**CHANGED MEDICINE NOTIFICATION**

FORM A

This form is to be used when notifying a material change (including self-assessable changes) to an approved Type I product (lower-risk medicine) or a Type II product (intermediate- or higher-risk medicine other than a biological or biotechnological product - but including antibiotics and like substances derived from micro-organisms).

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

Use the CRPN form for notifying a changed related product.

**Section 1: Product details**

Copy details from the database report for the currently approved product. A separate Section 1 must be completed for each different product (name + dose form + active ingredient(s) + strength + classification + flavour, as applicable).

**Product name:**

**Medsafe File No:** TT50-

**Dose form:**

**Strength:**

**Classification:**

**Product currently available[[1]](#footnote-1): Yes**  **No**

If no, please state the date the product was last supplied in New Zealand:

**Type of product:**

*(Tick one)*

|  |  |  |
| --- | --- | --- |
| **Type I** | **Lower-risk medicines** |  |
| **Type II** | **Intermediate-risk or Higher-risk medicine other than a biological or biotechnological products (but including antibiotics and like substances derived from micro-organisms)** |  |

## Section 2: Applicant and Sponsor details and declaration

**Name, designation and address of person submitting the notification:**

All correspondence about the application, including the invoice, will be sent to this person.

**Email address:**

**New Zealand sponsor name and street address:**

**Postal address of the New Zealand sponsor:**

(if different from street address)

***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.***

**Signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Section 3: Proposed changes**

**Instructions**

1. Tick the box(es) in the left hand column beside the description(s) that most accurately reflects the changes for which approval is sought. 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. Where no product type is specified in the “Product type and fee” column, the same fee applies to all product types.
2. Enter the number of changes in the “Tick box” where the product type and fee is based on a fee for *each* change.
3. It is not necessary to submit pages listing change descriptions that are not relevant to the notification.
4. When a self-assessable change is notified at the same time as other changes for which a fee is paid, the $360 administrative fee for the self-assessable change will not apply (except in the case of a data sheet update, where the update is independent and not a consequence of any of the proposed changes).
5. If applicable, the Consumer Medicine Information (CMI) for the product should also be updated in line with the changes and a revised version forwarded to Medsafe once the consent letter for the CMN or SACN has been received. There will be no additional fee for the CMI.
6. All fees listed are GST inclusive.
7. Until 28 February 2019, a change to the datasheet that is simply an update to align with the new required SPC-style format will not incur any additional fee, unless it is the sole change as part of a self-assessable notification, in which case the $360 administrative fee will still apply for each datasheet.

**Product name**

**Note:** If a product is to be marketed under a new name in addition to the existing name, it is a new product and a New Medicine Application must be completed.

|  |  |  |
| --- | --- | --- |
| ***Tick***  ***box*** | ***Description of change*** | ***Product type & fee*** |
|  | **Product name – non-umbrella branded**   1. **new product name with no umbrella branding component associated with it to replace existing name** 2. **no change in formulation**   Consequential changes included (if applicable) are:   1. revised data sheet and labelling | $720  for *each* new name |
|  | **Product name – umbrella branded**   1. **new product name with umbrella branding component associated with it to replace existing name** 2. **no change in formulation**   Consequential changes included (if applicable) are:   1. revised data sheet and labelling | I: $720  II: Not applicable  for *each* new name |

**Formulation**

**Note:** If a formulation change results in a change in the actual manufacturing process, this must be separately notified as a “Finished product manufacturing process” change in the “Finished product” section of this form.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| ***Tick***  ***box*** | | ***Description of change*** | | ***Product type & fee*** |
|  | **Formulation - Grade 1**   1. **change in overage of an active ingredient or excipient, or other excipient change where either:** 2. **the product is one for which comparative bioavailability data are not required; or** 3. **the change is not considered likely to affect bioavailability or stability**     Consequential changes included (if applicable) are:   1. new or revised specifications for excipient 2. revised specifications for finished product 3. revised labelling and data sheet 4. amended batch manufacturing documentation, provided there is no significant change in manufacturing process | | I: $1,440  II: $2,160  for any number of  excipient changes | |
|  | **Formulation - Grade 2**   1. **changed active ingredient salt, or change in status of ingredient from active to excipient, or removal of active ingredient with no other changes** 2. **change not considered likely to affect stability**   Consequential changes included (if applicable) are:   1. new specifications/test methods for active ingredient and finished product 2. revised labelling and data sheet 3. amended batch manufacturing documentation, provided there is no significant change in manufacturing process | | I: $1,440  II: Not permitted  (NMA required) | |
|  | **Formulation - Grade 3**   1. **changed active ingredient salt or removal of active ingredient with no other changes** 2. **stability study included**   Consequential changes included (if applicable) are:   1. new specifications/test methods for active ingredient and finished product 2. revised labelling and data sheet 3. amended batch manufacturing documentation, provided there is no significant change in manufacturing process | | I: $1,800  II: Not permitted  (NMA required) | |

