under pathway one, were supplied with an OCABR Certificate from a European member country.

1b (ii)

Yes, all batches were supplied with an OCABR certificate.

1b (iii-iv)

Yes, the testing for these batches was undertaken by the Austrian National Control Authority- BASG. One batch was supplied with a Certificate from the UK National Control Laboratory, NIBSC. Both are recognised as Official Medicines Control Laboratories within the European Directorate for the Quality of Medicines and HealthCare (EDQM). See the response to 1a (iii-iv) regarding the certificate/registration.

1b (v)

Yes, the methods used for testing were supplied to TGA by the Sponsor.