**Changed medicine notification Form A**

Use this form when notifying a change (including self-assessable changes) to an approved product. This includes lower-risk, intermediate or higher-risk medicines other than a biological or biotechnological product and includes antibiotics and like-substances derived from micro-organisms.

Use CMN Form B for biological or biotechnological products (i.e., vaccines, serum, allergens, medicinal product derived from human blood or plasma, immunological medicinal product, and any product derived from biotechnology).

Use the CRPN form for notifying a changed related product.

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

**Instructions for completing Section 3 of CMN Form A**

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 “Product type & fee” column.
2. Enter the number of changes in the right-hand column (Product type & 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 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.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Medsafe File No 1TT50- | Product name | Dose form | Drug Substance and Strength | Classification | Product currently available? Yes/No2 |
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2 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 email address:This should be the company’s generic email address (if available) |  |
| DMF holder 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.

|  |  |  |
| --- | --- | --- |
| ***Check box*** | ***Description of change*** | ***Product type & fee*** |
|[ ]  **Product name**– New product name to replace existing name with no change in formulationConsequential changes included (if applicable) are:1. revised data sheet and labelling
 | $865for *each* new nameNumber of new names: \_\_\_\_\_\_\_\_\_ |

### Changes to formulation

*Note:* If a change in formulation results in a change in the manufacturing process, the change in process must be notified separately under the change category **Finished product manufacturing process**.

|  |  |  |
| --- | --- | --- |
| ***Check*** ***box*** | ***Description of change*** | ***Product type & fee*** |
|[ ]  **Formulation – G1** **– Minor change that does not affect bioavailability, stability, or safety** * Examples include changes in ink, colourant, expression of units, quantities of buffer/pH adjusters; changes to a non-functional film-coat that doesn’t affect stability.

Consequential changes included (if applicable) are:* revised specification for finished product description
* revised specifications for excipient
* revised labelling and data sheet
 | $865 |

|  |  |
| --- | --- |
|[ ]  **Formulation – G2– Overage and/or excipient change without biostudy/stability*** Examples include:
* change in overage of an active ingredient where the product is one for which comparative bioavailability data are not required and the change does not affect bioavailability or stability
* excipient changes that do not affect bioavailability, stability or safety

Consequential changes included (if applicable) are:* new or revised specifications for excipient
* revised specifications for finished product
* revised labelling and data sheet
* revised shelf life/storage conditions
 | $1,730 for any number of active or excipient changes |
| [ ]  | **Formulation – G3– Change in active ingredient salt or function, lower risk medicines only*** changed active ingredient salt, or change in status of ingredient from active to excipient, or removal of active ingredient with no other changes
* a change in active ingredient salt that does not affect bioavailability – evidence of the lack of impact on bioavailability is required
* stability study included, or justification for why it is not required
* no significant change in manufacturing process

Consequential changes included (if applicable) are:* new specifications/test methods for active ingredient and finished product
* revised labelling and data sheet
* amended batch formulation documentation
 | $2,162 For lower risk medicines onlyNot applicable to intermediate or higher risk medicines - NMA required |
|[ ]  **Formulation – G4– Excipient change with biostudy/stability*** excipient change that may affect, or is considered likely to affect bioavailability, stability or safety

Consequential changes included (if applicable) are:* new or revised specifications/test methods for excipient and/or finished product
* revised labelling and data sheet
* minor revisions to the manufacturing process; for example, revised mixing times to accommodate excipients with different solubility
* revised shelf life/storage conditions
 | $3,334for any number of excipient changes |

### Changes to API manufacturing site and/or process

|  |  |  |
| --- | --- | --- |
| ***Check box*** | ***Description of change*** | ***Product type & fee*** |
|[ ]  **Active ingredient manufacture – G1 (Self-assessable)*** Updated Certificate of Suitability for currently approved site

Consequential changes included (if applicable) are:* revised specifications/test methods for active ingredient
 | $432 for any number of CEPs (Self-assessable) |
|[ ]  **Active ingredient manufacture – G2- new site, lower risk only*** new site of manufacture

