**Changed medicine notification Form B**

This CMN form is to be used when notifying a material change (including self-assessable changes) to an approved biological or biotechnological product (i.e. vaccines, serum, allergen, medicinal product derived from human blood or plasma, immunological medicinal product, and any product derived from biotechnology).

Use CMN Form A for any other medicine, including antibiotics and like substances derived from non-recombinant micro-organisms.

Use CMN Form A for changes that are specific to a separate diluent/solvent component of a biological or biotechnological product, if the diluent/solvent does not contain a biological or biotechnological active ingredient.

See **section 6** for notes on calculation and payment of fees.

**Instructions for completing CMN Form B Section 3**

1. Check the boxes in the left-hand column beside the descriptions that most accurately reflect the proposed changes. The main change and the consequential changes listed under the “Description of change” are all covered by the fee shown in the “Fee” column.
2. Enter the number of changes in the right-hand column (Fee) when you select a change category where the number of changes is requested. For example, enter ‘2’ when introducing two new manufacturing sites that both use the existing manufacturing process.
3. Delete unused change categories from Section 3. It is not necessary to submit pages listing change descriptions under Section 3 that are not relevant to the notification.
4. Update the Consumer Medicine Information (CMI) for the product in line with the changes, when applicable, and email the revised version to Medsafe once the consent letter for the CMN or SACN has been received. There is no additional fee for consequential updates to the CMI.
5. All fees listed are GST inclusive.
6. If identical changes are proposed for multiple products, a single CMN can be submitted to a maximum of 20 products per CMN.
7. The change categories in this form will not cover all possible changes. Information on the reason and justification for selecting a change category can be included in the cover letter. If the change to be notified does not fit into one of the change categories, please contact Medsafe at: medsafeapplications@health.govt.nz

**Section 1: Product details**

 1List the affected products in numerical order based on the TT50 file reference number (lowest to highest) the product with the lowest TT50 number will be used as the application reference product.

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| --- | --- | --- | --- | --- | --- |
| **Medsafe File No 1TT50-** | **Product name** | **Dose form** | **Drug Substance and Strength** | **Classification** | **Product currently available? Yes/No\*** |
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\*If no, please state the date the product was last supplied. Further information on the different registration situations is available on the Medsafe website: <https://www.medsafe.govt.nz/Medicines/registration-situation.asp>

**Section 2: Applicant and sponsor details**

|  |  |
| --- | --- |
| **Name, job title and address of person submitting the notification (the applicant):**All correspondence about the application, including the invoice, will be sent to this person.NB: If a letter of authorisation has not already been provided from the sponsor, please include this. |  |
| **Applicant’s email address:****This should be the company’s generic email address (if available)** |  |
| **DMF/PMF holder’s email address (if applicable):** |  |
| **New Zealand sponsor name and street address:** |  |
| **Customer reference code for invoice** **(maximum 20 characters)** |  |

**Section 3: Proposed changes**

Changes to product name

*Note:*If a product is to be marketed under a new name in addition to the existing name, Medsafe regards this as a new product and a New Medicine Application is required.

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| --- | --- | --- |
| ***Check box*** | ***Description of change*** | ***Product type & fee*** |
|[ ]  **Product name*** new product name to replace existing name
* no change in formulation

Consequential changes included (if applicable) are:* revised data sheet and labelling
 | $865for *each* new nameNumber of new names: \_\_\_\_\_\_\_\_\_ |

Changes to formulation

*Note:* If a formulation change is associated with a change in the manufacturing process, the change in process must be notified separately under the category **Finished product manufacturing process – G4**.

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| --- | --- | --- |
| ***Check*** ***box*** | ***Description of change*** | ***Product type & fee*** |
|[ ]  **Formulation – G1** **– Minor change that does not affect bioavailability, stability, or safety** Examples include expression of units, quantities of buffer/pH adjuster **- Strain update of active ingredient for influenza strains** Consequential changes included (if applicable) are:* revised specifications for finished product
* revised specifications for excipient
* revised labelling and data sheet
 | $865 |
|[ ]  **Formulation – G2- Change of excipients including the addition or removal of excipients**Consequential changes included (if applicable) are:* new or revised specifications for excipient and/or finished product
* amended batch manufacturing documentation, provided there is no significant change in the manufacturing process
* revised labelling and data sheet
 | $3,334 for any number of excipient changes |

Changes to active ingredient manufacturing/testing sites and/or manufacturing process

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| --- | --- | --- |
| ***Check box*** | ***Description of change*** | ***Fee*** |
|[ ]  **Active ingredient manufacturing site*** Change in site of manufacture at any stage in the process up to, and including, the manufacture of the final active ingredient.

