Medsafe Performance Statistics

Updated format for 2018 - July 2020

October 2020

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](#).

[Key performance indicators](#)
[New reporting format](#)
[Medicine applications](#)
[Processing and approval times](#)
[Lower risk medicines (N categories)](#)

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 7 - 9)

New reporting format

The pharmaceutical industry asked Medsafe to revise the format of the annual statistics reported by Medsafe to make the statistics easier to interpret. The suggested format is similar to those reported by the Australian Therapeutic Goods Administration (TGA). In order to see trends, we have applied the new format over several years, in some cases from 2016 to June 2020.

Please note the following:

- The statistics below are for calendar year (ie, January–December).
- Medsafe collects its statistics in a different way from the 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 to 3 show the number of medicine applications received each year by type and outcome. For 2020, there is only data from 1 January to 30 June.

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, 1 January to 30 June 2020

Application type	Received	Consented	Withdrawn	Refused
Higher risk	9	8	0	0
Higher risk (abbreviated)	8	17	1	0
Intermediate risk	3	12	0	0
Intermediate risk (abbreviated)	25	25	1	0
Priority review	5	3	0	0
Priority review (abbreviated)	0	0	0	0
Lower risk	29	17	1	0
Changed medicine notification (CMN)	780	628	6	0
Section 24(5) referral*	72	72	8	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

Table 3: Number of medicine applications by type and outcome, 2018

Application type	Received	Consented	Withdrawn	Refused
Higher risk	19	16	0	0
Higher risk (abbreviated)	25	15	0	0
Intermediate risk	20	18	1	0
Intermediate risk (abbreviated)	48	56	0	0
Priority review	4	3	0	0
Priority review (abbreviated)	2	1	0	0
Lower risk	68	30	11	0
Changed medicine notification (CMN)	1389	1292	19	0
Section 24(5) referral*	142	101	2	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 4 to 6 show the number of RFIs sent and responses received per consented application per year. See also tables 17 to 21 for lower risk medicines by category.

Table 4: Number of requests for information (RFIs) sent and responses received per consented application, 1 January 2020 to 30 June 2020

Application type	Number of RFIs			
	0	1	2	3+
Higher risk	0	1	2	5
Higher risk (abbreviated)	0	7	6	3
Intermediate risk	0	3	5	4
Intermediate risk (abbreviated)	0	7	13	4
Priority review	1	1	1	0
Priority review (abbreviated)	0	0	0	0
Lower risk	0	5	6	3
Changed medicine notification (CMN)	402	192	27	7
Section 24(5) referral*	12	22	20	6

Table 5: 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

Table 6: Number of requests for information (RFIs) sent and responses received per consented application, 2018

Application type	Number of RFIs			
	0	1	2	3+
Higher risk	0	10	5	6
Higher risk (abbreviated)	0	6	9	3
Intermediate risk	0	16	6	12
Intermediate risk (abbreviated)	0	30	13	5
Priority review	2	1	0	0
Priority review (abbreviated)	0	0	1	1
Lower risk	0	11	12	7
Changed medicine notification (CMN)	756	446	80	9
Section 24(5) referral	34	27	27	13

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 7 to 9 show 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.

See tables 23 to 27 for lower risk medicines.

