**New Medicine Application Form**

**Intermediate-Risk and Higher-Risk Medicines**

Notes on completing the form:

Complete one copy of this form for each separate intermediate-risk or higher-risk medicine (name + dose form + drug substance(s) + strength + classification + flavour, as applicable). If there is a lower risk presentation of the same medicine, then use the New Medicine Application Lower-Risk Medicine application form.

Refer to the Guide to completing a New Medicine Application – Intermediate-Risk and Higher-Risk Medicines form (Application Guide) to select the correct category of application

1. **Proposed product details, required for all applications**

|  |  |
| --- | --- |
| **Type of application** |  |
| **Type of high-risk medicine (if applicable)**  (Biological or biotechnological, vaccine, blood product) |  |
| **Justification for application type selection** |  |
| **Proposed trade name** |  |
| **Identifier**  (Only applicable if the proposed trade name is the drug substance name) |  |
| **Drug substance and strength** |  |
| **Dose form** |  |
| **Route of administration** |  |
| **Classification**  (Refer to the Classification Database on the Medsafe website) |  |
| **ATC classification** |  |
| **Proposed indications and/or label claims:** |  |

**New Zealand Medicines Terminology:**

A New Zealand Medicines Terminology Listing Certificate should be provided as part of the Medsafe application process.

The New Zealand Medicines Terminology Listing Certification has been attached

Refer to [http://www.nzulm.org.nz](http://www.nzulm.org.nz/) or email [listings@nzmt.org.nz](mailto:listings@nzmt.org.nz) for further details on NZMT listings.

1. **Additional information, where applicable:**

**All products**

The product is currently approved in the following countries:

The product is currently pending approval in the following countries:

**Application that includes clinical data and/or bioequivalence studies (if applicable)**

|  |  |  |
| --- | --- | --- |
| **Details of reference product (complete the row that applies)** | | |
|  | **New Zealand reference product and strength with which the biostudy was conducted:** |  |
|  | **Australian reference product and strength with which the biostudy was conducted:** |  |
|  | **Other reference product and strength with which the biostudy was conducted:** |  |

**Application based on a parent product**

|  |  |
| --- | --- |
| **Details of parent product** | |
| **Product name** |  |
| **Identifier** (if applicable) |  |
| **File reference number** (if applicable) | TT50- |
| **Drug substance and strength** |  |
| **Dose form** |  |
| **Route of administration** |  |
| **Classification** |  |
| **ATC classification** |  |
| **Differences between the parent product and the proposed product** |  |
| **Sponsor** |  |
| **Evidence is included that the sponsor of the parent product has granted full access rights to the product approval file(s) for the parent product** | Yes  N/A  Comments: |

**Application based on an overseas approval**

If this application is submitted via the abbreviated evaluation pathway and meets the eligibility criteria outlined in the guidelines for New Medicine Applications, indicate the following:

|  |  |
| --- | --- |
| **Abbreviated process** | |
| **Regulatory authority name** |  |
| **Regulatory authority country** |  |
| **If EU, specify the procedure used** |  |

1. **Applicant and Sponsor details**

|  |  |
| --- | --- |
| **Name, job title and address of person submitting the notification (the applicant)**  All correspondence about the application, including acknowledgement letter and invoice, will be sent to this person by email.  Note: Include a letter of authorisation from the sponsor if not provided previously |  |
| **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** |  |

1. **Fees and Invoice details**

Select all application types that apply

All fees are GST inclusive

|  |  |  |
| --- | --- | --- |
| **Full applications** | Fee | Select |
| New higher-risk medicine containing one or more new active substances (NCE) | 106,503 |  |
| Any other new higher-risk medicine, including biosimilars | 79,877 |  |
| New intermediate-risk medicine – prescription medicine | 53,251 |  |
| New intermediate-risk medicine – non-prescription medicine | 26,626 |  |
| Additional dose form – higher-risk medicine – Grade 1 or 2 | 53,252 |  |
| Additional dose form – intermediate-risk prescription medicine – Grade 1 or 2 | 53,252 |  |
| Additional dose form – intermediate-risk non-prescription medicine – Grade 1 or 2 | 26,626 |  |
| New combination product – novel combination of approved active ingredients | 70,292 |  |
| New combination pack containing two or more currently approved products | 3,835 |  |