Consequential changes included (if applicable):* minor changes to adapt to new facility (eg, changes described in ‘Active ingredient method of manufacture – Grade 2’, or minor equipment modifications without any change in process)
 | $3,334 for *each* sitePlease specify number:\_\_\_\_\_\_\_\_ |
|[ ]  **Active ingredient testing site*** Introduction of a new quality control testing site
* Introduction of new tests at a currently approved testing site
 | $1,730for *each* sitePlease specify number:\_\_\_\_\_\_\_\_ |
|[ ]  **Active ingredient method of manufacture – G1 (Self-assessable)*** Editorial changes to 3.2.S, with no changes to the manufacturing process, manufacturing equipment, or quality controls.
* Tightening in-process control limits
* Change to raw material specifications to adopt a different pharmacopoeia and/or tighten limits
* Plasma Master File update (via Letter of Access to an approved version)
* Introduction of updated TSE certificates of suitability (CEPs)
 | $432(self-assessable)For Plasma Master File updates, a single $432 fee applies irrespective of the number of products associated with the PMF |
|[ ]  **Active ingredient method of manufacture – G2****Minor changes**Changes include:* Updates to raw materials tests and specifications
* Change in starting material supplier and/or starting material manufacturing process
* Increase in chromatography column diameters with no increase in bed height or chromatography process parameters
* Changes to in-process control methods or limits (other than tightening limits)
* Removal of in-process tests
* New in-process test site (test methods unchanged)
* Changes to the shipping containers/conditions used to transport the bulk active ingredient
* Additional/alternative storage facilities for the cell bank
* Plasma Master File update (no new plasma supplier)
 | $865for any number of changesFor Plasma Master File updates, a single $865 fee applies irrespective of the number of products associated with the PMF |

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| [ ]  | **Active ingredient method of manufacture – G3*** Introduction of an additional manufacturing line at an approved active ingredient manufacturing site, with only minor changes in the manufacturing process or equipment for facility fit
 | $1730for *each* new manufacturing linePlease specify number: \_\_\_\_\_\_\_\_ |
| [ ]  | **Active ingredient method of manufacture – G4****Major changes**Change in any step of the method of manufacture. This would include, but is not restricted to:* batch scaling
* type of equipment
* purification methods
* in-process hold times
* lyophilisation process conditions
* new master cell bank
* new working cell bank for (unless conditions are met for notification by advisory note as described in [GRTPNZ Changed medicine notifications and non-notifiable changes](https://www.medsafe.govt.nz/regulatory/Guideline/GRTPNZ/changed-medicine-notifications-and-non-notifiable-changes.pdf))
* revised specifications/test methods for cell banks
* A Plasma Master File update that includes new suppliers of plasma for blood products (*described in the Plasma Master File;)*
* changes to the manufacturing processes used to isolate and purify drug substance from plasma (described in Module 3.2.S of a product dossier)
 | $3,334 for *each* step change to a maximum of $79,877Please specify number: \_\_\_\_\_\_\_\_\_For Plasma Master File updates, a single $3,334 fee applies irrespective of the number of products associated with the PMF |

Changes to finished product manufacturing, packing, and/or testing sites and/or manufacturing process

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| --- | --- | --- |
| ***Check******box*** | ***Description of change*** | ***Fee*** |
|[ ]  **Finished product manufacturing site*** New site for manufacturing product, lyophilising product, or dispensing final bulk finished product into primary containers, without any changes to the manufacturing, lyophilisation or dispensing process

