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: IQ24-000065

Is the department of health investigating the potential for a Covid-19 vaccine to cause cancer

Written

Senator: Ralph Babet

Question:

14. Even adjusting for the annual increase in cancer mortality (which requires its own explanation and investigation) there were 2,050 additional deaths over the same time period over and above the predicted annual rise. Is the department of health investigating the potential for a Covid-19 vaccine to cause cancer?

Answer:

The Therapeutic Goods Administration (TGA) has an extensive safety monitoring system in place to monitor the safety of all vaccines and to investigate any potential new safety issues. For COVID-19 vaccines, many of the TGA's already robust post-market surveillance processes have been dramatically enhanced, making it the most intensive safety monitoring of therapeutic goods ever conducted in Australia. To date, neither the TGA nor any international regulator has detected any safety signals to indicate that COVID-19 vaccines are associated with any type of cancer.

The TGA's existing safety monitoring system for vaccines involves:

- reviewing and analysing reports of adverse events submitted by health professionals and consumers
- requiring pharmaceutical companies (or sponsors) to have risk management plans for the vaccines they supply
- proactively reviewing medical literature and other potential sources of new safety information

- working with international regulators to assess significant adverse events detected overseas
- working with state and territory health departments and clinical experts to ensure a coordinated approach.

Pharmaceutical companies also have legal obligations to monitor, collect, manage and report on safety data as described in the *Pharmacovigilance responsibilities of medicine sponsors: Australian recommendations and requirements* document (see: www.tga.gov.au/publication/pharmacovigilance-responsibilities-medicine-sponsors). The sponsor's pharmacovigilance responsibilities outlined in this policy document is embedded within relevant sections and subsections under the legislations (the *Therapeutic Goods Act 1989* and the *Therapeutic Goods Regulations 1990*).

There is no credible evidence to suggest that COVID-19 vaccines have contributed to excess deaths in Australia or overseas. Independent analysis of Australian death data by the Actuaries Institute found that the timing and shape of excess mortality does not support a link to vaccination. There are several drivers, often interrelated, that may explain the mortality patterns observed across Australia in recent years. This includes reductions in the timeliness of routine healthcare (for example, health assessments, diagnostic testing and elective surgeries), which facilitates the early detection of cancers.

Vaccination against COVID-19 remains the most effective way to reduce deaths and severe illness from COVID-19 infection. The published real-world evidence on COVID-19 vaccination demonstrates that the protective benefits of COVID-19 vaccination far outweigh the potential risks, including those of serious but rare adverse events.

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: IQ24-000070

Provide evidence confirming that none of the deaths in the Pfizer Covid 19 vaccine trial were due to the vaccine

Written

Senator: Ralph Babet

Question:

10. In his correspondence with Dr Kunadhasan from Australian Medical Professionals Society (a witness earlier today), Professor Lawler stated " it is reassuring to note, that none of the deaths in the Pfizer COVID-19 trial were due to the vaccine " . Could you provide the evidentiary basis that Professor Lawler relied upon to state that none of the deaths in the Pfizer Covid 19 vaccine trial were due to the vaccine?

Answer:

10. When reviewing clinical trial data, the Therapeutic Goods Administration (TGA) relies on the assessment of clinicians familiar with trial patients to assess a cause of death within a framework that ensures independent reporting. This particular trial included an independent External Data Monitoring Committee that oversaw safety and efficacy data with a view to ensuring data integrity as part of overall Good Clinical Practice.

All clinical trial results and reports submitted to the TGA as part of a submission for registration must comply with the Guideline for Good Clinical Practice. This is an internationally accepted standard for the designing, conducting, recording and reporting of clinical trials. It provides assurances that clinical trial data is ethically obtained, credible, accurate, and that the rights, safety, and confidentiality of trial subjects are protected.

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: IQ24-000063

What is driving the sharp increase in cancer deaths

Written

Senator: Ralph Babet

Question:

13. Since 2021 the overall increase in cancer deaths based on an average of deaths from 2015-2020 compared to the actual deaths from 2021-2023 amounts to 11,579 additional deaths from cancer alone. What is driving the sharp increase in cancer deaths?

Answer:

13. The Australian Institute of Health and Welfare (AIHW) reports that the age-adjusted cancer incidence rate increased from 614.4 cases per 100,000 people in 2015 to an estimated 625.8 cases per 100,000 people in 2023. The increase in cancer cases is mainly due to increases in population size and increasing numbers of people reaching older ages for which cancer incidence rates are higher. Over the corresponding period, age-adjusted cancer mortality rates decreased from 216.6 deaths per 100,000 people in 2015 to an estimated 194.8 deaths per 100,000 people in 2023.

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: IQ24-000060

Pre-market, placebo randomised studies of transmission

Written

Senator: Ralph Babet

Question:

4. Can you please provide for us, on notice, pre-market, placebo randomised studies of transmission with case tracking/finding. Please note we do not want non-randomised studies in this list.

Answer:

4. The Senator has not provided the names of the products for which study data is requested.

If the Senator is requesting information regarding COVID-19 vaccines, the Therapeutic Goods Administration (TGA) confirms that prevention of transmission is not an approved indication for these products. COVID-19 vaccines were approved in Australia to prevent severe illness, hospitalisation and death.

Notwithstanding the above, there is an insurmountable weight of evidence that COVID-19 vaccines protect against infection, albeit at a level that has reduced since the emergence of Omicron COVID-19 in November 2021. This data is not limited to regulatory trials or studies sponsored by vaccine manufacturers. As the TGA has indicated in previous enquiries from the Senator, a reduction in transmission is not a separate effect to individual protection but a collective effect of mass vaccination making many individuals in the population 'individually' immune. The epidemiological relationship between the proportion of people in the population who are immune to an infection and epidemic transmission of that infection has been well understood for decades.

PARLIAMENTARY INQUIRY QUESTION ON NOTICE

Department of Health and Aged Care

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Inquiry into Excess Mortality

13 June 2024

PDR Number: IQ24-000058

Pfizer trial undisclosed or hidden deaths

Written

Senator: Ralph Babet

Question:

3. When the department reviewed the Pfizer data did you discover undisclosed or hidden deaths, especially in the vaccinated arm of the Pfizer trial. Is this a breach of Good Clinical Practice (GCP)?

Answer:

3. The Therapeutic Goods Administration (TGA) has assumed the Senator is referring to the studies submitted by Pfizer for the provisional registration of its COVID-19 vaccine, COMIRNATY. The TGA did not 'discover' any undisclosed deaths in the studies submitted by Pfizer for the provisional registration of this vaccine.

COMIRNATY was provisionally registered via the provisional registration pathway in Australia. The provisional approval clearly indicated that "the decision has been made on the basis of short-term efficacy and safety data. Continued approval depends on the evidence of longer-term efficacy and safety from ongoing clinical trials and post-market assessment". Noting that COMINARTY transitioned to full registration on 13 July 2023.

The initial clinical evaluation and provisional approval relied on an interim three-month study report, noting continued approval, and subsequent transition to full registration, was contingent on the submission of confirmatory follow up safety and efficacy data.

The TGA is aware that were five additional deaths that occurred in the three-month period, which were not included the interim report. Importantly, these deaths were included in the follow-up six-month report. It is likely that these additional deaths were not included in the interim data package due to reporting cut-offs, which is expected in large, multi-centre studies. It is also noted that the investigation of deaths is complex with strict standards around reporting. No new safety signal arose as a result of the inclusion of these deaths in the six-month follow-up report.