**Formulation (cont’d)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| ***Tick***  ***box*** | | ***Description of change*** | | ***Product type & fee*** | |
|  | **Formulation - Grade 4**   1. **excipient change that may affect, or is considered likely to affect, bioavailability, stability or safety**   Consequential changes included (if applicable) are:   1. new or revised specifications/test methods for excipient 2. revised labelling and data sheet | | I: $2,160  II: $2,880  for any number of  excipient changes | |

**Active ingredient**

|  |  |  |  |
| --- | --- | --- | --- |
| ***Tick***  ***box*** | ***Description of change*** | | ***Product type & fee*** |
|  | **Active ingredient manufacturing site**   1. **new site of manufacture** 2. **manufacturing process unchanged** | | I: $720  II: Not applicable  for any number of new sites |
|  | **Active ingredient manufacturing process - Grade 1**   1. **new manufacturing process** 2. **Certificate of Suitability provided in lieu of DMF** 3. **Updated Certificate of Suitability**   Consequential changes included (if applicable) are:   1. new site of manufacture | | I: $720  II: $720  for any number of  new sites |
|  | **Active ingredient manufacturing process - Grade 2**   1. **new manufacturing process** 2. **DMF or equivalent documentation supplied (Module 3.2.S)**   Consequential changes included (if applicable) are:   1. process validation for active ingredient 2. revised specifications/test methods for active ingredient 3. new site of manufacture | I: $2,880  II: $2,880  for *each* new process | |

**Active ingredient (cont’d)**

|  |  |  |
| --- | --- | --- |
| ***Tick***  ***box*** | ***Description of change*** | ***Product type & fee*** |
|  | **Active ingredient manufacturing process – Grade 3**   * **change in batch size, retest period, intermediate material supplier or specifications.** | I: $720  II: $720 |
|  | **Active ingredient specifications/test methods - Grade 1**   1. **tightening of limits for active substance** | $360  (self-assessable) |
|  | **Active ingredient specifications/test methods - Grade 2**   1. **new specifications/test methods for a substance controlled according to a pharmacopoeial monograph (resulting from change to a different pharmacopoeia, not simply updating to the latest edition)** | $720 |
|  | **Active ingredient specifications/test methods -**  **Grade 3**   1. **adoption of additional or different specifications/test methods not specified in the pharmacopoeial monograph for an active ingredient otherwise controlled according to a pharmacopoeial monograph** | $720  for *each* active |
|  | **Active ingredient specifications/test methods -**  **Grade 4**   1. **revised specifications/test methods/testing protocol for a substance not controlled according to a pharmacopoeial monograph** | I: $720  II: $1,440  for *each* active  ingredient |

**Excipient**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| ***Tick***  ***box*** | | ***Description of change*** | | ***Product type & fee*** |
|  | | **Excipient specifications/test methods - Grade 1**   1. **revised specifications/test methods for a substance controlled according to a pharmacopoeial monograph (resulting from change to a different pharmacopoeia, not simply updating to the latest edition)** | | $360  (self-assessable)    for any number of  excipients |
|  | | **Excipient specifications/test methods - Grade 2**   1. **revised specifications/test methods for a substance not controlled according to a pharmacopoeial monograph** | | $720  for *each* excipient |
|  | **Excipient specifications/test methods - Grade 3**   1. **adoption of additional or different specifications/test methods not specified in the pharmacopoeial monograph for an excipient otherwise controlled according to a pharmacopoeial monograph** | | $720  for *each* excipient | |