If there are major changes to the manufacturing, lyophilisation or dispensing process, then select “Finished product manufacturing process – Grade 4” instead.Consequential changes included (if applicable):* Introduction of the same site for secondary packaging
 | $3,334for *each* sitePlease specify number:\_\_\_\_\_\_\_\_ |
|[ ]  **Finished product secondary packaging site*** New secondary packaging site (that is not an approved finished product manufacturing site) where finished product is packed into cartons, pen devices, or other packaging components that are not stored in direct contact with the finished product
* Over-labelling
 | $865for any number of sites |
|[ ]  **Finished product testing site*** New site for testing finished product
* Implementation of an approved test methods(s) at a registered finished product testing site
 | $1,730for *each* new sitePlease specify number: \_\_\_\_\_\_\_\_\_ |
|[ ]  **Finished product manufacturing process – G1 (Self-assessable)*** Editorial changes to 3.2.P, with no changes to the manufacturing process, manufacturing equipment, or quality controls
* Tightening in-process control limits
* Update(s) to Section 3.2.A.1 ‘Facilities and Equipment’ information due to ‘like for like’ equipment changes or building/floor plan changes
 | $432 (self-assessable)  |
|[ ]  **Finished product manufacturing process – G2****- Minor changes**Changes include:* changes to in-process control test methods or limits other than tightening limits
* changes to manufacturing room classification(s)
* change from a single product to a multi-product manufacturing facility with no change to the finished product manufacturing process
 | $865for any number of changes |

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| --- | --- |
|[ ]  **Finished product manufacturing process – G3*** Introduction of a new filling line (or lines) at an approved site
* Introduction of a new or additional filtration step
 | $1,730for *each* process changePlease specify number:\_\_\_\_\_\_\_\_\_\_\_\_ |
| [ ]  | **Finished product manufacturing process – G4****- Major changes*** New type of manufacturing process
* Changes to approved manufacturing process, e.g mixing time, batch scale, type of equipment, etc

Consequential changes included (if applicable) are:* new site of manufacture and primary packing
* revision or reconfirmation of shelf life
 | $3,334for each *site* where the changes are introduced, to a maximum of $79,877Please specify number:\_\_\_\_\_\_\_\_\_\_\_\_\_ |

Changes to test methods and specifications

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| --- | --- | --- |
| ***Check******box*** | ***Description of change*** | ***Fee*** |
|[ ]  **Test methods and specifications – G1 (Self-assessable)*** Tightening of specification limits for active ingredient or finished product
* Change to secondary/working reference standard used in assessment of potency/assay if the protocol used for introducing a new secondary/working reference standard has been previously approved for use in a self-assessable change notification
* Editorial changes to test methods with no actual changes to test method procedures
 | $432for any number of active ingredients(self-assessable) |
|[ ]  **Test methods and specifications – G2** **- Physical/chemical/microbiological specifications and test methods*** Addition / removal / change to any specification used to describe physical, chemical, or microbiological properties of the active ingredient, finished product, or reference standard (used in the assessment of potency/assay)
* Addition / removal / change to any method used to assess other physical, chemical, or microbiological properties of the active ingredient, finished product, or reference standard (used in the assessment of potency/assay)
 | $1,730for *each* revised specification or test methodPlease specify number:\_\_\_\_\_\_\_\_\_\_\_\_ |
|[ ]  **Test methods and specifications – G3****- Assay/potency test methods and specifications*** Change to specifications used to describe assay/potency
* Change to any method used for assay/potency of each active moiety
 | $3,334 for *each* revised specification or test methodPlease specify number:\_\_\_\_\_\_\_\_\_\_\_\_ |
|[ ]  **Test methods and specifications – G4****- Reference standards*** Change to primary reference standard used in assessment of potency/assay
* Change to secondary/working reference standard used in assessment of potency/assay, if no protocol for use of a self-assessable change for introduction of a new secondary/working reference standard has been previously approved
 |  $3,334for *each* change to a reference standardPlease specify number:\_\_\_\_\_\_\_\_\_\_\_\_ |

Changes to excipients

**Where a category is marked by an asterisk symbol (\*) this category is only applicable to excipients that:**

* facilitate the absorption and/or clinical response to the active ingredient, for example hyaluronidase, lipids, adjuvants
* are derived from animal or human blood, (eg, albumin) or mammalian (including recombinant) cell lines

**Note: Changes to PMFs associated with excipients should be notified using the change categories described for active ingredient.**

If a change to an excipient type described above (except for excipients derived from human blood) has already been approved by Medsafe for another product with the same sponsor, then the category ‘Excipient methods of manufacture – G1 (Self-assessable)\*’ should be selected and the previous CMN ID number for which approval has been obtained described.

