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1 August 2019

Cody C

By email: fyi-request-9851-25dcf3d5@requests.fyi.org.nz
Ref: H201906202

Dear Cody C

**Response to your request for official information**

Thank you for your request of 4 July 2019 under the Official Information Act 1982 (the Act) for:

> *"Please advise why information relating to medicines, such as "Medsafe Product Detail", is released to the public but WAND data is not."*

Under section 20 of the Medicines Act 1981, the Minister of Health or his delegate must give consent before a medicine can be supplied and distributed in New Zealand. Information on the Medicines Act 1981 is available on the New Zealand Legislation website: http://www.legislation.govt.nz/act/public/1981/0118/latest/DLM53790.html#DLM55054.

This consent is granted following an assessment and recommendation by Medsafe. The assessment ensures that the medicine meets the required standards of safety, quality and efficacy. As a consequence, Medsafe holds information that it has verified, and that accurately describes the medicines supplied in New Zealand.

Further information regarding the medicines approval process is publicly available on the Medsafe website: https://www.medsafe.govt.nz/Medicines/medicines-landing.asp.

Information on medicines that have been verified by Medsafe and supplied within New Zealand is published on the Medsafe website: https://www.medsafe.govt.nz/regulatory/dbsearch.asp.

There is no pre-market assessment or approval process required for medical devices under the current legislation. The New Zealand sponsor (importer/manufacturer) must notify Medsafe via a database, within 30 days of supplying in New Zealand, unless the device is exempted under the Medicines (Database of Medical Devices) Regulations 2003. Additional information is available on the Medsafe website: https://www.medsafe.govt.nz/devices/devices-landing.asp.

There are a number of reasons why the Web Assisted Notification of Devices (WAND) database is not publicly available. These include:

- WAND is not an approval system for medical devices, as such publication of information by Medsafe may be misleading. The public may be led to believe that the products notified are approved as safe and effective by Medsafe, when that is not the case.
- Although sponsors are required to sign a declaration that indicates the information supplied is true and accurate, the information notified to the database is not reviewed or verified by Medsafe.
- The closest information to 'product type/name' is a field called the 'sponsor's own reference'. This may not describe an identifiable product name and may be a general description or code.
- Some medical devices are exempt from the requirement to notify them to the WAND database (e.g. In-Vitro Devices).

- When the WAND database was established, sponsors were told that the information contained within the notification would be kept confidential. Making the database public may discourage sponsors from notifying devices and there is public benefit in Medsafe's ability to access this information which may not otherwise be supplied.

When an issue is identified with a given medical device and further investigation is required, the WAND database is used by Medsafe to identify which sponsor(s) is/are supplying products to the New Zealand market. This is an important quality and safety measure.

New legislation is currently being developed and it is proposed to include an approval process for medical devices as well as a public database of approved medical devices. More information on the proposed regulatory regime and draft bill is publicly available on the Ministry of Health (the Ministry) website: https://www.health.govt.nz/our-work/regulation-health-and-disability-system/therapeutic-products-regulatory-regime.

I trust this information fulfils your request. Please note this response (with your personal details removed) may be published on the Ministry website.

Yours sincerely

Chris James
**Group Manager**
**MedSafe**