**Finished product**

|  |  |  |  |
| --- | --- | --- | --- |
| ***Tick***  ***box*** | | ***Description of change*** | ***Product type & fee*** |
|  | **Finished product packing site – Grade 1**   1. **new packing site that is not the site of manufacture and does not perform primary packing** 2. **includes overlabelling** | | $720  for any number of sites |
|  | **Finished product packing site – Grade 2**   * **new primary packing site that is not the site of manufacture** * **new finished product testing site** | | $1,440 |

**Finished product (cont’d)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| ***Tick***  ***box*** | | ***Description of change*** | | ***Product type & fee*** | |
|  | **Finished product manufacturing process - Grade 1**   1. **type of manufacturing process unchanged, but changes to mixing times, batch scaling, type of equipment etc.**   Consequential changes included (if applicable) are:   1. revised specifications/test methods 2. new site of manufacture and packing | | I: $1,440  II: $2,160  for *each* new process | |
|  | **Finished product manufacturing process - Grade 2**   1. **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 and packing | | I: $2,160  II: $2,880  for *each* new process | |
|  | **Finished product specifications/test methods - Grade 1**   1. **revised specifications/test methods** 2. **no change in manufacturing process** 3. **product controlled according to a pharmacopoeial monograph (resulting from change to a different pharmacopoeia, not simply updating to the latest edition)** 4. **change in shape, engraving or coding of tablets that does not include addition or removal of score lines** 5. **no change in dissolution or bioavailability** | | $360  (self-assessable) | |
|  | **Finished product specifications/test methods - Grade 2**   1. **tightening of limits for active substance** 2. **no other changes to specifications** 3. **no changes to test methods** | | $360  (self-assessable) | |

**Finished product (cont’d)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| ***Tick***  ***box*** | | ***Description of change*** | | ***Product type & fee*** | |
|  | **Finished product specifications/test methods - Grade 3**   1. **adoption of additional specifications/test methods not specified in the pharmacopoeial monograph for a product otherwise controlled according to a pharmacopoeial monograph** | | $360  (self-assessable) | |
|  | **Finished product specifications/test methods - Grade 4**   1. **adoption of different specifications/test methods not specified in the pharmacopoeial monograph for a product otherwise controlled according to a pharmacopoeial monograph** 2. **addition or removal of tablet score line** | | $720 | |
|  | **Finished product specifications/test methods - Grade 5**   1. **revised specifications/test methods** 2. **no change in manufacturing process** 3. **product not controlled according to a pharmacopoeial monograph** | | I: $720  II: $1,440 | |

**Product stability and packaging**

|  |  |  |
| --- | --- | --- |
| ***Tick***  ***box*** | ***Description of change*** | ***Product type & fee*** |
|  | **Shelf life/storage conditions - Grade 1**   1. **decrease in storage temperature from < 30°C to < 25°C with no change in shelf life and no other changes** 2. **addition of a statement such as “Protect from light”**   Consequential changes included (if applicable) are:   1. revised labelling and data sheet | $360  (self-assessable) |

**Product stability and packaging (cont’d)**

|  |  |  |
| --- | --- | --- |
| ***Tick***  ***box*** | ***Description of change*** | ***Product type & fee*** |
|  | **Shelf life/storage conditions - Grade 2**   1. **revised shelf life and/or storage conditions with no other changes**   Consequential changes included (if applicable) are:   1. revised labelling and data sheet | $1,440 |
|  | **Container/closure/packaging - Grade 1**   1. **new pack size** 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 | $360  (self-assessable) |
|  | **Container/closure/packaging - Grade 2**   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 | $720  for any number of new container/  closure/packaging combinations |
|  | **Container/closure/packaging - Grade 3**   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 | $1,440  for *each* new container/closure/  packaging combination |

**Product stability and packaging (cont’d)**

|  |  |  |
| --- | --- | --- |
| ***Tick***  ***box*** | ***Description of change*** | ***Product type & fee*** |
|  | **Container/closure/packaging - Grade 4**   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 (stability study included)** 3. **does not affect dose measurement or dose delivery**   Consequential changes included (if applicable) are:   1. revised labelling and data sheet 2. revised packaging specifications | $2,160  for *each* new container/closure/  packaging combination |
|  | **Container/closure/packaging - Grade 5**   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 (stability study included)** 3. **affects dose measurement or dose delivery**   Consequential changes included (if applicable) are:   1. revised labelling and data sheet 2. revised packaging specifications | $2,880  for *each* container/ closure/ packaging combination |

