

15<sup>th</sup> February 2023

By email: s 9(2)(a)  
Ref: H2023019666

Tēnā koe 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 28 January 2023 for information regarding the Mpox Vaccine. You requested:

*“Why has Mpox vaccine has taken so long to get approval by Medsafe? What stage is the approval process currently at? Are changes to the Medicines Act being considered to provide better ways of allowing for rapid vaccination of at-risk communities, without restrictions on advertisement and recommendation?”*

Under the Medicines Act 1981, the organisation responsible for the medicine must apply for approval and supply data for a medicine to be assessed and potentially be approved. At this stage, an application has not been received by Medsafe for the Mpox vaccine to be assessed as an approved medicine.

Medsafe has been in contact with the potential applicant for many months, including resolving any perceived barriers to applying, such as cost and ensuring the company understands the minimum data required for assessment (as stated in the Medicines Act 1981). The potential applicant for this vaccine has stated that an application is imminent. However, Medsafe are yet to receive the minimum data for a viable application. Medsafe stands ready to urgently assess the application once we have it.

Information on development of a modern, comprehensive, cost-effective regulatory regime for therapeutic products in New Zealand, which will replace the Medicines Act 1981, can be found here: [www.health.govt.nz/our-work/regulation-health-and-disability-system/therapeutic-products-regulatory-regime](http://www.health.govt.nz/our-work/regulation-health-and-disability-system/therapeutic-products-regulatory-regime).

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 becontacted by email at: [info@ombudsman.parliament.nz](mailto: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](http://www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests).

Nāku noa, nā

A handwritten signature in blue ink, appearing to read 'Chris James', with a stylized flourish at the end.

Chris James  
**Group Manager**  
**Medsafe**