

Medsafe Performance Statistics

1 July 2022 to 30 June 2023

Published August 2023



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This page contains information about Medsafe's processing times for applications. For more information about the types of applications, see [Guideline on the Regulation of Therapeutic Products in New Zealand, New Medicine Applications](#).

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Key performance indicators

Medsafe's key performance indicators are the time in calendar days to complete initial evaluation for new medicine applications and changed medicine notifications (see table 3).

Reporting format

Please note the following:

- The statistics below are for 12 months and correspond to Medsafe's financial reporting year (i.e., July – June).
- Some charts also include previous years for comparison purposes.
- Medsafe collects its statistics in a different way from the Australian Therapeutic Goods Administration (TGA) and therefore the performance measures of each agency cannot be aligned or directly compared. Key differences include:
 - Medsafe performance measures and statistics are in **calendar days**, unlike the TGA which reports in **working days**
 - some measures reported by the TGA are not captured by the Medsafe database and therefore cannot be reported
 - the total time to completion includes **both** Medsafe evaluation and sponsor response times. The TGA only report TGA times in their total time to completion.

Low-risk application categories

Medsafe changed the definitions for low-risk application categories in 2023, refer to the [Guideline on the Regulation of Therapeutic Products in New Zealand, New Medicine Applications](#), section 10.

This report includes performance statistics for both the old (N) categories, and the new (L) categories. This is because applications often span over multiple reporting years, therefore some applications submitted under the low-risk N categories are still under evaluation.

Medicine applications

Applications received and outcomes

Table 1 shows the number of medicine applications received each year by type and outcome.

Note that the number of applications received is different to the number of consents granted because the approval process may span over multiple reporting years. Applications consented in any given year typically include a proportion lodged in preceding years.

Table 1: Number of medicine applications by type and outcome, Jul 2022 – Jun 2023

Application type	Received	Consented	Withdrawn	Refused
Higher risk	14	20	0	0
Higher risk (abbreviated)	13	26	1	0
Intermediate risk	15	18	2	0
Intermediate risk (abbreviated)	29	37	1	0
Priority review	8	10	0	0
Priority review (abbreviated)	0	2	0	0
Lower risk	15	38	5	0
Changed medicine notification (CMN)	1531	1504	19	1
Section 24(5) referral*	73	104	3	1

* Section 24(5) referrals include extension of indications

Requests for information (RFIs) received for consented applications

RFIs are requests for information from Medsafe to the sponsor. Table 2 shows the number of RFIs sent and responses received per consented application per year. See also table 7 for lower risk medicines by category.

Table 2: Number of requests for information (RFIs) sent and responses received per consented application, Jul 2022 – Jun 2023

Application type	Number of RFIs			
	0	1	2	3+
Higher risk	0	6	9	5
Higher risk (abbreviated)	0	14	11	1
Intermediate risk	0	1	9	8
Intermediate risk (abbreviated)	0	27	10	2
Priority review	3	7	9	7
Priority review (abbreviated)	0	1	0	0
Lower risk	0	8	11	17
Changed medicine notification (CMN)	1028	413	50	13
Section 24(5) referral	24	38	34	8

Processing and approval times

Processing and approval times are defined as the number of calendar days from the payment of an application until formal notification of a decision, unless otherwise specified.

These exclude times where Medsafe is unable to progress the application due to screening (which can include requests for information to make an application complete) or waiting for the payment of fees.

Medsafe calendar days include public holidays and weekends.

Only changed medicine notifications (CMNs) timeframes are mandated by legislation: CMNs must be completed within 90 calendar days of receipt of payment. If they are not resolved within this timeframe, CMNs are referred to the Minister under section 24(5)(b) of the Medicines Act 1981. [Indicative processing timeframes](#) are set for other activities to help monitor Medsafe's performance and efficiency.

Time to complete the initial evaluation

Table 3 shows the times for Medsafe to complete the initial evaluation by medicine application type per year. Target times for completion of the initial evaluation range from 45 calendar days for CMNs to 200 calendar days for higher risk medicines. Figure 1 shows the mean time for completion of the initial evaluation by medicine application type per year.