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| --- | --- | --- |
| ***Check*** ***box*** | ***Description of change*** | ***Fee*** |
|[ ]  **Excipient manufacturing site\**** New manufacturing site
 | $3,334for *each* excipient |
|[ ]  **Excipient methods of manufacture – G1 (Self-assessable) \**** Editorial changes to CTD documentation, with no changes to the manufacturing process, manufacturing equipment, or quality controls
* Tightening in-process control limits
* Change to raw material specifications to adopt a different pharmacopoeia and/or tighten limits
* Introduction of a new manufacturing site or method of manufacture, where the same change(s) has already been approved by Medsafe for another product (with the same sponsor)
 | $432for any number of changes |
|[ ]  **Excipient methods of manufacture – G2\*****Minor changes**Changes include:* Updates to raw materials tests and specifications
* Change in starting material supplier and/or starting material manufacturing process (note: changes to PMFs for albumin are covered by change categories applying to active ingredients)
* Increase in chromatography column diameters with no increase in bed height or chromatography process parameters
* Changes to in-process control limits (other than tightening limits),
* Removal of in-process tests
* New in-process test site (test methods unchanged)
* Additional/alternative storage facilities for the cell bank used to manufacture the excipient
 | $865for any number of changes |

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|[ ]  **Excipient methods of manufacture – G3\*****Major changes**Change in any step of the method of manufacture. This would include, but is not restricted to:* batch scaling
* type of equipment
* new cell banks (unless conditions are met for notification by advisory note as described in [GRTPNZ Changed medicine notifications and non-notifiable changes](https://www.medsafe.govt.nz/regulatory/Guideline/GRTPNZ/changed-medicine-notifications-and-non-notifiable-changes.pdf))
* revised specifications for cell banks
 | $2,595for *each* step change to a maximum of $79,877Please specify number: \_\_\_\_\_\_\_\_\_ |
|[ ]  **Excipient specifications/test methods – G1 (Self-assessable)*** Revised specifications/test methods for an excipient controlled according to a pharmacopoeial monograph (resulting from change to a different pharmacopoeia, not simply updating to the latest edition)
* Tightening of specification for an excipient not controlled according to a pharmacopoeial monograph
 | $432for any number of excipients(self-assessable) |
|[ ]  **Excipient specifications/test methods – G2** * Revised specifications/test methods for an excipient not controlled according to a pharmacopoeial monograph
* Adoption of additional or different specifications/test methods not specified in the pharmacopoeial monograph for an excipient otherwise controlled according to a pharmacopoeial monograph
* Change from animal derived to non-animal derived source for an excipient, with no change in specifications
 | $865for each excipientPlease specify number: \_\_\_\_\_\_\_\_\_ |

Changes to stability

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| --- | --- | --- |
| ***Check*** ***box*** | ***Description of change*** | ***Fee*** |
|[ ]  **Shelf life/storage conditions – G1 (Self-assessable)****Active ingredient, intermediate bulks, finished product, or reference standards*** Revised stability protocol with no change in shelf-life or stability specifications
* Extension of reference standard expiry or retest period, if the protocol used for extension of the expiry or retest period has been previously approved for use in a self-assessable notification
 | $432 (Self-assessable) |
|[ ]  **Shelf life/storage conditions – G2****Active ingredient, intermediate bulks, or finished product*** Revised shelf-life and/or storage conditions with no other changes
* Introduction of a new in-use shelf life

Consequential changes included (if applicable) are:* revised labelling and data sheet
 | $1,730for *each* change to a shelf life or a storage conditionPlease specify number:\_\_\_\_\_\_\_\_\_\_\_\_ |
|[ ]  **Shelf life/storage conditions – Reference Standard** * Revised retest period/expiry/storage conditions for a reference standard if the protocol used for establishing the revised retest period/expiry/storage conditions has not been previously approved
 | $1,730 |

