MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

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19 December 2022

s 9(2)(a)

By email: s 9(2)(a)
Ref: H2022017910

Dear s 9(2)(a)

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to Manatū Hauora (the Ministry of Health) on 1 December 2022 for information regarding the New Zealand Blood Service (NZBS). I have sought advice from NZBS for some parts of your request. Each part of your request is responded to below.

> *Copies of all supply agreements between Medsafe and NZBlood*
>
> *Any other blood supply agreements Medsafe may have with any other suppliers of blood or any component of blood including albumin, platelets etc other than NZBlood*
>
> *Any communications, reports or other information between Medsafe and NZBlood about how to address risks or perceived risks from blood that may contain residues from the PfizerVax*
>
> *Any risk/benefit analysis about any risks to the quality or safety of blood from mRNA vaccines including for any vulnerable recipients*
>
> *Any communications between Medsafe and Ministry of health or any Minister or Cabinet about how to manage risks from vaccine related or any other identified contaminant in blood*
>
> *Information to show any active steps Medsafe takes to research or otherwise seek and/ or share NZ or international research about risks to the safety of blood blood blood from a) mRNA vaccines b) other vaccines or c) other contaminants*

These parts of your request are refused under section 18(e) of the Act, as the information requested does not exist.

Any other information to show criteria for ensuring blood and blood products are safe, and to show what tests Medsafe requires on blood supplied from NZBlood or any other source to ascertain quality and safety of the blood and any changes to these over the last 5 years

Any testing Medsafe requires of blood or blood products to show the residual level of any vaccine or vaccine components or consequential products of vaccines in the blood. For the Pfizer vaccine and other mRNA vaccines please include information about testing for artificial mRNA, for nanolipid particles, for spike protein or fragments of spike protein and for any other components or contaminants in blood that may be attributable to these mRNA vaccines including any such components/ factors etc that may cause myocarditis, Pericarditis, vasculitis, thrombocytopenia, anaphylaxis or any of the other safety signals recognised by Medsafe for mRNA vaccines

NZBS has very detailed procedures which govern how it collects, tests, processes, stores, releases and delivers blood and blood products. Those procedures are carefully designed to comply with good clinical practice and evidence-based guidelines, including the guidance documents issued by the European Directorate for the Quality of Medicines and Healthcare (EDQM). This is accepted as being international best practice.

There is no blood service restricting the use of blood from donors with any of the vaccines currently approved for use in New Zealand. If there was any evidence of risk, we expect that blood services would be implementing screening and/or restrictions, as is standard practice for other established risks. Specifically, the Food and Drugs Administration (USA) requires no blood donor stand-down for mRNA (or other approved vaccines) and the Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee (UK) recommend a 48-hour stand-down (stating that: "COVID-19 vaccines are non-live and as such do not pose a transfusion safety risk. A 48-hour deferral after immunisation is recommended to reduce the risk of a donation being discarded if a vaccine recipient develops symptoms directly related to the vaccine after donation").

All Medsafe guidance regarding the COVID-19 vaccine is in respect of the risks associated with direct administration of the vaccine. None of the Medsafe guidance addresses risk in the context of trace vaccine contained in blood or blood products. There is a distinct difference in receiving the vaccine directly and receiving blood or blood products that may or may not contain tiny traces of the vaccine that was received by the blood donor. There is no evidence that trace amounts of a vaccine in blood or blood products could cause myocarditis. Despite millions of transfusions occurring in the last couple of years, there has been no evidence of vaccination creating any risks for blood product recipients

While designated donation may be relied on in exceptional circumstances, directed donation is not supported by NZBS. The NZBS directed donations policy states that "NZBS does not support the practice of directed donations. NZBS will discourage requests to provide directed blood components for patients on the basis that there is no evidence such components lead to improved patient care nor that they reduce the risk of acquiring transfusion associated infections".

Information to show the risks associated with mad cow disease or other prions in blood or blood products and how these risks are a) managed in New Zealand and b) best international practice for managing this.
Information to show what qualitative or quantitative tests are available for identifying prions associated with mad cow disease or other prions in blood and/ or blood products

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I trust this information fulfils your request. Under section 28(3) of the Act, you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by email at: info@ombudsman.parliament.nz or by calling 0800 802 602.

Please note that this response, with your personal details removed, may be published on the Manatū Hauora website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Yours sincerely

Chris James
Group Manager
Medsafe