

Medsafe Performance Statistics

1 July 2021 to 30 June 2022

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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 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.

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 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, Jul 2021 – Jun 2022

| Application type | Received | Consented | Withdrawn | Refused |
|-------------------------------------|----------|-----------|-----------|---------|
| Higher risk | 20 | 22 | 0 | 0 |
| Higher risk (abbreviated) | 32 | 22 | 0 | 0 |
| Intermediate risk | 17 | 13 | 1 | 0 |
| Intermediate risk (abbreviated) | 40 | 33 | 1 | 0 |
| Priority review | 7 | 10 | 0 | 0 |
| Priority review (abbreviated) | 4 | 2 | 0 | 0 |
| Lower risk | 29 | 40 | 12 | 0 |
| Changed medicine notification (CMN) | 1510 | 1480 | 19 | 0 |
| Section 24(5) referral* | 121 | 136 | 4 | 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. 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 2021 – Jun 2022

| Application type | Number of RFIs | | | |
|-------------------------------------|----------------|-----|----|----|
| | 0 | 1 | 2 | 3+ |
| Higher risk | 1 | 7 | 10 | 4 |
| Higher risk (abbreviated) | 0 | 12 | 7 | 3 |
| Intermediate risk | 0 | 5 | 6 | 2 |
| Intermediate risk (abbreviated) | 0 | 16 | 15 | 2 |
| Priority review | 0 | 4 | 0 | 2 |
| Priority review (abbreviated) | 0 | 0 | 0 | 0 |
| Lower risk | 0 | 11 | 14 | 15 |
| Changed medicine notification (CMN) | 1000 | 415 | 57 | 9 |
| Section 24(5) referral | 43 | 44 | 42 | 7 |

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.

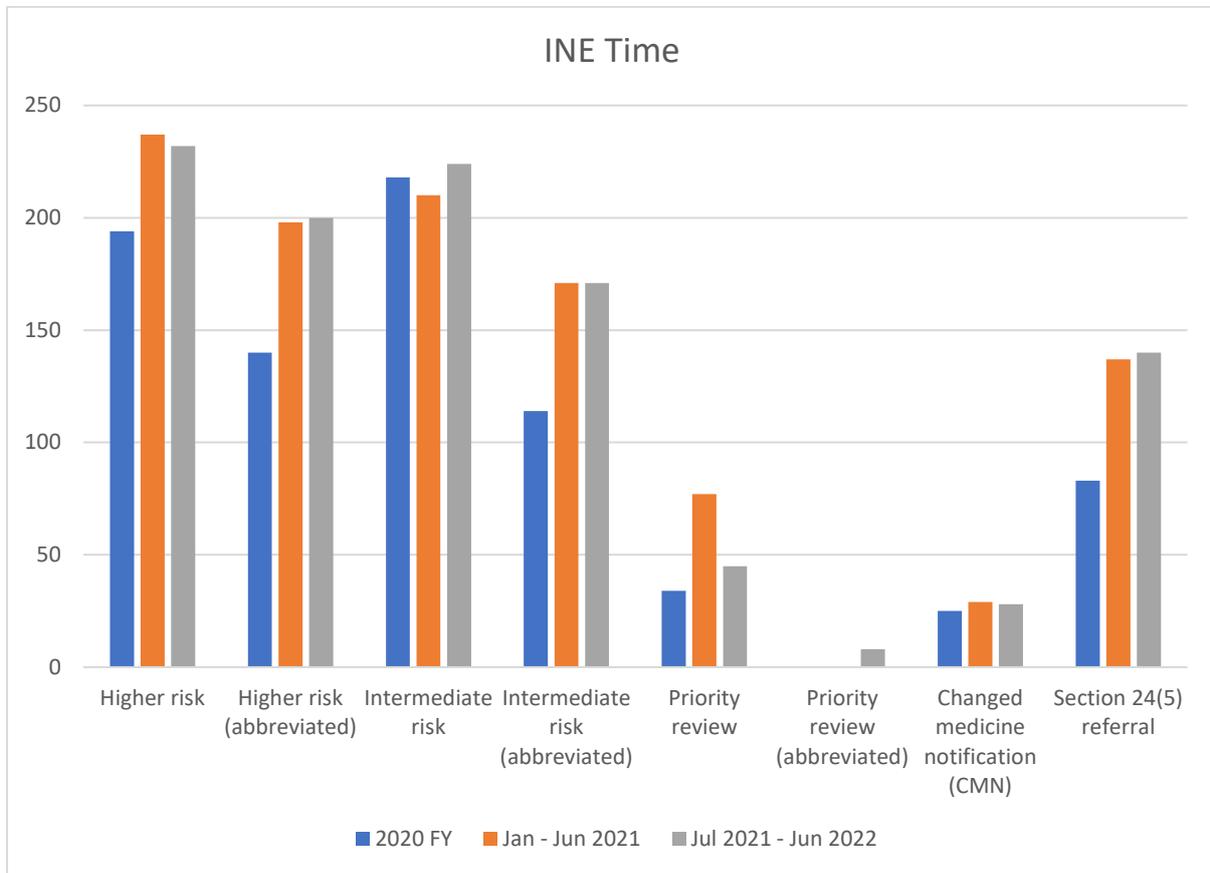
See tables 8 and 9 for lower risk medicines.