Changes to container/closure/packaging

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| --- | --- | --- |
| ***Check******box*** | ***Description of change*** | ***Fee*** |
|[ ]  **Container/closure/packaging – G1 (Self-assessable)*** Change to supplier of container/closure/packaging components, with no change to material(s) type or specifications for the container/closure/packaging components
* New pack size with evidence provided to show:
* stability data not required
* no effect on dose measurement or dose delivery

Consequential changes included (if applicable) are:* revised labelling and data sheet
* revised packaging specifications
 | $432(Self-assessable) |
|[ ]  **Container/closure/packaging – G2*** Revised specifications for container or closure, with no change to the container, closure, or pack size
 | $865 |
|[ ]  **Container/closure/packaging - G3 – Does not affect dose measurement or dose delivery*** New container or closure type and/or new pack size and/or new packaging material type that requires supporting stability data and extractable/leachable data (where applicable)

Consequential changes included (if applicable) are:* revised shelf life and/or storage conditions
* revised container/closure/packaging specifications
* revised labelling and data sheet

***Please note that new fill volumes for a parenteral product must be submitted as a New Medicine Application*** | $1,730for any number of new container/closure/packaging combinations |
|[ ]  **Container/closure/packaging – G4 – Affects dose measurement or dose delivery** * New container or closure type and/or new pack size and/or new packaging material type that requires supporting stability data and extractable/leachable data (where applicable)

Consequential changes included (if applicable) are:* revised shelf life or storage conditions
* revised container/closure/packaging specifications
* revised labelling and data sheet

***Please note that new fill volumes for parenteral product must be submitted as a New Medicine Application*** | $3,334for *each* new container/closure/packaging combinationPlease specify number: \_\_\_\_\_\_\_\_\_ |

Changes to indications and dosage

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| --- | --- | --- |
| **Check box** | **Description of change** | ***Fee*** |
|[ ]  **Indications/dosage – G1** **– Minor changes / alignment** * Revised wording of indications/dosage with no actual change to indications or dosage
* New or revised label claims that relate to indications and/or directions for use (claims for fast action, duration of effect etc).
* New or revised indications/dosage for a generic or biosimilar medicine to match indications approved for innovator product.
* Excludes changes to indications, dosage, administration, contraindications, precautions and warnings that require clinical data.

Consequential changes included (if applicable) are:* revised data sheet and labelling
 | $865 |
|[ ]  **Indications and/or dosage – G2****– Dosage regimen*** New dosage regimen or modified dosage regimen with no change to indication
* Supporting clinical data required

Consequential changes included (if applicable) are:* revised data sheet and labelling
 | $3,334 for *each* new or modified dosage regimenPlease specify number: \_\_\_\_\_\_\_\_\_ |
|[ ]  **Indications /dosage – G3****– New or modified indication*** New indication or modified indication
* Supporting clinical data required

Consequential changes included (if applicable) are:* new dosage instructions
* revised data sheet and labelling

Note: CMN will be referred under section 24(5). | Intermediate $18,638High (other) $27,957 High (NCE) $37,276Please specify number of new or modified indication: \_\_\_\_\_\_The fee cap is the corresponding NMA fee  |
|[ ]  **Contraindications, Warnings and Precautions – G1*** Addition of contraindications and/or tightening of warnings and precautions regarding use in pregnancy, lactation, or particular population/patient subgroups for an innovator product

Consequential changes included (if applicable) are:* revised data sheet and labelling
 | $1,730  |

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| --- | --- |
|[ ]  **Contraindications, Warnings and Precautions – G2*** Relaxation of contraindications for innovator product, and/or
* Relaxation of warnings and precautions regarding use in pregnancy, lactation, or particular population/patient subgroups for innovator product

Consequential changes included (if applicable) are:* revised data sheet and labelling
 | $3,334 |

