

20 October 2022

s 9(2)(a)

By email: s 9(2)(a)  
Ref: H202013256

Dear 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 22 September 2022 regarding adverse events reports relating to the Essure permanent contraception medical device. Each part of your request is responded to below:

- 1. The number of adverse events reports made between January 1, 2002 – September 1, 2022 related to the Essure permanent contraception medical device, broken down by year;*

The following table provides information on the number of adverse event reports received at Medsafe by year. It is possible that some adverse events were reported prior to 2014 before a formal record was kept. Information on these reports and searching if any such reports exist, would require a substantial amount of collation and research, as such this information is refused under section 18(f) of the Act.

Year	Number of Reports received
2014	2
2015	1
2016	4
2017	1
2018	3
2019	0
2020	0
2021	1
2022	1

### *2. Details of the adverse reactions experienced*

The adverse events reported include pain, heavy menstrual bleeding, perforation of the fallopian tubes, dislocation of the device, patent (open fallopian tubes) and one instance where a pregnancy commenced prior to the insertion of the device but was not detected at the time of insertion.

*3. Details of whether adverse events reports were lodged by consumers; healthcare professionals or industry, where known.*

Eleven of these adverse events reports were received from the supplier (industry) and two were received from patients.

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](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 Ministry 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).

Yours sincerely



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