Table 3: Time in calendar days to complete initial evaluation, Jul 2021 – Jun 2022

| Application type | Target time for completion* | Time to complete* | | | Standard Deviation* |
|-------------------------------------|-----------------------------|-------------------|--------|-----------|---------------------|
| | | Mean | Median | Range | |
| Higher risk | 200 | 232 | 235 | 52–375 | 84 |
| Higher risk (abbreviated) | 100 | 200 | 185 | 8 - 396 | 109 |
| Intermediate risk | 200 | 224 | 196 | 181 - 315 | 41 |
| Intermediate risk (abbreviated) | 100 | 171 | 179 | 134–250 | 37 |
| Priority review | 100 | 45 | 34 | 1–114 | 50 |
| Priority review (abbreviated) | 100 | 8 | 8 | - | - |
| Changed medicine notification (CMN) | 45 | 28 | 29 | 1–72 | 10 |
| Section 24(5) referral | 200 | 147 | 174 | 2–379 | 107 |

* 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 2021 – Jun 2022

| Application type | Target time | EAI1 ^a | | | Target time | EAI2 ^b | | |
|-------------------------------------|------------------|-------------------|--------|----------|-------------|-------------------|--------|-----------|
| | | Mean | Median | Range | | Mean | Median | Range |
| Higher risk | 120 | 133 | 133 | 37 - 366 | 120 | 112 | 106 | 11 – 224 |
| Higher risk (abbreviated) | 120 | 153 | 131 | 67 – 256 | 120 | 157 | 157 | 111 – 203 |
| Intermediate risk | 120 | 155 | 185 | 12 - 310 | 120 | 104 | 129 | 1 – 168 |
| Intermediate risk (abbreviated) | 120 | 160 | 144 | 25 – 310 | 120 | 128 | 159 | 26 – 237 |
| Priority review | 28 | 80 | 18 | 7 – 216 | 28 | - | - | - |
| Priority review (abbreviated) | 28 | - | - | - | 28 | - | - | - |
| Changed medicine notification (CMN) | N/A ^c | | | | N/A | | | |
| Section 24(5) referral | 120 | 60 | 54 | 0 - 179 | 120 | 73 | 53 | 11 - 245 |

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

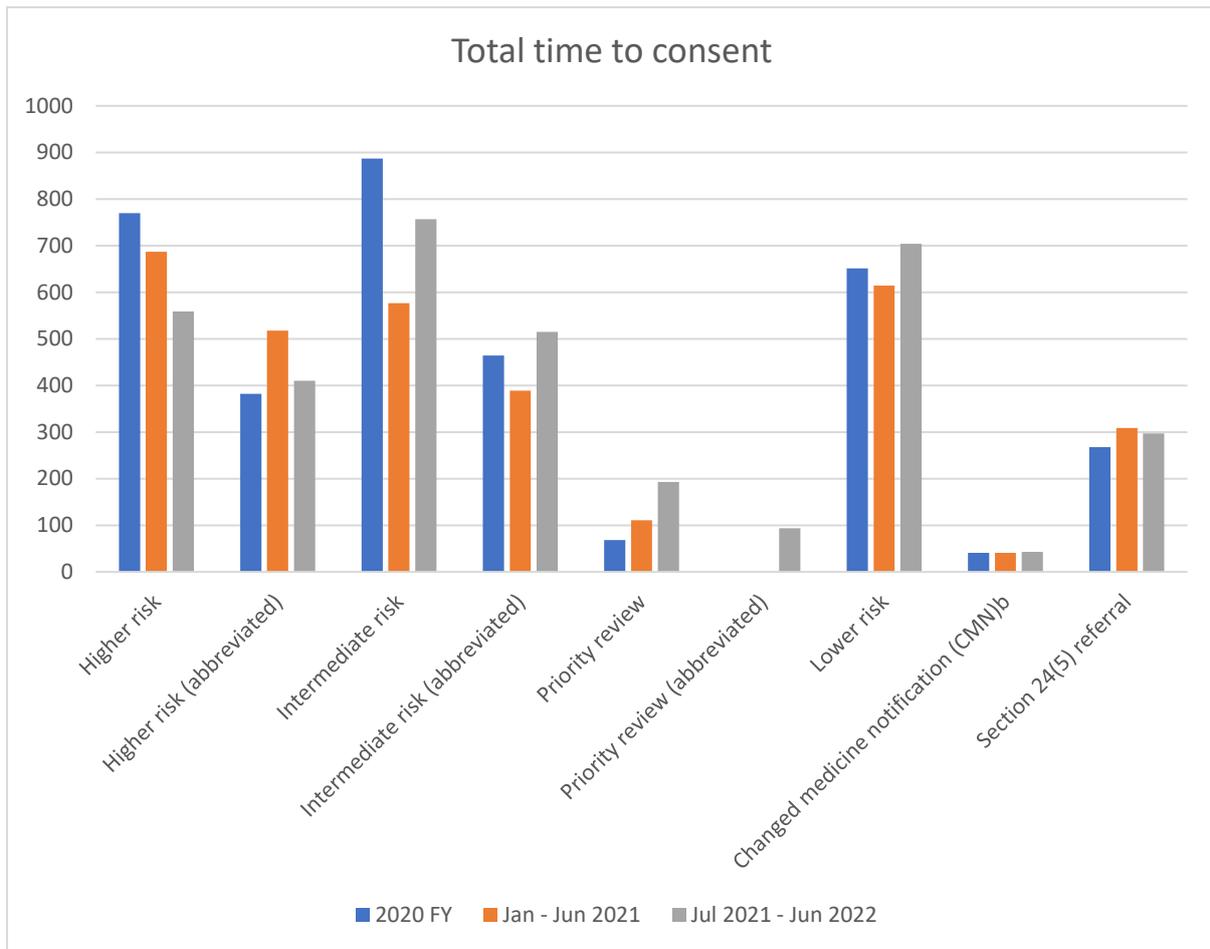
Table 5: Time to application consent, Jul 2021 – Jun 2022