Consequential changes included (if applicable) are:* revised specifications/test methods for active ingredient
 | $865for any number of new sitesFor lower risk products only |
|[ ]  **Active ingredient manufacture – G3- new site via CEP*** new site of manufacture
* current Certificate of Suitability provided for the new site
* replacement of DMF/3.2.S with a Certificate of Suitability for currently approved site

Consequential changes included (if applicable) are: * revised specifications/test methods for active ingredient
 | $865for any number of new sites |
| [ ]  | **Active ingredient manufacture – G4– Minor process changes** Changes to the DMF / 3.2.S other than changes to manufacturing process steps. For example:* change in batch size
* retest period
* starting and intermediate material supplier or specifications
* new testing site or micronisation site
* change in API container/closure

Note that if changes are made to manufacturing process steps then a higher category (G5) will be required. | $865for *each* change, with a limit of three of the changes listed in the description of change section.Please specify number: \_\_\_\_\_\_\_\_\_For four or more changes, use Active ingredient manufacturing process – G5. |
|[ ]  **Active ingredient manufacture – G5 – DMF/3.2.S update*** Updated manufacturing process
* Four or more changes to any section of the DMF /3.2.S as defined in Active ingredient manufacture - G4) and/or
* updated DMF or equivalent documentation supplied (Module 3.2.S)

Consequential changes included (if applicable) are:* process validation for active ingredient
* revised specifications/test methods for active ingredient
 | $2,595for *each* affected DMF/3.2.SPlease specify number: \_\_\_\_\_\_\_\_\_ |

|  |  |
| --- | --- |
|[ ]  **Active ingredient manufacture – G6– new DMF/3.2.S*** new site of manufacture and/or
* new manufacturing process
* DMF or equivalent documentation supplied (Module 3.2.S)

Consequential changes included (if applicable) are:* process validation for active ingredient
* revised specifications/test methods for active ingredient

**24(5) referral**New DMFs or equivalent documentation (Module 3.2.S) will be referred under section 24(5)(a) of the Medicines Act.  | Lower risk: $3,334Intermediate / high risk:$21,301 if referred under section 24(5)for *each* new process and/ or sitePlease specify number of DMFs/sites: \_\_\_\_\_\_\_\_\_ |

###  Changes to API specifications/test methods

|  |  |  |
| --- | --- | --- |
| ***Check******box*** | ***Description of change*** | ***Product type & fee*** |
|[ ]  **Active ingredient specifications/test methods – G1** **– (Self-assessable)**1. tightened limits for active ingredient with no change to test methods
2. additional test method detail with no change in the actual method
 | $432(Self-assessable) |
|[ ]  **Active ingredient specifications/test methods – G2**  **– Additional controls for monographed API**1. adoption of additional or different specifications/test methods for an active ingredient otherwise controlled to a pharmacopoeial monograph
2. new specifications/test methods for an active ingredient controlled to a pharmacopoeial monograph resulting from change to a different pharmacopoeia, not simply updating to the latest edition
 | $865for *each* active ingredient Please specify number: \_\_\_\_\_\_\_\_\_ |
|[ ]  **Active ingredient specifications/test methods – G3****– Non-pharmacopoeia** 1. revised specifications/test methods/testing protocol for an active ingredient not controlled to a pharmacopoeial monograph
 | $1,730 for *each* activeingredientPlease specify number: \_\_\_\_\_\_\_\_\_ |

### Changes to excipients

|  |  |  |
| --- | --- | --- |
| ***Check*** ***box*** | ***Description of change*** | ***Product type & fee*** |
|[ ]  **Excipient specifications/test methods – G1 (Self-assessable)**1. revised specifications/test methods for an excipient controlled to a pharmacopoeial monograph resulting from change to a different pharmacopoeia, not simply updating to the latest edition
2. tightened limits for an excipient
 | $432for any number of excipients(Self-assessable) |
|[ ]  **Excipient specifications/test methods – G2**1. revised specifications/test methods for an excipient not controlled to a pharmacopoeial monograph
2. adoption of additional or different specifications/test methods not specified in the pharmacopoeial monograph for an excipient otherwise controlled to a pharmacopoeial monograph
 | $865 for each excipientPlease specify number: \_\_\_\_\_\_\_\_\_ |