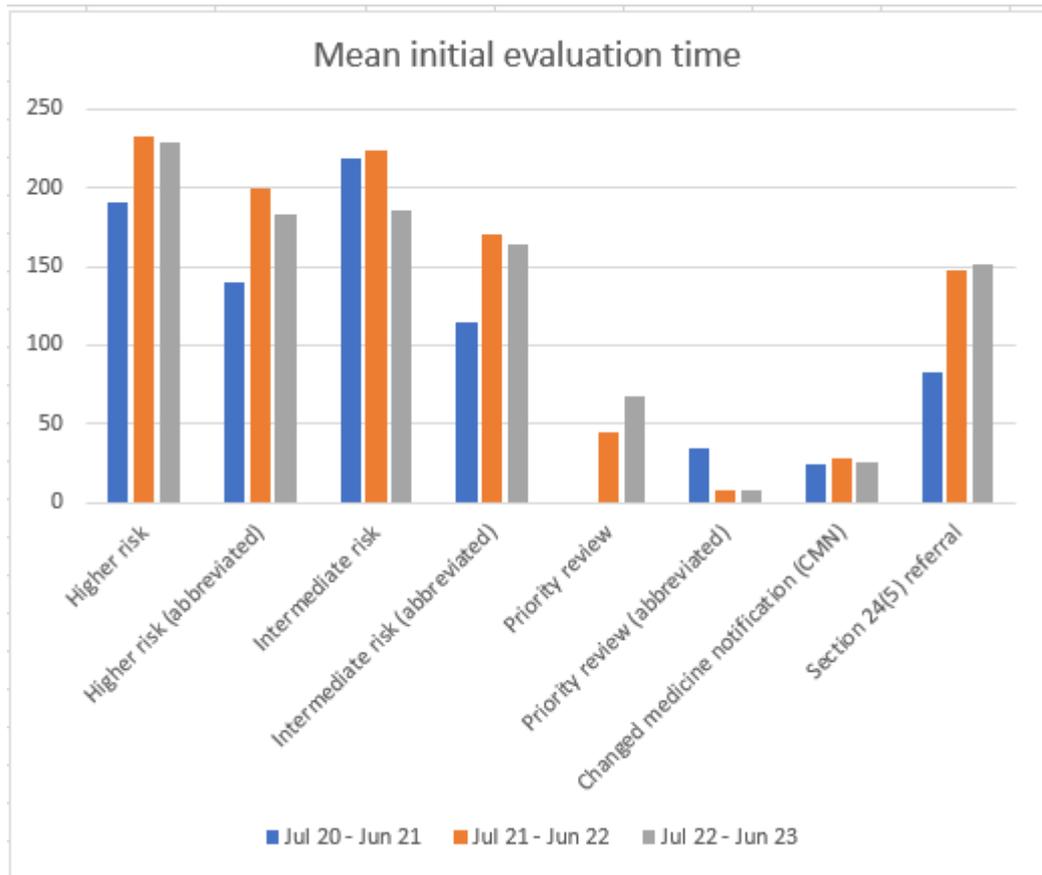
See tables 8 and 9 for lower risk medicines.

Table 3: Time in calendar days to complete initial evaluation, Jul 2022 – Jun 2023

Application type	Target time for completion*	Time to complete*			Standard Deviation*
		Mean	Median	Range	
Higher risk	200	229	199	19-486	123
Higher risk (abbreviated)	100	183	170	92-340	71
Intermediate risk	200	185	188	23-397	72
Intermediate risk (abbreviated)	100	164	176	64-302	48
Priority review	100	67	24	1-290	110
Priority review (abbreviated)	100	8	-	-	-
Changed medicine notification (CMN)	45	26	27	1-50	11
Section 24(5) referral	200	151	167	6-436	115

* Measured in calendar days.

Figure 1: Mean time to complete initial evaluation, by application type



Time to complete the evaluation of additional information (EAI)

The evaluation of additional information (EAI) measure is the time taken for Medsafe to evaluate the request for information (RFI) response from a sponsor. EAI1 is the time to evaluate the first RFI response and EAI2 is the time for the second RFI response. The EAI target times vary by application type, as shown in table 4.

See table 10 for lower risk medicines.

