

Medsafe Performance Statistics

1 January – 31 December 2020

March 2021

Medsafe Performance Statistics

This page contains information about Medsafe's processing times for applications. For more information about the types of applications, see [Part 2: Obtaining approval for new and changed medicines and related products the Guideline on Regulation of Therapeutic Products in New Zealand](#).

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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 tables 5 and 6).

Reporting format

Please note the following:

- The statistics below are for calendar year (ie, January–December).
- The reported timeframe also includes the previous year 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.

Medicine applications

Applications received and outcomes

Tables 1 and 2 show 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 be longer than 12 months. Applications consented in any given year typically include a proportion lodged in preceding years.

Table 1: Number of medicine applications by type and outcome, 2020

Application type	Received	Consented	Withdrawn	Refused
Higher risk	21	19	0	0
Higher risk (abbreviated)	35	32	1	0
Intermediate risk	13	20	0	0
Intermediate risk (abbreviated)	43	37	2	0
Priority review	14	9	0	0
Priority review (abbreviated)	0	0	0	0
Lower risk	52	44	1	0
Changed medicine notification (CMN)	1568	1522	16	0
Section 24(5) referral*	145	138	10	0

* Section 24(5) referrals include extension of indications.

Table 2: Number of medicine applications by type and outcome, 2019

Application type	Received	Consented	Withdrawn	Refused
Higher risk	18	20	2	0
Higher risk (abbreviated)	27	24	0	0
Intermediate risk	13	19	2	0
Intermediate risk (abbreviated)	31	44	4	0
Priority review	2	4	0	0
Priority review (abbreviated)	0	1	0	0
Lower risk	60	31	6	0
Changed medicine notification (CMN)	1353	1334	17	0
Section 24(5) referral*	119	132	0	0

* 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. Tables 3 and 4 show the number of RFIs sent and responses received per consented application per year. See also tables 12 and 13 for lower risk medicines by category.

Table 3: Number of requests for information (RFIs) sent and responses received per consented application, 2020

Application type	Number of RFIs			
	0	1	2	3+
Higher risk	0	3	7	9
Higher risk (abbreviated)	0	10	13	5
Intermediate risk	0	5	8	7
Intermediate risk (abbreviated)	2	13	16	6
Priority review	3	3	2	1
Priority review (abbreviated)	0	0	0	0
Lower risk	3	14	19	8
Changed medicine notification (CMN)	966	478	62	13
Section 24(5) referral	31	40	40	27

Table 4: Number of requests for information (RFIs) sent and responses received per consented application, 2019

Application type	Number of RFIs			
	0	1	2	3+
Higher risk	2	6	9	1
Higher risk (abbreviated)	0	9	9	6
Intermediate risk	0	7	9	5
Intermediate risk (abbreviated)	0	19	15	10
Priority review	0	1	1	2
Priority review (abbreviated)	0	1	0	0
Lower risk	0	6	15	10
Changed medicine notification (CMN)	796	455	71	11
Section 24(5) referral	36	23	51	22

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

Tables 5 and 6 show the times (mean, median and range) 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 14 to 16 for lower risk medicines.

Table 5: Time in calendar days to complete initial evaluation, 2020

Application type	Target time for completion*	Time to complete*			Standard Deviation*
		Mean	Median	Range	
Higher risk	200	194	195	92–261	34
Higher risk (abbreviated)	100	140	143	63–199	37
Intermediate risk	200	218	195	165–331	52
Intermediate risk (abbreviated)	100	114	113	48–172	29
Priority review	100	34	22	1–100	34
Priority review (abbreviated)	100	-	-	-	-
Changed medicine notification (CMN)	45	25	26	0–56	11
Section 24(5) referral	200	83	35	10–286	76