Changes to data sheets

|  |  |  |
| --- | --- | --- |
| ***Check******box*** | ***Description of change*** | ***Fee*** |
|[ ]  **Data sheet – G1 (Self-assessable)****-Minor updates to data sheet and/or alignment with innovator*** Update or addition to safety information to align with the New Zealand innovator with no change to approved product details
* Change in name or address of distributor with no change to approved product details
 | $432 (Self-assessable)NB: Only **one** data sheet per self-assessable submission |
|[ ]  **Data sheet – G2****-New or additional safety information*** Update to innovator data sheet to include additional safety information (changes to section 4.8) with no change to indications, dosage, administration, contraindications, precautions and warnings
* Update to innovator data sheet to include minor updates to pharmacological or pharmacokinetic data (minor changes to section 5)
* Update to generic or biosimilar data sheet against overseas innovator when the New Zealand innovator has left the market
* Introduction of a data sheet, including if it is a result of a change in classification

Consequential changes included (if applicable) are:* revised labelling
 | $865Only one data sheet per CMN unless the new or additional information is identical across up to five data sheets. |
|[ ]  **Data sheet – G3**-**New or additional clinical trial data*** Update to innovator data sheet to include the results of additional clinical trials in section 5.2, with no change to indications

Consequential changes included (if applicable) are:changes to contraindications and/or warnings and precautions regarding use in pregnancy, lactation, or particular population/patient subgroups | $3,334   Only **one** data sheet per CMN unless the new safety information is identical across up to five data sheet |

Changes to labelling

*Security labelling:* If labelling contains anti-fraud or other security features a description of the security features must be provided with the proposed labelling.

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| ***Check******box*** | ***Description of change*** | ***Fee*** |
|[ ]  **Labelling – G1 (Self-assessable)*** Minor re-design. Examples are changes to distributor details, relocation of text, change to logo, inclusion or change of sponsor details when not consequential to sponsor change, security features, barcodes and tamper evidence

Conditions: * no change to product name, the way the strength is expressed, dose form, dosage instructions, reconstitution or administration instructions, or indications
 | $432(Self-assessable)Not applicable if a change of the classification makes the product a Controlled Drug |
|[ ]  **Labelling – G2** * Design or re-design of a New Zealand compliant label
* No change in product strength but can include a change in the way the strength is expressed
* Addition of label claims that do not relate to indications or directions for use
* Addition or removal of package insert
* Change in the classification to a Controlled Drug
 | $865 |
|[ ]  **Labelling – G3** **– Labelling exemption*** Request for a labelling exemption or renewal of a labelling exemption

State the label for which the exemption is requested and what part of label that is non-compliant. Provide a justification for exemption in Section 5 of this form (see Guideline on the Regulation of Therapeutic Products in New Zealand, Part 5)***Controlled drugs are not eligible for a labelling exemption.*** | $865  |

Miscellaneous changes

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| --- | --- | --- |
| ***Check******box*** | ***Description of change*** | ***Fee*** |
|[ ]  **Sponsor (Self-assessable)*** Change in sponsor with associated changes to data sheet and labelling
 | $432(Self-assessable) |
|[ ]  **Change in Ownership** * Change in ownership of manufacturing or quality control site
 | $865 |

**Section 4: Summary of proposed changes**

Use a separate summary sheet for each change.

Description of change

*Note:* copy heading from “Description of change” box in Section 3.

Summary of current and proposed details

*Note:* A summary of details is required in this section. It is not sufficient to cross-reference the details from another section of this form or another document.

|  |  |
| --- | --- |
| **Current product details** | **Proposed details** |
| 1. | 1. |
| 2. | 2. |
| 3. | 3. |
| **Consequential changes (if applicable)**1.2.3. |
| **Reason for change** |
| **Acceptance overseas- include approval letter if available** |