### Changes to finished product packing and testing sites

|  |  |  |
| --- | --- | --- |
| ***Check*** ***box*** | ***Description of change*** | ***Product type & fee*** |
|[ ]  **Finished product secondary packing site**1. new packing site performing secondary packing activities such as over-labelling, removing or replacing packaging (cartons), removing and replacing package leaflets.
 | $865 for any number of sites |
|[ ]  **Finished product testing and/or primary packing site**1. new packing site performing primary packing activities
2. new finished product testing site
 | $1,730 For each new sitePlease specify number: \_\_\_\_\_\_\_\_\_ |

### Changes to finished product manufacturing site and/or process

|  |  |  |
| --- | --- | --- |
| ***Check*** ***box*** | ***Description of change*** | ***Product type & fee*** |
|[ ]  **Finished product manufacture – G1** **– Minor changes to the finished product manufacturing process** 1. Examples are changes to hold times, mixing times, batch scaling, in-process control limits, type of equipment etc. with no change to the type of manufacturing process at a registered manufacturing site
2. change in shape, engraving or coding of tablets, including addition or removal of score lines
3. change in markings on capsule shells

Consequential changes included (if applicable) are:* revised finished product specifications/test methods
* revised data sheet
 | $865for *each* minor process change Please specify number: \_\_\_\_\_\_\_\_\_ |
|[ ]  **Finished product manufacture – G2** **– Other changes to the finished product manufacturing process** 1. new site for sterilisation
2. introduction of a new filling line (or lines) at an approved site
3. Conditions:
* type of manufacturing process unchanged with or without changes to mixing times, batch scaling, type of equipment etc
 | $1,730for *each* process change Please specify number: \_\_\_\_\_\_\_\_\_ |
| [ ]  | **Finished product manufacture – G3**1. new site of manufacture
2. type of manufacturing process unchanged with or without changes to mixing times, batch scaling, type of equipment etc.

Consequential changes included (if applicable) are:1. new site of manufacture may also be registered as a site for testing and/or packing
2. reconfirmation of shelf life at the new site
 |  $2,595for *each* new sitePlease specify number: \_\_\_\_\_\_\_\_\_ |
|[ ]  **Finished product manufacture – G4**1. new site of manufacture
2. new type of manufacturing process

Consequential changes included (if applicable) are:1. revision or reconfirmation of shelf life
2. revised specifications/test methods
3. new site of manufacture may also be registered as a site for testing and/or packing without selection of an additional change category
 |  $3,334 for *each* new process and/or sitePlease specify number: \_\_\_\_\_\_\_\_\_ |

### Changes to finished product specifications/test methods

|  |  |  |
| --- | --- | --- |
| ***Check******box*** | ***Description of change*** | ***Product type & fee*** |
|[ ]  **Finished product specifications/test methods – G1** **(Self-assessable)**1. tightening of limits with no change to test method
2. additional test method detail with no change in the actual method
3. product controlled according to a pharmacopoeial monograph resulting from change to a different pharmacopoeia, not simply updating to the latest edition
 | $432(Self-assessable) |
|[ ]  **Finished product specifications/test methods – G2** **– Pharmacopoeial product with additional in-house specifications/tests**1. revised in-house specifications/test methods for a product otherwise controlled according to a pharmacopoeial monograph
2. addition of specifications/test methods not specified in the pharmacopoeial monograph for a product otherwise controlled to a pharmacopoeial monograph
 | $865  |
|[ ]  **Finished product specifications/test methods – G3– Non-pharmacopoeial product** 1. revised specifications/test methods
2. product not controlled to a pharmacopoeial monograph
 |  $1,730 |

### Changes to product stability

|  |  |  |
| --- | --- | --- |
| ***Check*** ***box*** | ***Description of change*** | ***Product type & fee*** |
|[ ]  **Shelf life/storage conditions – G1 (Self-assessable)**1. decrease in storage temperature from 30°C to 25°C (not due to Out of Specification and/or trend) with no change in shelf life and no other changes
2. additional or expansion of a storage instruction
3. decrease in shelf-life when not due to an out of specification or out of trend result (and when not consequential to a change in formulation or manufacturing process)