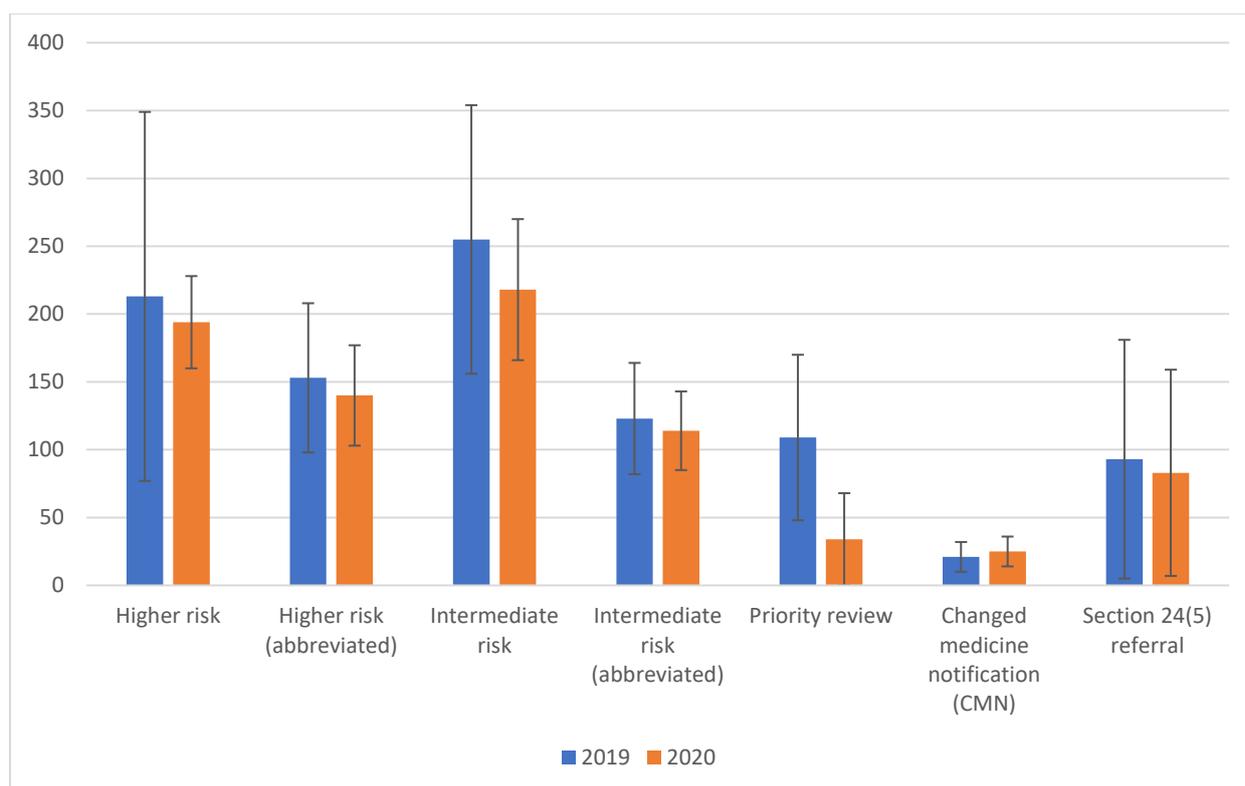
* Measured in calendar days.

Table 6: Time in calendar days to complete initial evaluation, 2019

Application type	Target time for completion*	Time to complete*		
		Mean	Median	Range
Higher risk	200	213	196	176–379
Higher risk (abbreviated)	100	153	157	64–272
Intermediate risk	200	255	233	108–452
Intermediate risk (abbreviated)	100	123	99	68–197
Priority review	100	109	108	23–195
Priority review (abbreviated)	100	115	115	115
Changed medicine notification (CMN)	45	21	21	0–49
Section 24(5) referral	200	93	38	8–336

* Measured in calendar days.

Figure 1: Mean time to complete the initial evaluation, by application type, 2019 and 2020



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 tables 7 and 8.

See tables 17 to 18 for lower risk medicines.

Table 7: Time in calendar days to complete evaluation of additional information (EAI), 2020

Application type	Target time	EAI1 ^a			Target time	EAI2 ^b		
		Mean	Median	Range		Mean	Median	Range
Higher risk	120	119	161	39–258	120	112	138	1–204
Higher risk (abbreviated)	120	127	145	9–209	120	101	133	37–147
Intermediate risk	120	132	135	36–204	120	120	132	8–207
Intermediate risk (abbreviated)	120	140	147	22–196	120	110	101	49–203
Priority review	28	9	2	1–32	28	20	20	20
Priority review (abbreviated)	28	-	-	-	28	-	-	-
Changed medicine notification (CMN)	N/A ^c				N/A			
Section 24(5) referral	120	81	75	1–221	120	80	53	10–335

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.

Table 8: Time in calendar days to complete evaluation of additional information (EAI), 2019

Application type	EAI1 ^a				EAI2 ^b			
	Target time	Time to complete			Target time	Time to complete		
		Mean	Median	Range		Mean	Median	Range
Higher risk	120	141	132	60–292	120	79	66	0–251
Higher risk (abbreviated)	120	116	122	3–179	120	86	78	0–194
Intermediate risk	120	144	151	39–239	120	115	115	3–205
Intermediate risk (abbreviated)	120	149	158	58–238	120	99	121	0–171
Priority review	28	15	15	15	28	7	7	0–20
Priority review (abbreviated)	28	3	3	3	28	N/A ^c	N/A	N/A
Changed medicine notification (CMN)	N/A				N/A			
Section 24(5) referral	120	61	52	1–220	120	56	30	3–160

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 All applications were withdrawn or superseded before an EAI2 was completed.

