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1 February 2021

[redacted]

By email: [redacted]
Ref: H202008538

Dear [redacted]

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) on 26 November 2020 for:

> *"(a) any aggregated data held by Medsafe or the Centre for Adverse Reaction Monitoring regarding the number of adverse events involving medical devices generally, or particular types of medical device, on an annual basis, for the years 2010 to the present; and*
> *(b) any subsequent analysis of such data."*

As requested, data on the number of adverse events involving medical devices from 2010 to 2020 is attached as Appendix One to this letter. Reports relating to medical device adverse events are sent directly to Medsafe. Further information about this can be found at the following link: https://www.medsafe.govt.nz/regulatory/DevicesNew/9AdverseEvent.asp). While the Centre for Adverse Reactions Monitoring (CARM) at the University of Otago primarily collects reports about adverse reactions to medicines, any medical devices reports received there have been sent to Medsafe and are included in the data.

Please note that on 1 July 2014, the definition of 'medical device' was refined to align with international definitions. Further information on this topic can be found at: www.medsafe.govt.nz/Medicines/policy-statements/definition-of-med.asp. Additionally, the definition of 'risk' changed during the period defined by your request and is likely to be responsible for a change in the numbers recorded in each category.

Under section 13 of the Act, Medsafe is also providing you with some information from two documents that might be helpful. The text labelled 'Triage *process'* is an excerpt from an internal document defining the risk criteria and the text labelled '*Guidance'* is information from the MDIR reporting form. Note that the terms MDIR and MDAER are interchangeable and mean Medical Device Incident Report. This information is attached as Appendix Two to this letter.

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
Group Manager
Medsafe

Table One. The number of adverse events involving medical devices from 2010 to 2020

Years	Risk			
	High	Medium	Low	Total
2010	2	412	11	425
2011		30	321	351
2012	2	10	350	362
2013		11	498	509
2014			571	571
2015		5	566	571
2016			398	398
2017		9	671	680
2018	1	69	440	510
2019	3	272	111	386
2020	4	330	47	381
Grand total	**12**	**1148**	**3984**	**5144**

6.3 Triage process

The triage process is used to ensure that risks associated with MDAERs and Quality Events are identified on initial receipt and throughout the investigation. The triage process helps to ensure that a risk-based approach is taken to investigating these events.

This triage process should be completed on notification of the event, and updated as new information is received. The peer review process ensures the triage process is consistently applied.

The following criteria should be considered when evaluating risk.

Measure	**High Risk**	**Medium**	**Low**
# of MDIRs received	More than 3	Second Report	First Report
Public concern	High		None
Level of harm	Serious / death	Moderate	Negligible
Number of units affected	High percentage	Low percentage (but acceptably low)	One
Significant issue flagged by other regulators	Yes		No
Level of control	New issue not addressed, or device to the market (e.g. cutting edge technology)		Known issue and corrective actions in place to manage, or well established device with known risks
User error		Multiple reports of user error	User error
Inherent risk of the device	e.g. life preserving decive such as pace maker	e.g. device providing major therapeutic benefit such as replacement hips, glucose meters	e.g. lower therapeutic benefit such as mobility assistance

Other low risk indicators:

- Already well known and documented in the IFU.
- The only issue is or cause was the device exceed its shelf life as specified by the IFU
- Where the device has 'malfunctioned' correctly, i.e. fail-safe

Guidance

Harm definitions

Serious injury
An injury which meets any of the criteria:

- life threatening illness or injury has occurred or is likely to have occurred.
- permanent impairment of a body function or permanent damage to a body structure
- an unexpected condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure

Minor injury
An injury which does not meet the criteria of serious as defined above occurred or is likely to have occurred.

Quality issue
If an issue is related to the quality of a medical device, but no serious injury occurred (i.e. no one was harmed by the device), and it is unlikely that a serious injury could have occurred, you can still report this to us using this form.

Report types
Initial*:* The first report that the reporter (sponsor, manufacturer) submits about the event. Submit this report if the investigation is not yet complete and the final report not available.

Follow-up*:* Where required, to provide an update to a previous report.

Final*:* Submit this report when the investigation is complete. For "minor injury" or "quality issue", where possible submit a final report only, once the investigation is complete.

Clinical event information
The event description should include sufficient details to allow a clear understanding of the event, this could include:

- What procedure was being undertaken at the time?
- Who was using the device at the time
- Was the device being used according to the IFU

Manufacturer's investigation
This investigation should include details such as:

- Rates of occurrence of similar adverse events, both within New Zealand and worldwide as appropriate.
- Is this potentially a quality issue which would affect other devices?
- Is this event a known issue with the device, and is it described in the IFU?