**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 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 |[ ]

|  |  |  |
| --- | --- | --- |
| **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 |
|  | [ ]  | [ ]  | [ ]  | [ ]  |
|  | [ ]  | [ ]  | [ ]  | [ ]  |
|  | [ ]  | [ ]  | [ ]  | [ ]  |
|  | [ ]  | [ ]  | [ ]  | [ ]  |
|  | [ ]  | [ ]  | [ ]  | [ ]  |

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 knownOr 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)