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7 June 2024

s 9(2)(a)

By email: s 9(2)(a)
Ref: 574418

Tēnā koe s

Your request for official information

I refer to your request under the Official Information Act 1982 (the Act) to the Ministry of Health – Manatū Hauora (the Ministry) on 21 December 2021. You requested:

> *"Please advise the batch numbers of the Pfizer vaccine that caused serious adverse effects. I also want to know how many different batches of the Pfizer vaccine have been used in NZ?*
> *I do not want personal information. I simply want to know if batch 2556 for example has 50 serious effects reported or that batch 2545 had 1 serious adverse reaction reported.*

On 8 February 2022, the Ministry responded and advised that:

> *Whist the batch numbers are linked to AEFI in the CARM database, the database does not support the generation of AEFI by batch number report in the manner you have requested. This would require a significant manual collation of information. There is no requirement under the Act for agencies to create new information. Therefore this part of your request is refused under section 18(g) on the grounds that the information requested is not held.*

In 2020, the COVID-19 Centre for Adverse Reactions Monitoring (CARM) database was built specifically for COVID-19 adverse events reporting and was always intended to be a temporary database. As such the database did not have all the functionality normally incorporated into such a database. The Ministry initially refused your request under section 18(g)(i) of the Act, as the information you requested was not held by the Ministry and there were no grounds to believe that the information was held by another department.

Since the date of your request, a new database has been created and the Ministry is now in a position to reconsider your original request for information and to make a new decision on your request.

. Please note that we have interpreted your request to be for the Comirnaty vaccine, not other vaccines manufactured by Pfizer.

Please find attached a spreadsheet detailing the batch numbers that were provided with reports to CARM where the reporter stated that the events were serious, and the number of serious events reported per batch within the time frame of your request.

Please note, there are the following caveats associated with the data:

- Reporting suspicions of an adverse event to a vaccine is voluntary. Therefore, the AEFI reports provided to CARM) represent a fraction of the total number of AEFI's.
- In order to report an AEFI, a link must be made between an event and the vaccine by the person who experienced the AEFI or the healthcare professional they consulted about the event.
- In order to report an AEFI, the person and/or their healthcare professional must know how to report an AEFI and have the time to report an AEFI.
- Reporting may be influenced by many factors such as media publicity. Therefore, the proportion of events reported is likely to change over time.
- There may be a difference in reporting in different age groups, genders, at different vaccination sites and by ethnicity.
- Reporters may choose to report a diagnosis which would be counted as one event or report the symptoms of the condition/diagnosis, which will be many events. The Ministry considers that the two reports would essentially be the same, but for the purposes of this request would have a significant differential effect on the numbers requested.
- Reporters choose if they think the events they experienced were 'serious', and different reporters would have different thresholds as to whether something was deemed serious or not and this may also vary between reporter types, e.g., a consumer vs a general practitioner.
- The seriousness was assigned to the 'case', not individual events. Therefore, if a person reported one serious event and 10 non-serious events, all 11 events would be considered as serious. The Ministry can't distinguish between the events as this data was not captured.
- The batch number is as reported, and the Ministry does not know how accurate the recording of batches was.
- The Ministry does not know the size of the batches (and each batch may have been distributed across several countries).
- The Ministry does not know how many doses were obtained from each of the multidose vials.
- The Ministry does not know how much wastage there was from each batch.
- The Ministry does not know if batches were distributed evenly throughout the country, or if there was regional variation which may have coincided with a regional variation in reporting.

The part of your request for *how many different batches of the Pfizer vaccine have been used in NZ* no longer is the responsibility of the Ministry of Health following the establishment of Health New Zealand – Te Whatu Ora. Therefore, the Ministry is transferring this part of your request to Health New Zealand under section 14(b)(i) of the Act. You can expect a response from Health New Zealand in due course.

The Ministry sincerely apologises for overlooking this part of your request in our original response of 2022.

I trust this information fulfils your request. If you wish to discuss any aspect of your request with us, including this decision, please feel free to contact the OIA Services Team on: oiagr@health.govt.nz.

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.