Time to application consent

Tables 9 and 10 show the time in calendar days (mean, median and range) for Medsafe to consent (approve) an application per year. The time includes both Medsafe evaluation and sponsor RFI response times. As stated above, only CMNs have a target timeframe, which is 90 calendar days from receipt of payment.

Figure 2 shows the mean time to application consent by application type, for 2019 and 2020.

Table 9: Time to application consent, 2020

Application type	Time to consent ^a			Standard deviation ^a
	Mean	Median	Range	
Higher risk	770	741	231–1752	338
Higher risk (abbreviated)	382	335	37–1038	198
Intermediate risk	887	740	433–1672	398
Intermediate risk (abbreviated)	464	373	40–1464	279
Priority review	68	37	10–231	77
Priority review (abbreviated)	-	-	-	-
Lower risk	651	645	24–1808	365
Changed medicine notification (CMN) ^b	41	31	1–364	28
Section 24(5) referral	268	207	37–1640	194

a. Measured in calendar days.

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

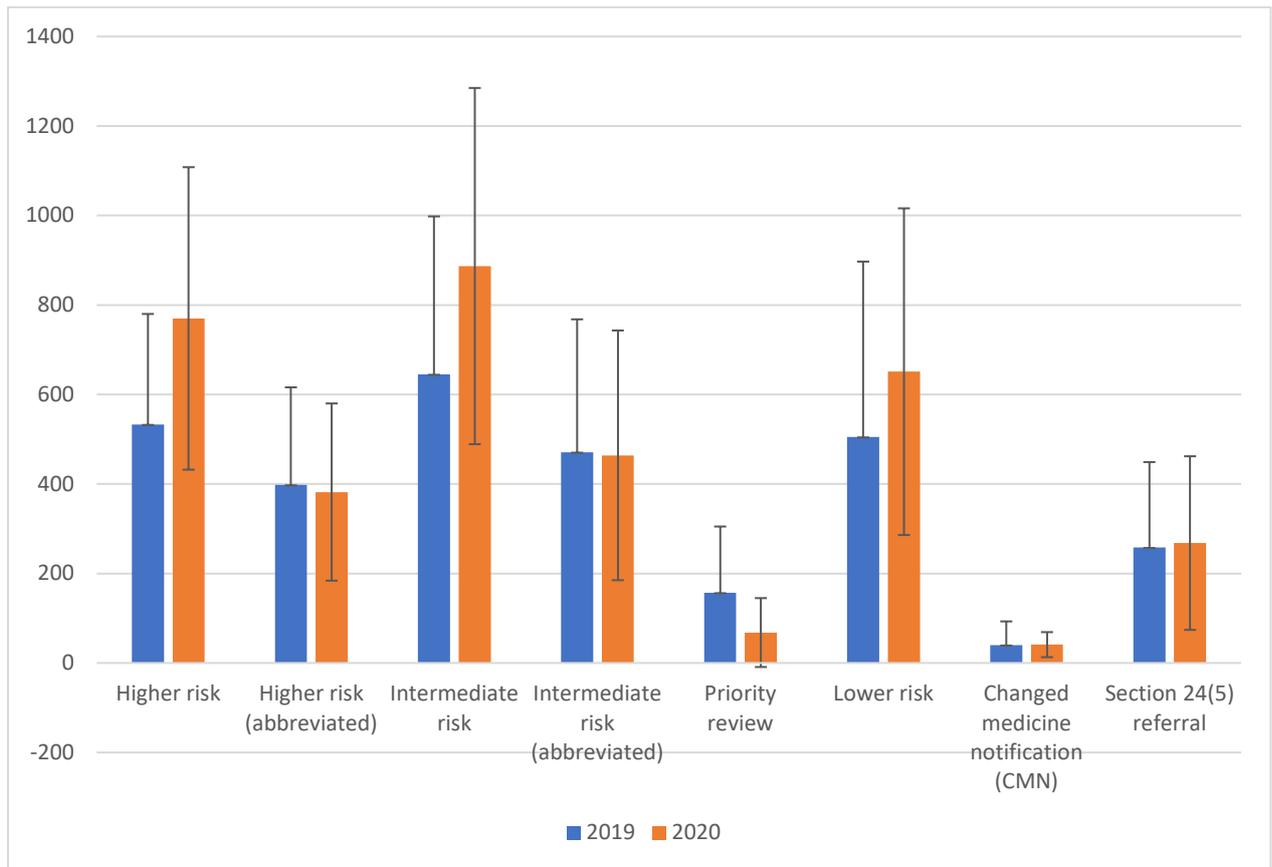
Table 10: Time to application consent, 2019