Table 7: Time in calendar days to complete initial evaluation, 1 January 2020 to 30 June 2020
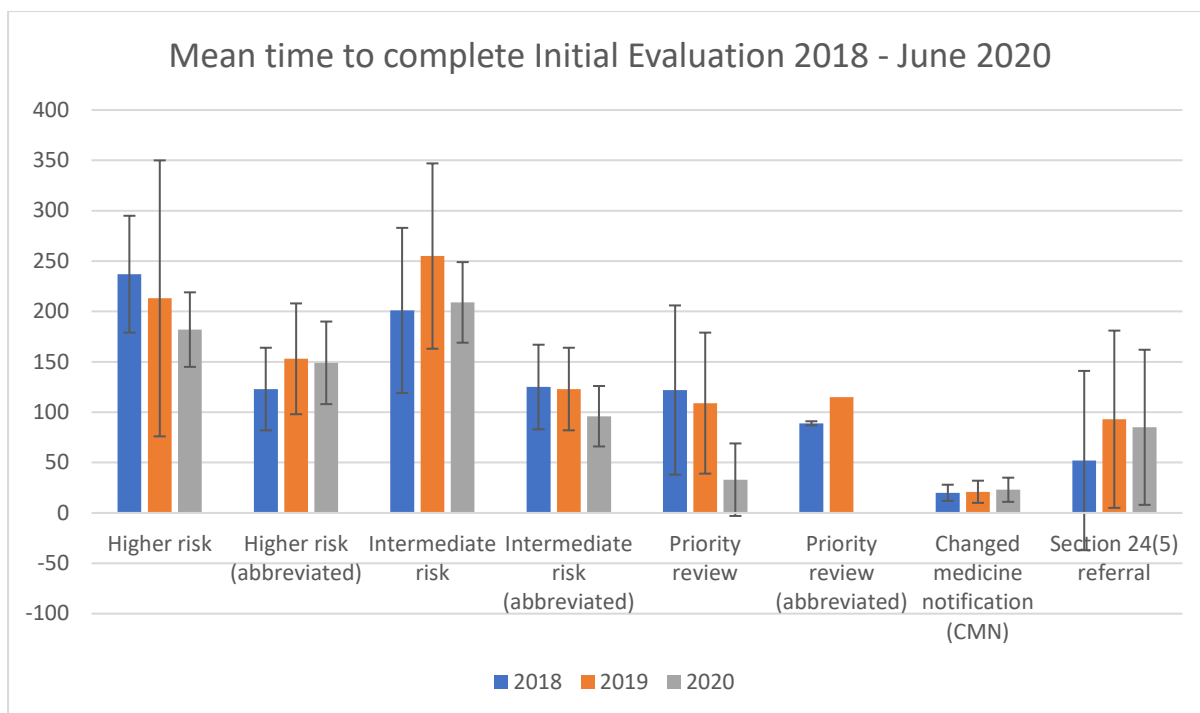
Application type	Target time for completion (calendar days)	Time to complete (calendar days)		
		Mean	Median	Range
Higher risk	200	182	195	92–198
Higher risk (abbreviated)	100	149	155	91–199
Intermediate risk	200	209	195	165–266
Intermediate risk (abbreviated)	100	96	90	48–162
Priority review	100	33	20	1–92
Priority review (abbreviated)	100	-	-	-
Changed medicine notification (CMN)	45	23	23	0–56
Section 24(5) referral	200	85	35	10–270

Table 8: Time in calendar days to complete initial evaluation, 2019

Application type	Target time for completion (calendar days)	Time to complete (calendar days)		
		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

Table 9: Time in calendar days to complete initial evaluation, 2018

Application type	Target time for completion (calendar days)	Time to complete (calendar days)		
		Mean	Median	Range
Higher risk	200	237	211	153–387
Higher risk (abbreviated)	100	123	109	67–191
Intermediate risk	200	201	216	1–365
Intermediate risk (abbreviated)	100	125	117	62–217
Priority review	100	122	144	16–200
Priority review (abbreviated)	100	89	89	87–90
Changed medicine notification (CMN)	45	20	20	0–40
Section 24(5) referral	200	52	25	7–358

Mean time to complete Initial Evaluation 2018 - June 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 10 to 12.

See tables 29 to 33 for lower risk medicines.

Table 10: Time in calendar days to complete evaluation of additional information (EAI), 1 January to 30 June 2020

Application type	Target time	EAI1[a] Time to complete			Target time	EAI2[b] Time to complete		
		Mean	Median	Range		Mean	Median	Range
Higher risk	120	154	152	39–246	120	126	150	1–204
Higher risk (abbreviated)	120	117	118	9–209	120	85	85	37–133
Intermediate risk	120	112	114	36–177	120	86	79	8–173
Intermediate risk (abbreviated)	120	104	115	22–155	120	115	100	84–203
Priority review	28	16.5	16.5	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	84	85	5–175	120	37	19	10–100

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

Application type	EAI1[a]				EAI2[b]			
	Target time	Mean	Median	Range	Target time	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.

Table 12: Time in calendar days to complete evaluation of additional information (EAI), 2018

Application type	Target time	EAI1[a] Time to complete Mean	Median	Range	Target time	EAI2[b] Time to complete Mean	Median	Range
Higher risk	120	154	172	17–270	120	62	51	17–149
Higher risk (abbreviated)	120	156	140	80–229	120	38	27	13–114
Intermediate risk	120	149	130	0–366	120	81	41	9–365
Intermediate risk (abbreviated)	120	113	120	1–148	120	64	50	3–177
Priority review	28	-	-	-	28	-	-	-
Priority review (abbreviated)	28	-	-	-	28	-	-	-
Changed medicine notification (CMN)	N/A				N/A			
Section 24(5) referral	120	100	94	1–346	120	143	110	18–253

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.