**Section 5: Declarations and commitments**

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| --- |
| **Complete the checkbox for each declaration and/or commitment that is relevant to the CMN.** All relevant declarations and commitments must be selected, and the signature section located at the end of the section must be completed to validate the notification.**These first two declarations are compulsory for all CMNs.** |
|[ ]  In accordance with section 24 of the Medicines Act 1981, I hereby notify the Director-General of Health of material changes proposed for this product. I certify that the information supplied is correct to the best of my knowledge and that no relevant information has been omitted. |
|[ ]  I confirm that other than the changes described in this CMN form, all other aspects of active ingredient and finished product quality, equipment, process, and packaging etc, are the same as those previously approved. |
|  |  |
|[ ]  **New Zealand Medicines Terminology**A New Zealand Medicines Terminology Listing Certificate should be provided as part of the Medsafe application process for changes to product name, pack size and container.The New Zealand Medicines Terminology Listing Certification has been attached.Refer to [www.nzulm.org.nz](http://www.nzulm.org.nz) or email listings@nzulm.org.nz for further details on NZMT listings |
|[ ]  **Removal of sites from TPDR** I confirm that there is no further stock, currently marketed or stockpiled for future sale or use in New Zealand, either manufactured at or using any ingredients sourced from the site(s) required to be removed.Note: Site(s) cannot be removed until all stock manufactured, tested or packed at the site has been depleted from the New Zealand market. |
|[ ]  **CMN relating to an Out of Specification or trend issue**I confirm that the Compliance Product Safety Team has been informed of the out of specification or out of trend issue via an email to Recalls@health.govt.nz and all correspondence has been included in this application.Date of notification to Product Safety Team or Incident Reference Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| [ ] [ ] [ ] [ ]  | **Labelling**One representative label has been submitted for all pack sizes of the same strength and presentation. I certify that all other pack sizes are identical, except for the statement of pack size.Labels are provided at % of full scale, in colour and single sided.I certify that all of the label(s) for all of the proposed products have been assessed and are in compliance with the requirements of the legislation. All information on the label(s) is consistent with the details of the medicine currently approved in New Zealand or described in the current Changed Medicine or Related Product Notification.**OR**A labelling exemption is requested as follows (repeat as necessary):Label for which the exemption is requested (eg, blister, bottle, carton):Part of label that is non-compliant:Justification for exemption (see Guidelines on the Regulation of Therapeutic Products in New Zealand, Part 5), for the circumstances under which an exemption can be considered: |
|  | **Declaration to accompany a data sheet submitted for approval** |
|[ ]  **Requires evaluation (CMN)**I declare that this data sheet has been prepared in compliance with the current edition of the Guideline on the Regulation of Therapeutic Products in New Zealand and that it accurately reflects the changes proposed in the CMN. |
|[ ]  **Is self-assessable (SACN)**I declare that this data sheet has been prepared in compliance with the current edition of the Guideline on the Regulation of Therapeutic Products in New Zealand and that it accurately reflects the existing New Zealand terms of approval for the medicine.  |
|[ ]  **CMI**Following consent to distribute, an electronic copy of the CMI will be submitted to Medsafe and will comply with the requirements published on the Medsafe website. The CMI will not be used or included as a package insert unless these requirements have been met. |
|[ ]  **Post approval stability** At least one commercial scale batch of each strength, pack size and pack type of the changed product will be placed on stability trial (with bracketing as appropriate) under real time conditions for the duration of the proposed shelf life per year of production. The batches will be identical in every respect to those destined for the New Zealand market and Medsafe will be informed of any out of specification results or data indicating that batches may be out of specification before the shelf life is reached.For stability studies that are on-going (active ingredient or finished product), Medsafe will be informed of any out of specification results or data indicating that batches may be out of specification before the shelf life is reached. |
|[ ]  **Declaration for reduced shelf life not linked to out-of-specification results**I declare that the reduced shelf is not linked to any out-of-specification or out-of-trend stability data. |
|  | **Signature section:****I certify all of the declarations and commitments selected in section 5 of this form:**Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**Section 6: Notes on calculation and payment of fees**

*Note 1:* In no case will the CMN fee for a single product exceed the fee for a new medicine application for a product of the same type.

*Note 2:* When the same change or set of changes is made to other names, dose forms, strengths and flavours of a product, a $432 (administrative) fee is charged for each of the other affected products, except if the change is associated with a Plasma Master File. A maximum of four self-assessable category fees will be applied per CMN. For SACMN notifications, a fee of $432 is charged per category and per product. For updates to a Plasma Master File Letter of Access, only one fee for $432 is charged irrespective of the number of products associated with the PMF.

*Note 3:* Upon receipt of an notification Medsafe will issue a tax invoice which will be sent to the applicant with the acknowledgement letter. Payment will be requested within 7 days and will be required to validate the notification. Payments are to be made on an invoice basis only - do not send payment with the notification.

*Note 4:* Please email remittance advice to receivables@health.govt.nz once you have made the payment.