| Application type | Time to consent ^a | | | Standard deviation ^a |
|--|------------------------------|--------|------------|---------------------------------|
| | Mean | Median | Range | |
| Higher risk | 559 | 598 | 91 - 1133 | 237 |
| Higher risk (abbreviated) | 410 | 428 | 145 - 597 | 111 |
| Intermediate risk | 757 | 744 | 166 - 1899 | 442 |
| Intermediate risk (abbreviated) | 515 | 486 | 182 - 515 | 182 |
| Priority review | 193 | 155 | 18 - 455 | 149 |
| Priority review (abbreviated) | 94 | 94 | 43 - 144 | 71 |
| Lower risk | 704 | 690 | 18 - 1611 | 316 |
| Changed medicine notification (CMN) ^b | 43 | 34 | 1–490 | 35 |
| Section 24(5) referral | 297 | 239 | 5-836 | 173 |

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 is reviewing the N categories to improve the indicative timeframes.

Applications received

Table 6: Number of lower risk medicine applications received (excluding withdrawn) by N categories, 2018 to Jul 2021 – Jun 2022

| Year | N1 | N3 | N4 | N5 | Total |
|---------------------|----|----|----|----|-------|
| Jul 2021 – Jun 2022 | 7 | 13 | 4 | 4 | 28 |
| Jan–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 |

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 2021 – Jun 2022).

Table 7: Number of requests for information (RFIs) sent and responses received per lower risk medicine application, by category, Jul 2021 – Jun 2022

| Category | Number of RFIs | | | |
|----------|----------------|---|---|----|
| | 0 | 1 | 2 | 3+ |
| N1 | 0 | 5 | 3 | 3 |
| N3 | 0 | 4 | 8 | 9 |
| N4 | 0 | 0 | 1 | 0 |
| N5 | 0 | 2 | 2 | 3 |

Processing times

Table 8 shows the time taken to complete initial lower risk medicine evaluation, with data shown in groups of 200 days.

Table 9 shows the mean time to complete each N categories initial evaluation.

Table 10 shows the percentage of each N category that met target timeframe for initial evaluation.

Table 8: 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 | |
| | No. | % | No. | % | No. | % | No. | % | No. | % |
| Jul 21 – Jun 22 | 0 | 0.0 | 44 | 85 | 7 | 13 | 1 | 2 | 0 | 0 |
| Jan-Jun 2021 | 0 | 0.0 | 14 | 70.0 | 6 | 30.0 | 0 | 0.0 | 0 | 0.0 |
| 2020 | 0 | 0.0 | 45 | 86.5 | 7 | 13.4 | 0 | 0.0 | 0 | 0.0 |
| 2019 | 0 | 0.0 | 50 | 84.7 | 6 | 10.1 | 3 | 5.0 | 0 | 0.0 |
| 2018 | 1 | 2.0 | 40 | 80.0 | 9 | 16.0 | 0 | 0.0 | 1 | 2.0 |

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

Table 9: Time in calendar days to complete initial N categories evaluation, by category, Jan–Jun 2021

| Category | Target time for initial evaluation completion (calendar days) | Time to complete initial evaluation (calendar days) | | |
|----------|---|---|--------|-----------|
| | | Mean | Median | Range |
| N1 | 30 | 136 | 158 | 1 - 199 |
| N3 | 60 | 214 | 196 | 154 - 356 |
| N4 | 90 | 196 | 196 | NA |
| N5 | 120 | 210 | 192 | 154 - 370 |

Table 10: 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 | 10% | 7 | 27% | 7 | 11% |
| N3 | 60 | 0% | 30 | 53% | 30 | 0% |
| N4 | 90 | 0% | 30 | NA | 30 | 0% |
| N5 | 120 | 0% | 60 | 60% | 60 | 11% |

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.