Application type	Time to consent ^a		
	Mean	Median	Range
Higher risk	533	503	211–1175
Higher risk (abbreviated)	398	337	143–989
Intermediate risk	645	569	49–1724
Intermediate risk (abbreviated)	471	459	146–1011
Priority review	157	147	85–308
Priority review (abbreviated)	-	-	-
Lower risk	505	546	73–1204
Changed medicine notification (CMN) ^b	40	29	1–332
Section 24(5) referral	258	195	9–1169

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, 2019 and 2020



Lower risk medicines (N categories)

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

Note: Medsafe is reviewing the N categories to improve the indicative timeframes.

Applications received

Table 11: Number of lower risk medicine applications received (excluding withdrawn) by N categories, 2016 to 2020

Year	N1	N3	N4	N5	Total
2020	19	20	3	8	50
2019	12	30	3	9	54
2018	17	30	4	6	57
2017	13	21	11	7	52
2016	5	14	3	3	25

Requests for information (RFIs) for lower risk medicines

Tables 12 and 13 show the number of RFIs sent and responses received per lower risk medicine application, by category, per year.

Table 12: Number of requests for information (RFIs) sent and responses received per lower risk medicine application, by category, 2020

Category	Number of RFIs			
	0	1	2	3+
N1	2	8	4	0
N3	0	4	6	7
N4	0	2	5	0
N5	0	0	4	1

Table 13: Number of requests for information (RFIs) sent and responses received per lower risk medicine application, by category, 2019

Category	Number of RFIs			
	0	1	2	3+
N1	0	2	6	1
N3	0	4	6	4
N4	0	1	3	1
N5	0	0	1	4

Processing times

Table 14 shows the key performance measure of initial evaluations, broken down by N category and by volume and percentage. Under 200 days is the target timeframe. Tables 15 and 16 show the time to complete the initial N categories evaluations, by category, each year, and tables 17 and 18 show the percentage of medicine applications that met the indicative timeframes each year.

Table 14: Number and percentage of completed initial N categories evaluations, by year and time period

Year	Time period to complete initial evaluation (calendar days)									
	<0		0–199		200–399		400–599		600–799	
	No.	%	No.	%	No.	%	No.	%	No.	%
2020	0	0.00	45	86.5	7	13.4	0	0.0	0	0.0
2019	0	0.00	50	84.7	6	10.1	3	5.0	0	0.0
2018	1	2.00	40	80.0	9	16.0	0	0.0	1	2.0
2017	0	0.00	38	97.4	1	2.5	0	0.0	0	0.0
2016	0	0.00	23	85.7	4	14.2	0	0.0	0	0.0

Note: <0 means that the evaluation was done before the fee was paid. This was for an urgent low risk medicine.

Table 15: Time in calendar days to complete initial N categories evaluation, by category, 2020

Category	Target time for initial evaluation completion (calendar days)	Time to complete initial evaluation (calendar days)		
		Mean	Median	Range
N1	30	166	191	14–196
N3	60	210	196	190–314
N4	90	189	191	177–198
N5	120	216	194	188–348

Table 16: Time in calendar days to complete initial N categories evaluation, 2019

Category	Target time for initial evaluation completion (calendar days)	Time to complete initial evaluation (calendar days)		
		Mean	Median	Range
N1	30	131	121	93–168
N3	60	206	194	61–477
N4	90	226	189	185–413
N5	120	224	197	191–380

Table 17: Percentage of lower risk medicine applications, by N categories, that met the indicative timeframes, 2020

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	7%	7	50%	7	13%
N3	60	0%	30	11%	30	0%
N4	90	0%	30	33%	30	33%
N5	120	0%	60	29%	60	0%

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.

Table 18: Percentage of lower risk medicine applications, by N categories, that met the indicative timeframes, 2019

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	30%	7	0%
N3	60	0%	30	8%	30	6%
N4	90	0%	30	25%	30	13%
N5	120	0%	60	29%	60	0%

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.