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| --- | --- | --- |
| **Abbreviated applications**  Names, strengths, flavours, and classifications must be notified at the same time as the parent application. | Fee | Select |
| Abbreviated new higher-risk medicine containing one or more new active substances (NCE)\* | 53,251 |  |
| Abbreviated any other new higher-risk medicine\* | 39,939 |  |
| Abbreviated new intermediate-risk medicine – prescription medicine\* | 26,626 |  |
| The list below is for any abbreviated application that includes significant post-approval variations **approved** by the overseas regulatory authority (refer to the New Medicine Application guideline, section 5.3, for the definition of a significant post-approval variation).  A limit of 5 significant post-approval variations can be included, with a maximum of 3 allowed without regulatory authority assessment reports. The assessment reports must be issued by the same regulatory authority upon who’s approval the abbreviated application is based.  Provide a brief sentence describing the change, followed by the corresponding Medsafe CMN form and CMN category this would have been notified under  *(eg, 1. Addition of a finished product manufacturing site*  *CMN Form A - Finished product manufacture - G2)*  Note: A fee will be charged for any significant post-approval variations that are included in an abbreviated application without regulatory authority assessment reports.  A fee will also be charged for the 3rd or more post-approval variation(s) submitted with regulatory authority assessment reports. The additional fee(s) will be the equivalent to that used for the equivalent CMN category(ies). | Indicate next to each variation if regulatory authority evaluation reports are provided (Y/N) |  |
| 1. |  |  |
| 2. |  |  |
| 3. |  |  |
| 4. |  |  |
| 5. |  |  |

|  |  |  |
| --- | --- | --- |
| **Additional names and strengths – concurrent with parent product**  The following fees apply when the additional products are applied for at the same time as the parent product[[1]](#footnote-2) | Fee | Select |
| Additional name − Grade 1 | 432 |  |
| Additional name − Grade 2 | 865 |  |
| Additional classification (with/without new name) | 432 |  |
| Additional strength − Grade 1 | 1,298 |  |
| Additional strength − Grade 2 | 1,730 |  |
| Additional strength − Grade 3 | 3,460 |  |
| Additional strength − Grade 4 | 10,785 |  |
| Additional strength − Grade 5 | 16,177 |  |
| Additional flavour or type of sweetening | 865 |  |

|  |  |  |
| --- | --- | --- |
| **Additional names and strengths – subsequent to the approved parent product**  The following fees apply when the additional products are subsequent to approval of the parent product (ie, when additional product applications are submitted after approval of the parent product).[[2]](#footnote-3) | Fee | Select |
| Additional name − Grade 1 | 865 |  |
| Additional name − Grade 2 | 1,730 |  |
| Additional classification (with/without new name) | 865 |  |
| Additional strength − Grade 1 | 2,595 |  |
| Additional strength − Grade 2 | 3,459 |  |
| Additional strength − Grade 3 | 6,919 |  |
| Additional strength − Grade 4 | 21,569 |  |
| Additional strength − Grade 5 | 32,354 |  |
| Additional flavour or type of sweetening | 1,730 |  |

|  |  |  |
| --- | --- | --- |
| **Provisional consent** | Fee | Select |
| Provisional consent to distribute a new medicine (clinical need)  High risk NCE | 70,292 |  |
| Provisional consent to distribute a new medicine (clinical need)  High risk other | 52,719 |  |
| Provisional consent to distribute a new medicine (stock shortage)  High risk other | 15,975 |  |
| Provisional consent to distribute a new medicine (stock shortage)  Intermediate risk | 10,650 |  |
| Provisional conversion to full approval (clinical need)  High risk NCE | 35,146 |  |
| Provisional conversion to full approval (clinical need)  High risk other | 26,359 |  |
| Provisional conversion to full approval (stock shortage)  High risk other | 63,902 |  |
| Provisional conversion to full approval (stock shortage)  Intermediate risk | 42,601 |  |
| Application for renewal of provisional consent | 11,982 |  |

**Invoice details**

|  |  |
| --- | --- |
| **Calculated fee** | $ |
| **Comments** |  |
| **Customer reference code for invoice**  (Optional; maximum 20 characters): |  |

1. **Product formulation:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Name of ingredient**  (For drug substance, identify amount equivalent to free base, if applicable) | **Type of ingredient** | **Quantity**  (Specify units) | **Quality standard** |
| Component name (if applicable) | | | |
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**Proprietary ingredients**