Table 4: Time in calendar days to complete evaluation of additional information (EAI), Jul 2022 – Jun 2023

Application type	Target time	EAI1 ^a			Target time	EAI2 ^b		
		Mean	Median	Range		Mean	Median	Range
Higher risk	120	97	97	11-239	120	124	143	31-206
Higher risk (abbreviated)	120	123	111	52-286	120	122	123	26-196
Intermediate risk	120	141	130	5-248	120	120	137	3-216
Intermediate risk (abbreviated)	120	137	136	62-243	120	101	107	2-202
Priority review	28	23	11	1-69	28	20	12	1-48
Priority review (abbreviated)	28	-	-	-	28	25	25	1-48
Changed medicine notification (CMN)	N/A ^c				N/A			
Section 24(5) referral	120	115	90	3-902	120	88	88	3-281

a EAI1 is the time in calendar days to evaluate the first request for information (RFI) response received from the sponsor.

b EAI2 is the time in calendar days to evaluate the second RFI response received from the sponsor.

c CMN EAI times are not captured by the database.

Time to application consent

Table 5 shows the time in calendar days for Medsafe to consent (approve) an application per year. Only CMNs have a legislative timeframe, which is 90 calendar days from receipt of payment.

Figure 2 shows the mean time to application consent by application type.

The time includes both Medsafe evaluation and sponsor RFI response times.

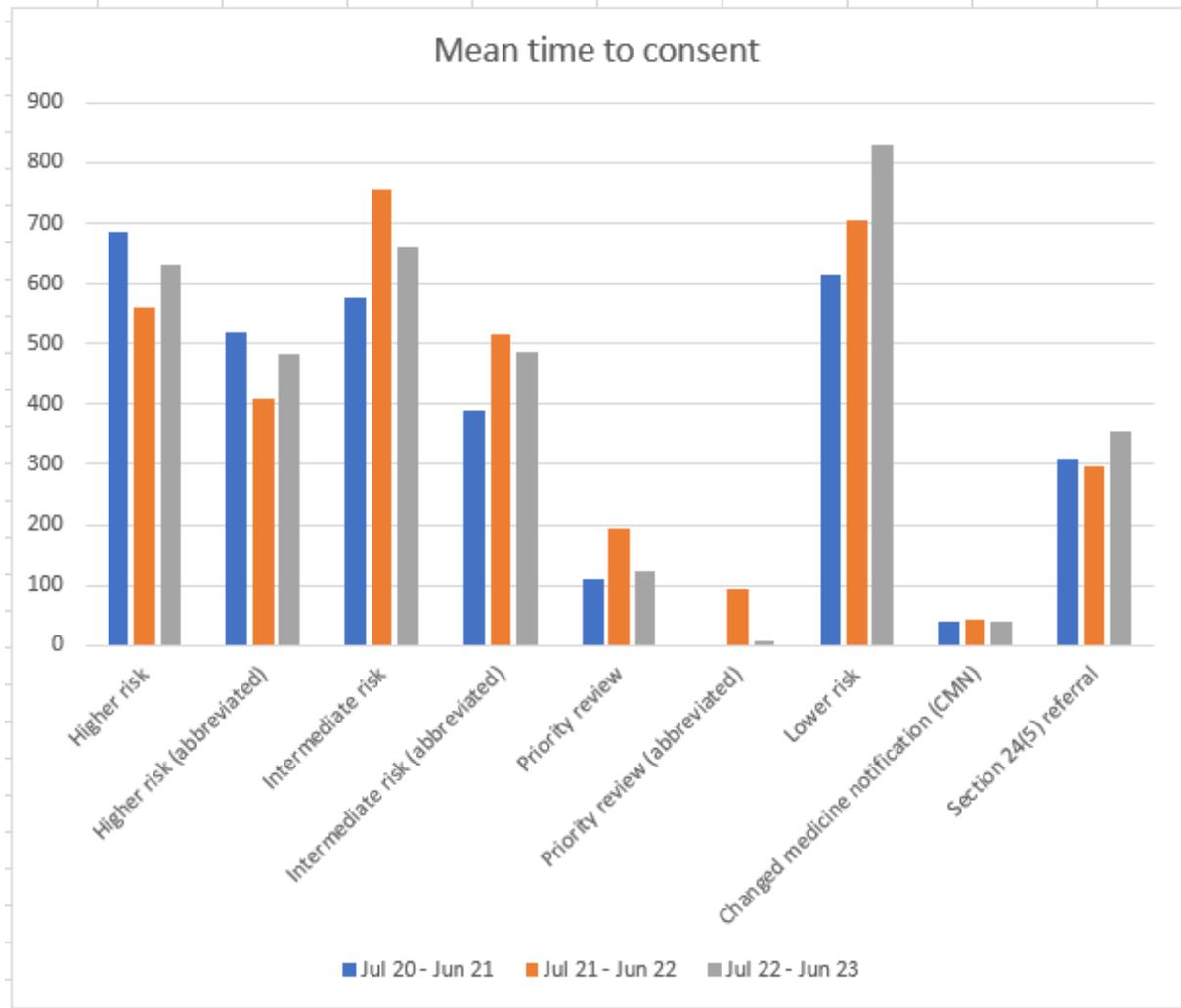
Table 5: Time to application consent, Jul 2022 – Jun 2023