Nāku noa, nā

s 9(2)(g)(ii)
Group Manager
Medsafe

BatchNumber as re	Serious'ReactionCount
None	173
325921P	26
EP2163	61
EP2163 034	4
EP2163-003	2
EP2163-009	8
EP2163-046	8
EP2163-048	1
EP2163-051	13
EP2163-054	10
EP2163-055	9
EP2163-057	1
EP9605	139
EP9605-002	7
EP9605-005	3
EP9605-007	13
EP9605-012	12
EP9605-013	5
EP9605-014	22
EP9605-015	2
EP9605-016	19
EP9605-017	5
EP9605-019	7
EP9605-022	18
EP9605-024	1
EP9605-025	1
EP9605-026	17
EP9605-028	9
EP9605-034	4
EP9605-035	3
EP9605-036	10
EP9605-037	2
EP9605-038	6
EP9605-040	11
EP9605-041	7
EP9605-042	12
EP9605-044	2
EP9605-15	1
EP9605-301	15
EP9605012	11
EP9605023	1
EP9605034	4
EP9605041	1
ER7449	76
ER7449-001	20
ER7449-002	20
ER7449-003	2
ER7449-005	1
ER7449-006	8

ER7449-010	4
ER7449-011	2
ER7449-013	2
ER7449-014	10
ER7449-015	5
ER7449-017	4
ER7449-021	23
ER7449-024	26
ER7449-025	3
ER7449-026	5
ER7449-028	9
ER7449-029	3
ER7449-032	4
ER7449-033	7
ER7449-035	4
ER7449-036	27
ER7449-039	3
ER7449-040	3
ER7449-041	1
ER7449-10	1
ER7449-27	1
ER7449-36	11
ET3045	22
ET3045-003	1
ET3045-007	5
ET3045-008	9
ET3045-009	6
ET3045-011	4
ET3045-013	6
ET3045-015	17
ET3045-016	11
ET3045-017	13
ET3045-019	8
ET3045-020	16
ET30450-11	8
ET9096	37
ET9096 - 005	9
ET9096 -010	1
ET9096 002	6
ET9096 049	2
ET9096 056	6
ET9096-0000	12
ET9096-001	8
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ET9096-006	1
ET9096-007	10
ET9096-008	6
ET9096-009	14
ET9096-010	14
ET9096-011	3

ET9096-012	8
ET9096-013	8
ET9096-014	13
ET9096-016	5
ET9096-017	1
ET9096-018	1
ET9096-019	36
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ET9096-035	7
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ET9096-040	2
ET9096-041	6
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ET9096-045	15
ET9096-046	5
ET9096-047	15
ET9096-048	3
ET9096-052	29
ET9096-054	7
ET9096-055	1
ET9096-057	25
ET9096-060	3
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ET9096010	8
ET9096047	7
EX 2405-023	4
EX2405	41
EX2405 - 048	1
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EX2405 028	9
EX2405- 003	11
EX2405-005	8
EX2405-007	10
EX2405-008	3
EX2405-014	8
EX2405-015	4
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EX2405-019	3
EX2405-021	20

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EX2405.057	5
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EX2405057	3
FA5833	12
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FA5833-005	21
FA5833-006	9
FA5833-007	53
FA5833007	9
FC3558	1
FC3558-001	2
FC3558-002	6
FC3558-003	26
FC3558-004	19
FC3558-005	49
FC3558-006	2
FC3558-007	2

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FC3558-04	2
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FC5029-002	33
FC5029-003	5
FC5029-004	13
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FC5029004	16
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FD0927-005	12
FD0927-006	5
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FD9234-003	6
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FE2090-001	4
FE2090-002	13
FE2090-004	1
FE2090-005	4
FE2090-006	7
FE2090002	6
FE3064	11
FE3064-001	3
FE3064-002	47
FE3064-003	3
FE3064.002	1
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FE8163 D0029	3
FE8163-001	16
FE8163-002	33
FE8163-003	16
FE8163-004	37
FE8163-005	34
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FH0114.001	9
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FH3219-006	24

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FH3219-D00117	24
FH3219-D00118	5
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FH3219-D00120	20
FH3219-D0013	2
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FH3219-DOO119	2
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FH3219D0014	11
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FH4092 007	2
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FH4092-007	52
FH4092-008	1
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FH4092-010	5
FH4092-D0060	23
FH4092-D0061	9
FH4092-D0062	4
FH4092-D0064	22
FH4092D0064	5
FH4752 D00134	3
FH4752-001	5
FH4752-002	61
FH4752-003	170
FH4752-0031	11
FH4752-005	1
FH4752-D00121	5
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FH9678-002	135
FH9678-003	30
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FH9678-005	48
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FL1072-004	49
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