Time to application consent

Tables 13 to 15 show the time (mean, median and range) in calendar days 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.

Table 13: Time to application consent, 1 January 2020 to 30 June 2020

Application type	Time to consent (calendar days)		
	Mean	Median	Range
Higher risk	743	726	353–1113
Higher risk (abbreviated)	386	370	202–631
Intermediate risk	962	755	574–1588
Intermediate risk (abbreviated)	526	440	184–1464
Priority review	58	15	10–150
Priority review (abbreviated)	-	-	-
Lower risk	597	602	195–911
Changed medicine notification (CMN)*	38	29	1–218
Section 24(5) referral	256	218	51–751

* The CMN target time is 90 calendar days from receipt of payment.
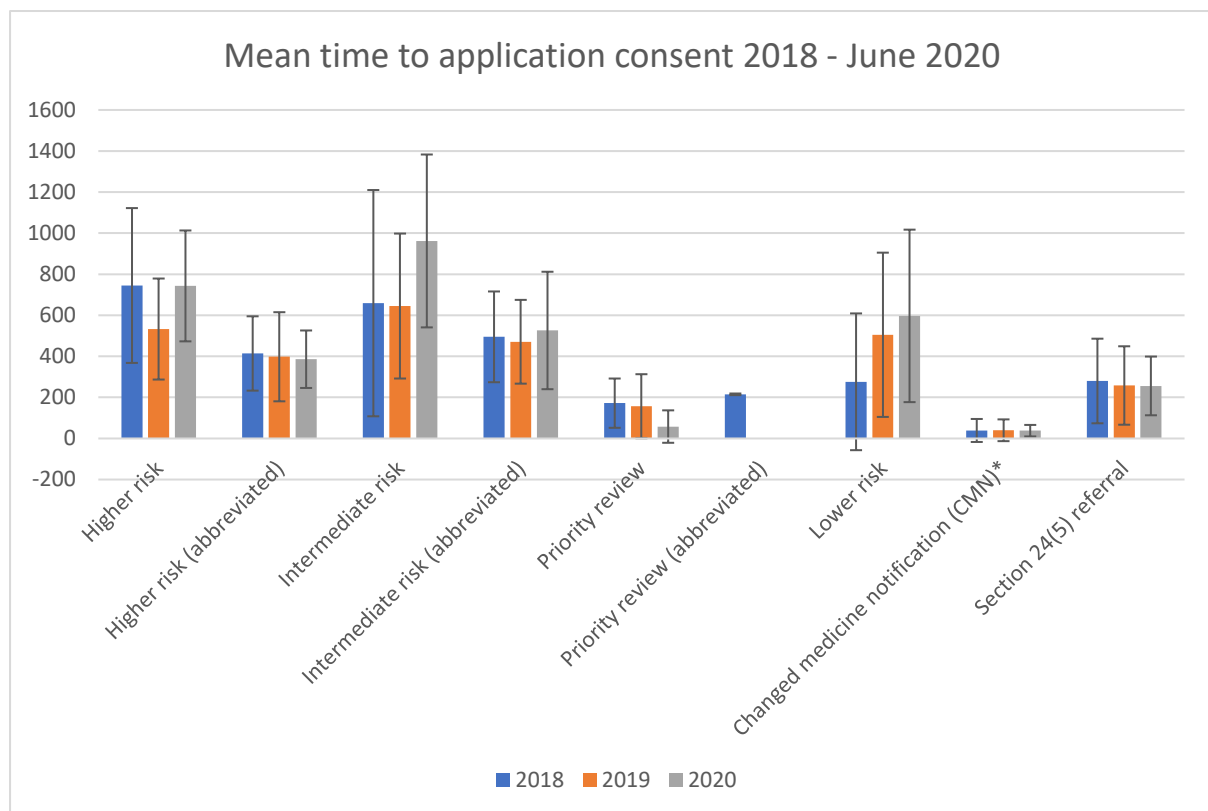
Table 14: Time to application consent, 2019

Application type	Time to consent (calendar days)		
	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)*	40	29	1–332
Section 24(5) referral	258	195	9–1169