Consequential changes included (if applicable) are:1. revised labelling and data sheet
 | $432 (Self-assessable) |
|[ ]  **Shelf life/storage conditions – G2**1. revised shelf life and/or storage conditions (when not consequential to a change in formulation or manufacturing process)
2. revised or introduction of a new in-use shelf life

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

### Changes to container/closure/packaging

|  |  |  |
| --- | --- | --- |
| ***Check******box*** | ***Description of change*** | ***Product type & fee*** |
|[ ]  **Container/closure/packaging – G1 (Self-assessable)**1. new pack size or change in container closure specifications with no change to container type or dimensions. For example, adding a specification parameter, change in cap colour.
2. Conditions:
* evidence provided that stability study not required
* no effect on dose measurement or dose delivery

Consequential changes included (if applicable) are:1. revised labelling and data sheet
2. revised packaging specifications
 | $432(Self-assessable) |
|[ ]  **Container/closure/packaging – G2 – Does not affect dose measurement** 1. new container or closure type and/or new pack size and/or new packaging material type
2. evidence provided that stability study not required
3. no effect on dose measurement or dose delivery

Consequential changes included (if applicable) are:1. revised labelling and data sheet
2. revised packaging specifications
 | $865for any number of new container/closure/packaging combinations |
|[ ]  **Container/closure/packaging – G3 – Affects dose measurement or dose delivery** 1. new container or closure type and/or new pack size and/or new packaging material type
2. evidence provided that stability study not required
3. affects dose measurement or dose delivery

Consequential changes included (if applicable) are:1. revised labelling and data sheet
2. revised packaging specifications
 | $1,730 for *each* new container/closure/packaging combinationPlease specify number: \_\_\_\_\_\_\_\_\_ |
|[ ]  **Container/closure/packaging – G4****– Stability data required**1. new container or closure type and/or new pack size and/or new packaging material type
2. revised shelf life and/or storage conditions
3. does not affect dose measurement or dose delivery

Consequential changes included (if applicable) are:* revised labelling and data sheet
* revised packaging specifications
 | $2,595 for *each* new container/closure/packaging combinationPlease specify number: \_\_\_\_\_\_\_\_\_ |

|  |  |
| --- | --- |
|[ ]  **Container/closure/packaging – G5** **– Stability and dose measurement/delivery data required*** new container or closure type and/or new pack size and/or new packaging material type
* revised shelf life and/or storage conditions (stability study included)
* affects dose measurement or dose delivery

Consequential changes included (if applicable) are:* revised labelling and data sheet
* revised packaging specifications
 | $3,334for *each* container/ closure/ packaging combinationPlease specify number: \_\_\_\_\_\_\_\_\_ |

### Changes to indications and dosage

|  |  |  |
| --- | --- | --- |
| **Check box** | **Description of change** | **Product type & fee** |
|[ ]  **Indications/dosage – G1****– Minor changes / alignment**1. revised wording of indications/dosage with no actual change to indications or dosage
2. new or revised label claims that relate to indications and/or directions for use (claims for fast action, duration of effect etc).
3. new or revised indications/dosage for a generic medicine to match indications approved for innovator product.
4. excludes changes to indications, dosage, administration, contraindications, precautions and warnings that require clinical data.

Consequential changes included (if applicable) are:1. revised data sheet and labelling
 | $865 |
|[ ]  **Indications/dosage – G2****– Dosage regimen**1. new dosage regimen or modified dosage regimen with no change in indication
2. supporting clinical data required

Consequential changes included (if applicable) are:1. revised data sheet and labelling
 | $3,334 for each new or modified dosage regimenPlease specify number: \_\_\_\_\_\_\_\_\_ |
|[ ]  **Indications /dosage – G3****– New or modified indication**1. new indication or modified indication
2. supporting clinical data required

Consequential changes included (if applicable) are:1. new dosage instructions
2. revised data sheet and labelling