For products that include one or more proprietary ingredient, select and complete the option(s) that apply:

|  |  |  |
| --- | --- | --- |
|  | The quantitative formulation was previously provided to Medsafe | Name:  Supplier code: |
|  | The quantitative formulation has not previously been provided to Medsafe and is presented in Module 3 | Module 3 page: |
|  | The quantitative formulation has not previously been provided to Medsafe, and will be sent directly from the supplier with the Proprietary ingredient registration form <https://www.medsafe.govt.nz/regulatory/forms.asp> | Name:  Supplier code:  Supplier: |

1. **Product packaging, patient information, and storage conditions:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Notes:  Complete this table for each proposed container/closure/package type. Create a copy of the table for each additional container/closure/package type. | | | | | |
| Primary container description | |  | | | |
| materials of construction | |  | | | |
| Closure description | |  | | | |
| materials of construction | |  | | | |
| Secondary package description | |  | | | |
| materials of construction | |  | | | |
| Administration device description | |  | | | |
| materials of construction | |  | | | |
| Pack size(s) to be registered: | |  | | | |
| A package insert is to be supplied with the product | | **Yes**  **No** | | | |
| Proposed shelf life and storage conditions: | Protect from light | | Protect from moisture | Do not refrigerate | Do not freeze |
|  |  | |  |  |  |
|  |  | |  |  |  |
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|  |  | |  |  |  |

1. **Production**

**Manufacturing of the drug substance**

|  |  |
| --- | --- |
| Name of drug substance |  |
| Name of manufacturer |  |
| Manufacturing site address |  |
| Regulatory authority which issued the GMP evidence |  |
| GMP evidence date of expiry |  |
| DMF number, if known  Or Certificate of Suitability number | TT60-  R -CEP     -   -Rev |
| Letter of access provided |  |

**Manufacturing of the drug product**

|  |  |
| --- | --- |
| Name of manufacturer |  |
| Manufacturing site address |  |
| Regulatory authority which issued the GMP evidence |  |
| GMP evidence date of expiry |  |
| Manufacturing steps carried out at this site |  |

**Packing of the drug product**

|  |  |
| --- | --- |
| Name of packer |  |
| Site address |  |
| Regulatory authority which issued the GMP evidence |  |
| GMP evidence date of expiry |  |
| Packing steps carried out at this site |  |

**Testing of the drug product**

|  |  |
| --- | --- |
| Name of testing site |  |
| Address |  |
| Regulatory authority which issued the GMP evidence |  |
| GMP evidence date of expiry |  |
| Testing carried out at this site |  |

**Biostudy/clinical site (if applicable)**

|  |  |
| --- | --- |
| Name of testing site |  |
| Address |  |

**Bioanalytical testing site (if applicable)**

|  |  |
| --- | --- |
| Name of testing site |  |
| Address |  |

**New Zealand site of batch release**

|  |  |
| --- | --- |
| Name of release site |  |
| Street address of batch release site |  |

1. **Provided information**

|  |  |
| --- | --- |
| **Documentation** (Please ensure ALL relevant sections in this table are completed) | **Section** |
| **Module 1** |  |
| * Detailed table of contents for the dossier |  |
| * Labels |  |
| * Data sheet |  |
| * Package Insert |  |
| * GMP documentation |  |
| * CEP with declaration of access |  |
| **Abbreviated process documentation** |  |
| * Detailed table of the overseas regulatory history |  |
| * Evaluation reports from overseas regulatory authorities |  |
| * Company responses to issues raised and evaluation of the responses by overseas regulatory authorities |  |
| * Overseas approval details (approval letter, specifications) |  |
| **CTD Module 2**  Overviews and Summaries |  |
| **CTD Module 3**  Chemical, pharmaceutical, and/or biological documentation |  |
| * Drug product formulation/Batch formula |  |
| * Drug product release and expiry specifications |  |
| * Proprietary ingredients formulation |  |
| **CTD Module 4**  Toxicological and pharmacological (pre-clinical) documentation |  |
| **CTD Module 5**  Clinical Documentation |  |
| * Bioequivalence study results |  |
| * Bridging study between the reference product used in the biostudy and the New Zealand reference product |  |
| * Bioanalytical method validation |  |
| **Drug Master File(s) or Plasma Master File(s)** |  |
| Letter(s) of access to the Drug Master File(s) or Plasma Master File(s) |  |

**The electronic dossier should be hyperlinked and copy-enabled**

1. Fees for this category are cumulative. That is, an applicable fee is charged for each additional name, strength, etc. [↑](#footnote-ref-2)
2. Fees for this category are cumulative. That is, an applicable fee is charged for each additional name, strength, etc. [↑](#footnote-ref-3)