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

Table 15: Time to application consent, 2018

Application type	Time to consent (calendar days)		
	Mean	Median	Range
Higher risk	745	768	231–1323
Higher risk (abbreviated)	414	406	212–909
Intermediate risk	659	658	8–1214
Intermediate risk (abbreviated)	495	456	162–856
Priority review	172	186	37–280
Priority review (abbreviated)	215	215	212–217
Lower risk	276	246	5–738
Changed medicine notification (CMN)*	39	26	1–425
Section 24(5) referral	280	205	23–1109

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

Mean time to application consent 2018 - June 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 16: Number of lower risk medicine applications received (excluding withdrawn) by N categories, 2016 to 2020

Year	N1	N3	N4	N5	Total
2020 (Jan-Jun)	10	13	1	4	**28**
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 17 to 21 show the number of RFIs sent and responses received per lower risk medicine application, by category, per year.

Table 17: Number of requests for information (RFIs) sent and responses received per lower risk medicine application, by category, 1 January to 30 June 2020

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

Table 18: 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

Table 19: Number of requests for information (RFIs) sent and responses received per lower risk medicine application, by category, 2018

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

Table 20: Number of requests for information (RFIs) sent and responses received per lower risk medicine application, by category, 2017

Category	Number of RFIs			
	0	1	2	3+
N1	0	3	1	5
N3	0	1	5	13
N4	0	0	1	0
N5	0	0	1	8

Table 21: Number of requests for information (RFIs) sent and responses received per lower risk medicine application, by category, 2016

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

Processing times

Table 22 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 23 to 27 show the time to complete the initial N categories evaluations, by category, each year, and tables 28 to 32 show the percentage of medicine applications that met the indicative timeframes each year.

Table 22: 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 (Jan–Jun)	0	0.00	22	88.3	2	11.6	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 23: Time in calendar days to complete initial N categories evaluation, by category, 1 January to 30 June 2020

Category	Target time for initial evaluation completion (calendar days)	Time to complete initial evaluation (calendar days)		
		Mean	**Median**	**Range**
N1	30	186	194	164–196
N3	60	219	197	196–314
N4	90	186	186	177–196
N5	120	193	193	188–196

Table 24: 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 25: Time in calendar days to complete initial N categories evaluation, 2018

Category	Target time for initial evaluation completion (calendar days)	Time to complete initial evaluation (calendar days)		
		Mean	**Median**	**Range**
N1	30	110	90	0–168
N3	60	197	186	16–202
N4	90	193	274	139–637
N5	120	196	196	189–199

Table 26: Time in calendar days to complete initial N categories evaluation, 2017

Category	Target time for initial evaluation completion (calendar days)	Time to complete initial evaluation (calendar days)		
		Mean	**Median**	**Range**
N1	30	45	29	11–156
N3	60	105	97	51–208
N4	90	106	99	72–162
N5	120	159	191	119–200

Table 27: Time in calendar days to complete initial N categories evaluation, 2016

Category	Target time for initial evaluation completion (calendar days)	Time to complete initial evaluation (calendar days)		
		Mean	**Median**	**Range**
N1	30	45	34	27–85
N3	60	119	103	55–208
N4	90	99	76	52–161
N5	120	167	171	107–256

Table 28: Percentage of lower risk medicine applications, by N categories, that met the indicative timeframes, 1 January to 30 June 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	0%	7	29%	7	0%
N3	60	0%	30	0%	30	0%
N4	90	0%	30	0%	30	0%
N5	120	0%	60	33%	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 29: 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.

Table 30: Percentage of lower risk medicine applications, by N categories, that met the indicative timeframes, 2018

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	16%	7	18%	7	20%
N3	60	8%	30	11%	30	38%
N4	90	0%	30	17%	30	0%
N5	120	0%	60	0%	60	25%

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 31: Percentage of lower risk medicine applications, by N categories, that met the indicative timeframes, 2017

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	58%	7	27%	7	25%
N3	60	47%	30	6%	30	50%
N4	90	25%	30	0%	30	0%
N5	120	25%	60	0%	60	33%

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 32: Percentage of lower risk medicine applications by, N categories, that met the indicative timeframes, 2016

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	60%	7	25%	7	25%
N3	60	6%	30	0%	30	57%
N4	90	0%	30	0%	30	0%
N5	120	14%	60	0%	60	23%

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.