MINISTRY OF HEALTH
MANATŪ HAUORA

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Robust assessment ahead of Medsafe approval of vaccine

Media release

3 February 2021

The decision by medicines regulator Medsafe to provisionally approve the Pfizer/BioNTech vaccine (Comirnaty) to be used in New Zealand follows a robust assessment of the safety, effectiveness and quality of the vaccine.

In a joint statement, the Director-General of Health Dr Ashley Bloomfield and Medsafe Group Manager Chris James have today outlined the process involved.

"Medsafe began assessing the clinical data provided by Pfizer/BioNTech in November, working over weekends and through the Christmas break," said Dr Bloomfield.

"The data was provided on a rolling basis, which streamlined the assessment process and enabled a timely approval without compromising the rigour of the review of the vaccine.

"I want to reinforce that this has been a carefully considered decision every step of the way. It's only been made after following the vigorous assessment processes which are an integral part of all New Zealand's decision-making around medicines."

Chris James said Medsafe needed to be assured the vaccine would be safe and effective for use in a New Zealand setting, and that it was of a high quality.

"There are three key aspects assessed: the effectiveness of the vaccine, the safety data (both determined by clinical study results), and finally manufacturing data," said Mr James.

"All the data is considered and we then complete a benefit risk assessment, which allows us to balance the benefits of the vaccine against any known risks such as side effects. We have determined there may be some minor side effects such as a painful arm and headaches – these are not uncommon in other vaccines.

"We have also wanted to ensure the company can manufacture the vaccine to a high quality, and that all batches are consistent.

"Medsafe's assessment went to the Medicines Assessment Advisory Committee (MAAC) yesterday (2.2.21) for its review, so the committee could provide Medsafe with advice and recommendations. The MAAC is made up of a range of industry experts from around New Zealand, and it met for six hours to help Medsafe come to a decision.

The MAAC supported Medsafe's proposal to grant provisional approval for the Pfizer/BioNTech vaccine."

"Provisional approval of the vaccine allows us to place conditions on the company.

"Medsafe has placed 58 conditions on the approval for the Pfizer and BioNTech vaccine.

"Of these, 52 relate to requiring additional manufacturing data from the company, for instance as it upscales its manufacturing. Six of the conditions relate to additional clinical information such as regular updates from clinical trials, and ensuring we receive any information on safety concerns from around the world.

"Medsafe's work doesn't stop here. As with all medicines and vaccines, we will monitor the use of the vaccine in New Zealand such as analysing reports of potential side effects. Medsafe's website will have the latest published information around Pfizer and BioNTech vaccine.

"This will include the medicine data sheet, which includes all the known information about the vaccine including the full list of ingredients. Information specifically tailored for consumers will also be published.

Dr Bloomfield again acknowledged the ongoing commitment of New Zealanders during the pandemic.

"This provisional approval is very much the start of a new chapter in our COVID-19 response and I want to reassure New Zealanders we will also be applying the same rigour to all subsequent vaccine applications.

"Vaccination is a key next step in our ongoing response to this virus. It's also a good point to recognise the incredible amount of work New Zealanders have put in to support our successful response to date.

There is more work to do, we are not out of the woods yet — but the provisional approval of the Pfizer and BioNTech vaccine is a significant milestone."

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