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26 November 2021

Matthew Hooton

By email: fyi-request-17402-6c3ca330@requests.fyi.org.nz
Ref: H2020115478

Dear Matthew

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to the Ministry of Health (the Ministry) on 30 October 2021. You specifically requested:

> *"...any medicines, in the last five years, that you have turned down for use in New Zealand after they had been approved for use in the USA by the FDA."*

The following new medicine applications were either refused approval or withdrawn by the sponsor following referral by Medsafe to the Medicines Assessment Advisory Committee under section 22(2) of the Medicines Act 1981 during this period. More information about these applications is available at: www.medsafe.govt.nz/regulatory/DbSearch.asp.

Medicine	**Status**
Lidocaine (B.Braun)	Refused
Nasovac-S	Withdrawn
Heberprot-P	Withdrawn
Liposomal Doxorubicin SUN	Withdrawn
Azmasol HFA Aerosol	Withdrawn
Diclofenac Mylan	Withdrawn
Travoprost-multichem	Withdrawn
Clonazepam BNM	Withdrawn
Iberogast	Withdrawn

Medsafe does not hold information on the approval status of medicines in other jurisdictions. Therefore, your request for information on the approval status of these applications in the USA is refused under section 18(g)(i) of the Act, as the information requested is not held by the Ministry and there are no grounds for believing it is held by another agency subject to the Act.

Further information
Applications for consent to distribute a new medicine may be referred to the MAAC committed by the Minister of Health under section 22(2) of the Medicines Act 1981, if he is not satisfied that he should give his consent to the distribution of the medicine. This includes medicines that have undergone full evaluation and where there remain outstanding questions regarding the safety, efficacy, or quality of the medicine. Applicants may choose to withdraw their medicine application at any time during the consent process, and it is common that applicants withdraw their applications prior to them being referred to the MAAC.

Medsafe has an abbreviated evaluation pathway in which review of overseas regulatory evaluation reports forms the basis of our evaluation. The abbreviated evaluation pathway has shorter evaluation timeframes and reduce costs to applicants. Medsafe is considered a leader in reliance pathways for medicine applications as we have had abbreviated pathway in place for more than a decade.

Medsafe approval of medicines helps to ensure that medicines approved for supply within New Zealanders are suitable and appropriate. For example, it may take into account other medicines that are commonly used in New Zealand, the way in which different medicines are used in New Zealand, and proposed supply chain for New Zealand. Medsafe's independent premarket evaluation helps to manage the risk of medicines and provides the public assurance that approved medicines are of acceptable efficacy, safety and quality.

Note that although medicines may have similar 'brand names' in various jurisdictions and are mostly the same, the exact nature of the medicine can differ depending on where it is supplied. This can include for example sites or manufacture and testing, release specifications, indications and contraindications, warning statements, shelf life.

It is also important to note there are difference in medicines legislation employed by various international regulators. For example, the US FDA has the ability to grant 'Emergency Use Authorisation' for medicines, and did so with the Pfizer COVID-19 vaccine, Comirnaty, in December 2020. This allowed the FDA to authorise use of Comirnaty based on a review of the very limited data available at the time and make a decision based on the benefit of the vaccine weighed up against the risk to public of the COVID-19 outbreak in the USA at the time. The FDA later approved Comirnaty following a full evaluation, in August 2021. Medsafe used our provisional consent pathway to grant approval of Comirnaty with conditions imposed in February 2021.

Medsafe pre-market evaluation of medicines also ensures that we have ready access to technical information and are able to understand and respond to post-market issues promptly. This includes for example assessment of adverse event reports, investigation of suspected product quality issues, and overseeing market recalls. Data reviewed during premarket evaluation is critical to these post market functions. The New Zealand public has a high expectation that Medsafe is able to effectively manage such risks.

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 Ministry website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Yours sincerely

Chris James
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Medsafe