Application type	Time to consent ^a			Standard deviation ^a
	Mean	Median	Range	
Higher risk	630	593	98-1436	338
Higher risk (abbreviated)	482	450	254-841	171
Intermediate risk	661	551	29-1122	493
Intermediate risk (abbreviated)	486	469	237-913	154
Priority review	122	112	29-309	103
Priority review (abbreviated)	8	8	8	NA
Lower risk	830	840	24-1511	357
Changed medicine notification (CMN) ^b	38	32	1-302	25
Section 24(5) referral	356	308	37-1504	257

a. Measured in calendar days.

b. The CMN target time is 90 calendar days from receipt of payment.

Figure 2: Mean time to application consent, by application type



Lower risk medicines (N categories)

Lower risk medicines include those that are available without prescription, e.g., they are available over the counter. Lower risk medicines are further categorised into application types: N1, N3, N4 and N5.

Note: Medsafe has reviewed the N categories, current categories are now L1, L2, L3.

Applications received

Table 6: Number of lower risk medicine applications received (excluding withdrawn) by N categories, 2018 to Jul 2022 – Jun 2023

Year	N1	N3	N4	N5	L1*	L2*	L3*	Total
Jul 2022 – Jun 2023	5	4	1	3	3	5	1	22
Jul 2021 – Jun 2022	7	13	4	4	-	-	-	28
Jan 2021-Jun 2021#	6	6	0	3	-	-	-	15
2020	19	20	3	8	-	-	-	50
2019	12	30	3	9	-	-	-	54
2018	17	30	4	6	-	-	-	57

* Some L1 applications were received in Jul 2022 - Jun 2023 year under N-categories, and screened in Jul 2023-Jun 2024 year, under new L-categories.

Statistics for half year only

Requests for information (RFIs) for lower risk medicines

Table 7 shows the number of RFIs sent and responses received per lower risk medicine application, by category, per year (for those applications approved between Jul 2022 – Jun 2023).

Table 7: Number of requests for information (RFIs) sent and responses received per lower risk medicine application, by category, Jul 2022 – Jun 2023

Category	Number of RFIs			
	0	1	2	3+
N1	0	4	2	1
N3	0	4	6	10
N4	0	1	1	2
N5	0	2	4	5
L1	-	-	-	-
L2	-	-	-	-
L3	-	-	-	-

Processing times

Table 8 shows low risk category timeframes.

Table 8 Time in calendar days to complete initial N categories evaluation, by category, Jul 2022 – Jun 2023

Category	Target time for initial evaluation completion (calendar days)	Time to complete initial evaluation (calendar days)		
		Mean	Median	Range
N1	30	210	186	181-263
N3	60	179	195	122-197
N4	90	192	195	184-197
N5	120	176	181	145-197
L1*	50	44	44	44
L2	100	-	-	-
L3	150	-	-	-

* Only one application received as L1 in the reporting year.

Table 9: Percentage of lower risk medicine applications, by N categories, that met the indicative timeframes, Jan–Jun 2021

Category	INE ^a		RFI1 ^b		EAI1 ^c	
	Target time (calendar days)	Percentage meeting timeframe	Target time (calendar days)	Percentage meeting timeframe	Target time (calendar days)	Percentage meeting timeframe
N1	30	0%	7	0%	7	0%
N3	60	0%	30	33%	30	0%
N4	90	0%	30	33%	30	0%
N5	120	0%	60	75%	60	0%
L1	50	100%	30	-	30	-
L2	100	-	60	-	60	-
L3	150	-	90	-	90	-

a INE: the time in calendar days for Medsafe to complete the initial evaluation.

b RFI1: the time in calendar days for the sponsor to submit the first request for information (RFI) response.

c EAI1: the time in calendar days for Medsafe to evaluate the first RFI response from the sponsor.