**Indications and dosage**

|  |  |  |
| --- | --- | --- |
| ***Tick***  ***box*** | ***Description of change*** | ***Product type & fee*** |
|  | **Indications/dosage - Grade 1**   1. **new 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 generally be referred under section 24(5). | $2,880  for *each* new indication |

**Indications and dosage (cont’d)**

|  |  |  |
| --- | --- | --- |
| ***Tick***  ***box*** | ***Description of change*** | ***Product type & fee*** |
|  | **Indications/dosage - Grade 2**   1. **modified indication supporting clinical data required**   Consequential changes included (if applicable) are:   1. new dosage instructions 2. revised data sheet and labelling   **Note:** CMN will generally be referred under section 24(5). | $2,880  for *each* modified indication |
|  | **Indications/dosage - Grade 3**   1. **new dosage regimen** 2. **no change to indications** 3. **supporting clinical data required**   Consequential changes included (if applicable) are:   1. new dosage instructions 2. revised data sheet and labelling | $2,880  for *each* new dosage regimen |
|  | **Indications/dosage - Grade 4**   1. **revised wording of indications/dosage with no actual change to indications or dosage**   Consequential changes included (if applicable) are:   1. revised data sheet and labelling | $720 |
|  | **Indications/dosage - Grade 5**   1. **new or revised indications/dosage for a multi-source medicine to match indications approved for innovator product**   Consequential changes included (if applicable) are:   1. revised data sheet and labelling | $720 |

**Indications and dosage (cont’d)**

|  |  |  |
| --- | --- | --- |
| ***Tick***  ***box*** | ***Description of change*** | ***Product type & fee*** |
|  | **Contraindications, Warnings and Precautions**   1. **relaxation of contraindications, and/or** 2. **relaxation of warnings and precautions regarding use in pregnancy, lactation or particular population/patient subgroups** 3. **supporting clinical data required**   Consequential changes included (if applicable) are:   1. revised data sheet and labelling | $2,880 |

**Data sheet**\*

|  |  |  |
| --- | --- | --- |
| ***Tick***  ***box*** | ***Description of change*** | ***Product type & fee*** |
|  | **Data sheet - miscellaneous changes**   1. **update or addition to safety information with no change to approved product details, and/or** 2. **expansion of pharmacokinetic and/or pharmacodynamic data, and/or** 3. **change in name or address of distributor with no change to approved product details** | $360 for each data sheet. Please state the number of data sheets.  (self-assessable) |
|  | **Data sheet – format change**   1. **update to the SPC-style format only (required as part of any changes to the data sheet from 1 March 2017)** 2. **no change to the content or information provided within the datasheet** | No additional fee.  A $360 administrative fee applies per data sheet if this is the sole change. |

\*Both categories should be selected if applicable (ie, if there are miscellaneous changes AND the data sheet is being updated to the SPC-style format). All data sheets updated after 1 March 2017 must be in the SPC-style format.

**Labelling**

|  |  |  |
| --- | --- | --- |
| ***Tick***  ***box*** | ***Description of change*** | ***Product type & fee*** |
|  | **Labelling - Grade 1**   1. **re-design of label, and/or** 2. **change in name and address of distributor** 3. **no change to product name, strength, dose form, dosage instructions or indications** | $360  (self-assessable)  Not applicable if a change of the classification makes the product a Controlled Drug |

**Labelling (cont’d)**

|  |  |  |
| --- | --- | --- |
| ***Tick***  ***box*** | ***Description of change*** | ***Product type & fee*** |
|  | **Labelling - Grade 2**   1. **design or re-design of a New Zealand compliant label and/or** 2. **change in the classification to Controlled Drug** 3. **no change in actual strength, but a change in the way the strength is expressed (if applicable)** | $720 |
|  | **Labelling - Grade 3**   1. **request for a labelling exemption, or** 2. **request for renewal of a labelling exemption**   **NOT APPLICABLE for a CONTROLLED DRUG** | $720  (plus $360 for *each* additional name/ dose form/ strength/ flavour) |

