Medsafe industry engagement June 2025

Questions and answers

This document provides responses to questions from our industry meetings in June 2025.

Several questions which were asked in early presentations, were addressed later in the day and so are not repeated here. In some cases, related questions and responses have been consolidated for clarity and efficiency.

A number of questions related to the Verification Pathway. As the associated legislation is currently before the Select Committee, we are not in a position to provide detailed responses on those matters at this stage.

Questions relating to bioequivalence are not addressed here, as the updated Bioequivalence Guideline consultation has now been published.

1. ***Does Medsafe have any plans to reform the CMN Section 24(5) referral process, especially for CMC variations? Streamlining and improving the evaluation timeline for CMC variations deferred under Section 24(5) would assist sponsors in managing supply situations and mitigating the risk of medicines shortages.***

   Medsafe has significantly improved timelines for evaluation of all New Medicine Application types. With timelines well within target (mean initial evaluation of 24(5)'s being 92 working days against a 150-day target), we also appreciate the benefit that shorter target timeframes may provide.

   We will review target timeframes once the 2024 / 2025 reporting year performance report is published. In addition, we are developing an abbreviated pathway for which some 24(5) CMNs will be eligible. These will have shorter timeframes than the current CMC variations that are referred under section 24(5).

   We have published a statement regarding to potential medicine supply issues, companies should notify Medsafe as soon as possible to ensure that we can manage any regulatory changes needed efficiently.

2. ***(For abbreviated NMA RFI responses) Our understanding was that it is a response within 28 days not 21 days. Can you please clarify?***

   The requirement is that responses need to be submitted within 28 **calendar** days. This is equivalent to 21 **working** days. There has not been a change to the relative timeframe.

3. ***Are there any updates for the group on Medsafe's plans for/progress towards joining international work-sharing collaborations (e.g. Project ORIBS and ACCESS Consortium) and also whether joining the ICH is under consideration still?***

   Medsafe has indicated to its members a desire to explore participation in ACCESS. To date, no formal agreement or commitment to initiate discussions in principle has been reached.

4. ***When a Data Sheet is approved (ie for an indication extension) and there has been an interim data sheet approved (ie safety update in a separate application), the two Data Sheets then need to be merged at approval of the indication. Does Medsafe have a preferred approach to handle this? Medsafe mentioned the final stages of submissions are to be reviewed – is there an opportunity to include a process here?***

   To ensure that the datasheet reflects the most up to date information, and is harmonised with other countries, updates to include new safety information should be implemented as soon as possible rather than delaying to coincide with other applications.

   To maintain flexibility these are generally managed on a case-by-case basis. Applicants should raise this with Medsafe early and prior to completion of evaluation. This helps to ensure that an up to date and harmonised datasheet is published in New Zealand and can be prepared without delaying the QA and/or Gazetting process.

5. ***Is there any information on possible reasons for the increase in time for intermediate risk Medsafe evaluations and Applicant response times vs. High risk (non abbreviated), where intermediate risk appears significantly higher for both?***

   Medsafe's mean time to complete initial evaluation is well within target times, and comparable for high-risk and intermediate-risk applications.

   We have not investigated the difference between high versus intermediate risk evaluation and RFI times, however we generally find the documentation submitted for high-risk applications is of better quality than that received for many intermediate-risk applications. This results in a fewer RFI questions for high-risk products which reduces the time required for companies to respond and for Medsafe to complete additional evaluation.

   We would be interested in any feedback from industry as to any actions that may improve efficiency here.

6. ***Will there be any potential changes in the fee schedule over the next five years? Will the fee charged for DMF – G6 change?***

   Medsafe follows treasury guidelines, which recommends fees are reviewed every three years. The last fee review was effective 1 July 2022. A fees review is due, and we will need to consider any new pathways that may be put in place. We will also review a small number of CMN categories that may need to be refined – particularly DMF-G6.

7. ***There is a current requirement to list stability testing sites on TPDRs but Medsafe's online guidance does not clearly state this requirement. Would you please clarify the basis for this requirement?***

   It's been Medsafe's practice for some time to record all finished product manufacturing, testing (including stability) and packing sites in our database. This has practical benefits and meets expectations that our work is open and transparent. We would welcome feedback, namely if there are specific examples or trends that cause issues for sponsors.

8. ***Medsafe talked about harmonisation of products to ensure supply of products, can you please comment why for gluten, the threshold is reduced from 20ppm to 3ppm? (EU, AU requirements are all 20ppm)***

   Medsafe consulted on this requirement in 2020, refer to the outcome of consultation.

   There are options that would enable product to meet requirements of both Australia and New Zealand markets, we have discussed these with the TGA. Please contact Medsafe if you would like advice.

9. ***Does the CMN 24(5) referral apply for Biological products? e.g., addition of API site, CMN form B doesn't give any mention of referral as is in CMN form A.***

   CMN 24(5) referrals can apply to biological products. Unlike CMN Form A, CMN Form B does not include a category that that is automatically referred under CMN 24(5). Whether a CMN for a biological product if referred under 24(5) depends on the number and complexity of the changes notified.

   This flexibility ensures that changes notified under the 'G4' categories are assessed on a case-by-case basis to determine if referral is necessary. It also helps to prevent unnecessary referrals for changes for biological products, where the change can be managed within standard CMN timeframes—such as the introduction of new Working Cell Banks.

10. ***Is there any intent to introduce an orphan drug designation pathway in NZ?***

    The Medicines Act 1981 does not include provisions that enable an orphan drug pathway in New Zealand. The Medical Products Bill is being developed, this will likely include provisions for orphan drug approval. We encourage industry to follow this legislation as it progresses, and make submissions when these are called for.

11. ***Can the Medsafe EFT file naming convention document be clarified in future? It is often not entirely clear, eg date format.***

    Details on naming convention is supplied when EFT profiles are created. We will provide this to industry groups for circulation to members, and include guidance at our next Guideline update.

12. ***How could an abbreviated process be used for 24(5)a CMNs which are quality changes (ie a new API manufacturing site which is currently a 24(5) CMN) where foreign evaluation reports are not available due to the minor nature of the variation in other jurisdictions and only an approval letter is available?***

    Medsafe is developing this extension to the abbreviated pathway, to include major manufacturing changes and indication extensions. We will be consulting when we have our first guideline drafted, over the coming months.

    As with the current abbreviated pathway for New Medicine Applications, overseas evaluation reports will be essential for this reliance pathway.

Regardless of the application pathway, we encourage applicants to provide any relevant overseas approval documents to support Medsafe decision making

13. ***For ADRs that have been reported directly to Medsafe and are on SMARS will Medsafe notify the sponsor always if their medicine is identified?***

    No Medsafe does not notify sponsors to ADR reports received for their products. If the sponsor identifies a case on SMARS that could be related to their product, the sponsor can ask Medsafe for further information.

14. ***Hi, could Medsafe please provide further details on which health authorities are sharing evaluation reports direct to Medsafe?***

    Medsafe is open to receiving reports directly from health authorities, however this can be inefficient as it creates administrative burden. Our preference is for the applicant to provide evaluation reports directly with their application.

15. ***How many quality changes can be submitted in a single CMN? What quality changes are usually categorised as Section 24(5)(a) instead? What are the current timelines for Section 24(5)(a) CMN applications?***

    This depends on the overall evaluation work needed for the change, so it isn't practical to set rules regarding the number of changes that would result in referral under 24(5)(a).

16. ***Can we expect the CT guidelines to be finalised within 2025?***

    Our first priority is managing resource to make sure that we can maintain evaluation timelines within targets. Following that, completing the Clinical Trial guidelines as soon as possible is a high priority.