

PARLIAMENTARY INQUIRY QUESTION ON NOTICE

Department of Health and Aged Care

Senate Community Affairs References Committee

Inquiry into Excess Mortality

13 June 2024

PDR Number: IQ24-000089

Notifications of deaths from the COVID vaccines

Written

Senator: Malcolm Roberts

Question:

18. When the TGA took the 1024 notifications of deaths from the COVID vaccines and reduced that to 14, did the Health Department see such a massive reduction as a reason to review the process the TGA used?

Answer:

18. No. As previously advised, the TGA encourages consumers and healthcare professionals to report all suspected adverse events, even if there is only a very small chance a vaccine was the cause. It is standard pharmacovigilance practice to encourage a low threshold for reporting, followed by a robust mechanism for post-reporting analysis and validation.

Notably, the number of deaths assessed as linked to vaccination by the TGA closely correlates with the Australian Bureau of Statistics (ABS) Causes of Death reports for 2021 and 2022. The ABS uses the International Classification of Diseases (ICD) to code information on the cause of death identified by a health professional or coroner. There is an ICD code for COVID-19 vaccine-related deaths.

Detailed information on the processes used by the TGA to assess reports of death in people who have been vaccinated has previously been provided in:

- SQ21-001136 (published 7 April 2022)
- SQ21-001181 (published 21 June 2022)
- SQ21-001218 (published 22 June 2022)
- SQ22-000096 (published 21 June 2022)
- SQ22-000099 (published 28 June 2022)
- SQ22-000104 (published 30 June 2022)
- SQ22-000105 (published 20 June 2022)
- SQ22-000527 (published 16 December 2022)
- SQ23-000140 (published 30 March 2023)
- SQ23-000545 (published 2 June 2023)
- SQ24-000233 (published 12 April 2024)

PARLIAMENTARY INQUIRY QUESTION ON NOTICE

Department of Health and Aged Care

Senate Community Affairs References Committee

Inquiry into Excess Mortality

13 June 2024

PDR Number: IQ24-000082

Unsafe levels of endotoxin in COVID vaccines

Written

Senator: Malcolm Roberts

Question:

8. A sample of the Pfizer Covid “vaccine” from Australia was tested in Canada because no Australian lab would do it. It was found to be contaminated with endotoxins several hundred times above the safe level. I have asked this before, so let me ask again – is it still your testimony that the Australian COVID “vaccines” are not contaminated with unsafe levels of endotoxin?

9. If no, then it means that the first time an independent lab tested the product and found massive contamination was a once-off. Have you ever gone into the field, taken a bottle of the “vaccine” and tested it yourself to make sure the lab-supplied reports you are being sent are accurate across the entire batch?

Answer:

8. COVID-19 vaccines are not contaminated with endotoxin. The TGA notes that no information has been provided by Senator Roberts regarding where the vials were sourced, the testing methodology or the name, accreditation or GMP status of the laboratory used.

9. The TGA has tested every batch of COVID-19 vaccine released in Australia in our own laboratories and every batch released has passed the test for endotoxin.

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Senate Community Affairs References Committee

Inquiry into Excess Mortality

13 June 2024

PDR Number: IQ24-000083

COVID vaccines made using GMP

Written

Senator: Malcolm Roberts

Question:

10. I have also asked this before and not received a straight answer, with references to documents that prove they were however upon reading those documents do not prove they were. SO one more time. Have the COVID “vaccines” been made using GMP for the entire period of their use in Australia? Please answer yes or no.

Answer:

10. Yes. All COVID-19 vaccines registered on the Australian Register of Therapeutic Goods and supplied in Australia were, and continue to be, manufactured in Good Manufacturing Practice (GMP)-approved facilities.

PARLIAMENTARY INQUIRY QUESTION ON NOTICE

Department of Health and Aged Care

Senate Community Affairs References Committee

Inquiry into Excess Mortality

13 June 2024

PDR Number: IQ24-000086

Pfizer tested vaccine

Written

Senator: Malcolm Roberts

Question:

13. Is the Health Dept aware that Pfizer tested a version of the vaccine based on normal growing medium but the vaccine imported into Australia was grown on a derivative of e-coli bacteria – in other words the product that was tested was different from the product you authorised?
14. When did you know that, and what measures did you take to test or obtain testing of the product Australia actually bought?
15. What extra precautions, if any, did the Health Dept recommend be put in place in lieu of the lack of testing? If none, why not?

Answer:

13. The statement “the product that was tested was different from the product you authorised” is not accurate.

It is unclear which “testing” the Senator is referring to. Any differences between the early and later clinical trial materials were fully justified against the relevant guidelines and were considered carefully by the TGA before being accepted (please refer to Question 14 for more information).

Every batch of COVID-19 vaccine supplied to the public has been tested by the TGA Laboratories for quality and all batches released have met the approved specifications.

14. The TGA closely aligns its regulatory approaches to therapeutic products with those of comparable international regulatory counterparts wherever possible. Technical data requirements for applications to register medicines in Australia are closely aligned with requirements set out in relevant international guidelines including the International Council on Harmonisation (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use.

Specifically, the ICH Q8(R2) Pharmaceutical Development¹ scientific guideline requires that changes between the commercial formulation and formulations used in pivotal clinical batches be clearly described and justified. ICH Q8(R2) also states that data from comparative studies that link clinical formulations to the commercial formulation should be provided.

At the time of provisional registration, Pfizer provided data about the methods used to manufacture the plasmid DNA. The TGA assessed this information in accordance with ICH Q8(R2) and found the starting materials (DNA templates) comparable and safe for use in the manufacturing process.

As stated in response to Q13, every batch of COVID-19 vaccine supplied to the public has been tested for quality by the TGA Laboratories and all batches released have meet the approved specifications.

15. The statement that there was a lack of testing is not accurate. Refer to Question 14 for further information.

¹ https://www.ema.europa.eu/en/documents/scientific-guideline/international-conference-harmonisation-technical-requirements-registration-pharmaceuticals-human-use-considerations-ich-guideline-q8-r2-pharmaceutical-development-step-5_en.pdf