Note: CMN will be referred under section 24(5). | Fee is dependent on corresponding NMA risk categoryLower $3,334Intermediate $18,638High (other) $27,957High (NCE) $37,276Please specify number of new or modified indications: \_\_\_\_\_\_\_\_\_The fee cap is the corresponding NMA fee. |
| [ ]  | **Contraindications, Warnings and Precautions – G1**1. Addition of contraindications and/or tightening of warnings and precautions regarding use in pregnancy, lactation, or particular population/patient subgroups for an innovator product
2. Not applicable to generics aligning with the New Zealand innovator. In this case, use change category Indications/dosage – G1

Consequential changes included (if applicable) are:* revised data sheet and labelling
 | $1,730 |
|[ ]  **Contraindications, Warnings and Precautions – G2**1. relaxation of contraindications for innovator product, and/or
2. relaxation of warnings and precautions regarding use in pregnancy, lactation or particular population/patient subgroups for innovator product
3. Not applicable to generics aligning with the New Zealand innovator. In this case, use change category Indications/dosage – G1

Consequential changes included (if applicable) are:1. revised data sheet and labelling
 | $3,334  |

### Changes to data sheets

|  |  |  |
| --- | --- | --- |
| ***Check******box*** | ***Description of change*** | ***Product type & fee*** |
|[ ]  **Data sheet – G1 (Self-assessable)****– Minor updates to data sheet and/or alignment with innovator**1. update or addition to safety information to align with the New Zealand innovator, with no change to approved product details
2. 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**1. 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
2. update to innovator data sheet to include minor updates to pharmacological or pharmacokinetic data (minor changes to section 5)
3. update to generic data sheet against overseas innovator when the New Zealand innovator has left the market
4. introduction of a data sheet, including if it is a result of a change in classification

Consequential changes included (if applicable) are:1. 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**1. 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:1. 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 clinical trial data is identical across up to five data sheets |

### Changes to labelling

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

|  |  |  |
| --- | --- | --- |
| ***Check******box*** | ***Description of change*** | ***Product type & fee*** |
|[ ]  **Labelling – G1 (Self-assessable)**1. 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:1. 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**1. design or re-design of a New Zealand compliant label
2. no change in product strength but can include a change in the way the strength is expressed
3. addition of label claims that do not relate to indications or directions for use
4. addition or removal of package insert
5. change in the classification to a Controlled Drug
 | $865 |
|[ ]  **Labelling – G3** **– Labelling exemption**1. 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 Labelling of medicines and related products guideline)***Controlled drugs are not eligible for a labelling exemption.*** | $865  |

### Miscellaneous changes

|  |  |  |
| --- | --- | --- |
| ***Check******box*** | ***Description of change*** | ***Product type & fee*** |
|[ ]  **Editorial updates to Module 3 Documents (Self-assessable)** 1. Editorial changes to 3.2.S and/or 3.2.P, with no changes to manufacturing processes, manufacturing equipment, or quality controls

Note: Updates to CTD modules that relate to an assessable change can be notified as a consequential change to the applicable change category. | $432for editorial changes to any number of CTD sections(Self-assessable) |
|[ ]  **Sponsor (Self-assessable)**change in sponsor Consequential changes included (if applicable) are:* Revised data sheet and labelling
 | $432(Self-assessable) |
|[ ]  **Change in ownership** * change in ownership of manufacturing or quality control site
 | $865 |

**CMN Form A**

**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**

|  |
| --- |
| **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 applicationDate 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 the labels for all other pack sizes are identical to the label provided except for the statement of pack size.I certify that labels are provided in colour at % of full scale.I certify that all of the label(s) for all of the products included in this CMN have been self-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 are described in this CMN.**OR**A labelling exemption is requested as follows (repeat as necessary):Label for which the exemption is requested (e.g. blister, bottle, carton):Part of label that is non-compliant:Justification for exemption (see Part 5 of the Guidelines on the Regulation of Therapeutic Products in New Zealand 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, 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. 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.

*Note 3:* Upon receipt of a notification Medsafe will issue a tax invoice which will be sent to the applicant by email, with the acknowledgement letter. Payment is requested within 7 days and is 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.