HEALTH & DISABILITY COMMISSIONER
TE TOIHAU HAUORA, HAUĀTANGA

Information about myocarditis risk from Comirnaty vaccine not clearly highlighted or communicated

22HDC02256

Health and Disability Commissioner Morag McDowell has today released a report relating to the vaccination of a man in his twenties who died from myocarditis. The death was found, by the Coroner, to have been directly caused by the Comirnaty (Pfizer/BioNTech) COVID-19 vaccine.

Following his vaccination at a pharmacy, the man experienced chest discomfort and heart flutters. Apparently unaware that myocarditis (inflammation of the heart) was a potentially serious side effect of the vaccine, the man experienced these symptoms for 12 days before making the decision to go to hospital. Tragically, he collapsed and died before he got there.

During his vaccination the man was informed of the common, but not the potentially serious, side effects of the vaccine. In the specific circumstances, failing to provide this information was a prima facie breach of the Code of Health and Disability Services Consumers' Rights (the Code).

Ms McDowell was satisfied that the risk of myocarditis was intended by official agencies to be communicated to consumers as part of the consent process and that consumers were also to be given safety-netting advice about myocarditis symptoms following their vaccination.

However, Ms McDowell concluded that, in light of significant mitigating factors, it would be disproportionately harsh to find the pharmacy in breach of the Code, and that an educational approach was more appropriate.

Ms McDowell also noted that that the Comirnaty vaccine was, at the time, relatively new and new information about its use, risk and side effects was still forthcoming.

The broader public context was also relevant for this case, Ms McDowell said. The event took place during the unprecedented international and national response prompted by the pandemic which was accompanied by a concurrent steady flow of information from official sources.

However, she found that none of the sources of official information explicitly required vaccinators to disclose the risk of myocarditis as part of the informed consent process prior to vaccination. She also noted there was evidence that the importance of new information, relative to other information, was not made clear to vaccination providers.

“Given the seriousness of the risk of myocarditis and the information volume, one could reasonably expect that in communication to the providers the risk would be emphasised or highlighted in some way,” she said.

While she did not find the pharmacy in breach of the Code, Ms McDowell was critical that it did not update its standard operating procedure to ensure consumers were given adequate safety netting advice about the risk of the symptoms of myocarditis to look out for.

She also made an adverse comment about the pharmacist who vaccinated the man, but similarly did not find her in breach due to the mitigating factors outlined.

Ms McDowell made an educational comment to Manatū Hauora|Ministry of Health, stating that, in relation to the Comirnaty vaccine it needed to provide clear and unambiguous guidance to vaccinating providers about what and when they needed to tell consumers about myocarditis.

This was particularly relevant following the first death in New Zealand from myocarditis following the Comirnaty COVID-19 vaccine, which occurred prior to this event.

Ms McDowell made a number of recommendations, outlined in the report, for both the pharmacy and Te Whatu Ora (given that the National Immunisation Programme is now part of Te Whatu Ora rather than Manatū Hauora).

20 May 2024

Editor’s notes

Please only use the photo provided with this media release. For any questions about the photo, please contact the communications team.

The full report of this case can be viewed on HDC’s website - see HDC's 'Latest Decisions'.

Names have been removed from the report to protect privacy of the individuals involved in this case.

The Commissioner will usually name providers and public hospitals found in breach of the Code unless it would not be in the public interest or would unfairly compromise the privacy interests of an individual provider or a consumer. More information for the media, including HDC’s naming policy and why we don't comment on complaints, can be found on our website here.

HDC promotes and protects the rights of people using health and disability services as set out in the Code of Health and Disability Services Consumers' Rights (the Code).

In 2022/23 HDC made 592 quality improvement recommendations to individual complaints and we have a high compliance rate of around 96%.

Read our latest Annual Report 2023

Health and disability service users can now access an animated video to help them understand their health and disability service rights under the Code.

Learn more: Education Publications

For more information contact:

Communications team, Health and Disability Commissioner

Email: communications@hdc.org.nz, Mobile: +64 (0)27 432 6709