**Other**

|  |  |  |
| --- | --- | --- |
| ***Tick***  ***box*** | ***Description of change*** | ***Product type & fee*** |
|  | **Sponsor**   1. **change of product sponsor from one company to another (not simply a change in the name or address of an existing sponsor)**   Consequential changes included (if applicable) are:   1. change of name and address of distributor on label and in data sheet. | $360  (self-assessable)  **Note:** A CMN for change in packing site(s) may also be required. |
|  | **Change in ownership**   * **change in ownership of manufacturing, testing or packing site for active ingredient, intermediate or finished product** | $720  for any number of new affected sites |

**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** |
|  |  |
| **Reason for change:** | |
| **Consequential changes:** | |
| **Acceptance overseas:** | |

**Section 5: Declarations and Commitments**

|  |
| --- |
| **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 <http://nzulm.org.nz> or email [listings@nzulm.org.nz](mailto:listings@nzulm.org.nz) for further details on NZMT listings)   1. **Compulsory declaration for all CMNs**   I confirm that other than the changes proposed in this CMN, all other aspects of API and finished product quality, equipment, process, and packaging etc, are the same as those previously approved.  Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   1. **Removal of sites from TPDR**   **Not applicable**  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.  Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   1. **Labelling**   **Not applicable**  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.  Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  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.  Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **or**  A labelling exemption is requested as follows (repeat as necessary):  Label for which the exemption is requested:  Part of label that is non-compliant:  Justification for exemption (see Guideline on the Regulation of Therapeutic Products in New Zealand Part 5):   1. **Security labelling**   **Not applicable**  If labelling contains anti-fraud or other security features a physical copy will be provided to Medsafe prior to the product being distributed in New Zealand.  Note: a description of any security features on labelling must be described as part of the proposed labelling.   1. **Declaration to accompany a DATA SHEET submitted for APPROVAL**   **Not applicable**  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.  Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  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.  Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Changes made are to align with the SPC-style format ONLY  I declare that this data sheet has been prepared with updates to the format only. No information has been added, removed, or amended.  Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   1. **CMI**   **Not applicable**  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.  Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   1. **Post approval stability**   **Not applicable**  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.  Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**Section 6: Other products affected**

Complete this section once for each notification package submitted. If you are simultaneously notifying an identical change or set of changes to a number of products, list all the products covered by the notification in the following table. Each dose form and each strength and flavour of each dose form of a product must be separately listed.

**Note:** A separate copy of Section 1 of this notification form must be completed for each of the products listed. Only one copy of Sections 2, 3, 4, 5 and 6 is required. All the forms must be submitted in the same notification package.

|  |  |  |  |
| --- | --- | --- | --- |
| **File No.** | **Product name** | **Dose form** | **Strength** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**Check and indicate that the notification package sent to Medsafe contains the following (as applicable):**

|  |  |
| --- | --- |
|  | *(Y or N/A)* |
| A completed copy of Section 1 of the CMN form for each product covered by the notification |  |
| One completed copy of Sections 2, 3, 4, 5 and 6 of the CMN form |  |
| One copy of the supporting data |  |
| A copy of an assessment report from an appropriate overseas regulatory authority |  |

**Notes on Calculation and Payment of Fees**

**Note 1:** If you are notifying identical changes to a number of products, the evaluation fee shown will be the largest fee that would apply to any single product. For example, if the notification covers Type I and Type II products, the evaluation fee applicable for a Type II product will apply.

**Note 2:** 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 3:** When the same change or set of changes is made to other names, dose forms, strengths and flavours of a product, a $360 (administrative) fee is charged for each of the other affected products.

**Note 4:** The fee for a changed data sheet (with the exception to a change to the format to align with the SPC-style requirements) is $360 **per data sheet**.

**Note 5**: Upon receipt of an application/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 application/notification. Payments are to be made on an invoice basis only - do not send payment with the application/notification.

**Note 6**: A customer reference (maximum 20 characters) can be quoted on the invoice. Quote reference here:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*(End of form)*

1. For further information on the meaning of not available please refer to <http://www.medsafe.govt.nz/Medicines/registration-situation.asp>. [↑](#footnote-ref-1)