Guide to completing a New Related Product Application

Introduction

This guide is provided to assist you with putting together a New Related Product application.

For lower-risk, intermediate-risk, or higher-risk medicines please refer to the relevant guides (ie, Guide to completing a New Medicine Application – Lower-Risk Medicines; and the Guide to completing a New Medicine Application – Intermediate-Risk & Higher-Risk Medicines).

Not everything in this document applies to every new related product application and the guide should only be used as a reference to completing the application form.

Additional resources that you should utilise when putting together your application include:

- the relevant New Zealand medicines legislation
- international guidelines
- pharmacopoeias
- the Guidelines for Regulation of Therapeutic Products in New Zealand (GRTPNZ), particularly the 'New and Changed Related Products' guideline.

NOTE: Please do not send this document to Medsafe with your application.

Contents

1. Instructions for using the form for a New Related Product Application

The New Related Product Application Form (the form) is designed for electronic completion. All fields of the form should be completed.

2. Application form for a New Related Product Application

The form should be used when applying for consent to distribute a new related product.

The form should be used for line extension applications, including applications for additional name, strength or flavour.

Each new application should be accompanied by a completed Related Product Declarations and Commitments form.

3. Determining the application category

Before submitting an application, check that your product meets the definition of a related product. Refer to the Guideline on the Regulation of Therapeutic Products in New Zealand; New and Changed Related Products.

4. Application format

Applications must be submitted in the CTD format.

The only allowable exemption to the requirement for CTD format is for responses to RFIs, but only when the additional information or data is limited in volume. It is important for all RFI responses that the additional information or data be cross-referenced to the outstanding questions/issues in the RFI letter in numerical order.

The application must be submitted electronically. Refer to Section 3 of the 'Overview of Regulatory Processes for New and Changed Medicines, Fees, and Timelines' guideline.

One copy of the application form must be completed for each separate product – this means that any variation in the name, dose form, strength, classification, or identifier (eg. different flavour) will require a separate form.

5. Proposed product details, required for all applications

Type of application:

Enter the type that best describes your application. The fee will be calculated from this information.

One copy of the application form must be completed for each separate product – this means that any variation in the name, strength, or identifier (eg, different flavour) will require a separate form.

If you are submitting several forms for the same product, all additional versions should have "Based on a parent product" as the type of application.

If you are submitting an application based on a previously approved product, the first form should have "Based on a parent product" as the type of application.

Proposed trade name:

This is the proposed name under which the product will be marketed in New Zealand.

Identifier:

If the proposed product is an extension of an existing product range, or the trade name is the drug substance name, the point of difference between the proposed and existing products should be stated (e.g. manufacturer, flavour, strength).

Drug substance:

This is the active ingredient in the proposed product. If the medicine contains multiple active ingredients, separate these by commas.

Dose form:

Proposed dose form(s) should be listed.

Strength:

The strength should be as stated on the labelling for each presentation of the product. The strength should be stated as the content of the active ingredient base form.

New Zealand Classification:

New Zealand schedule of classifications can be found at the Medsafe website.

Enter the name of the drug substance and click search.

Route of administration:

The route of administration should be listed. For a related product, this is most likely to be oral or transdermal.

ATC Classification:

The ATC classification system can be accessed at the WHO website.

Search for the drug substance in the product field and enter the found description and the code into the Application Form field.

Proposed indications and/or label claims:

Proposed indications or label claims should be listed for all products.

6. Additional information, where applicable

All products:

Please list the details of the overseas approvals or submissions - country name, regulatory agency, and approval or submission date should be specified. Separate multiple entries by commas.

Application based on a parent product:

An ‘approved parent product’ is a previously approved product where the safety, efficacy and quality of the medicine have been acceptably demonstrated, and that complies with current standards. The name and TT50 number of the approved parent product should be provided.

If the parent product is not approved (that is, it is part of the current application), the details should be consistent with the first (parent) application form.

The relationship between the two products should also be detailed in the cover letter. Full access rights to the parent product must be provided.

The differences between the parent product and new product must be described in the application form. Additional information may be included in the cover letter.

Differences between parent product and new product:

Additional name - Grade 1	• new name to be used in addition to existing name • all other details identical to parent product except for labelling • new label displays new name, but all other information on the label is essentially the same as on the parent product label (even if layout is different)
Additional name - Grade 2	• new name to be used in addition to existing name • all other details identical to parent product except for labelling • new label displays new name • layout of label may be different from that of parent product • some other information on the label is different from that on the parent product label
Additional strength	• new and parent products have the same dose form
Additional flavour or type of sweetening	• new and parent products have the same dose form • new product has a flavour or type of sweetening different from the parent product • all other details identical to parent product except for labelling (if applicable) and specifications

7. Applicant and Sponsor details

New Zealand Sponsor:

Details, including the street address, of the licence holder (entity responsible for the product on the New Zealand market) should be provided.

Applicant:

Details of the company or individual responsible for submitting the application and for responding to all correspondence should be provided. A letter of authorisation should be included in the application, if not previously provided.

8. Fees and Invoice details

Calculate the fee based on a parent product information. Medsafe will verify the calculation and fee. All fees are GST inclusive. A space is included for comments relevant to invoicing.

On acceptance of the application (following screening), a tax invoice and acknowledgement letter will be sent to the applicant. The invoice will be made out to the New Zealand Sponsor as this is the entity legally responsible for the application.

A customer reference can be quoted on the invoice, if required.

9. Product formulation

Formulation details should be entered as provided in Module 3.2.P.1 of the dossier. Appropriate quality standards and units should be specified for each ingredient.

The salt form of the drug substance should be entered into the table and the amount of free base should be included in brackets beside the salt form.

The details of the proprietary ingredients should be supplied. If the ingredient has been previously registered with Medsafe, include the name and the reference number. If the ingredient has not been previously registered with Medsafe, include in the dossier or arrange for the supplier to provide Medsafe with details of the unique company identifier (name, number), quality specifications, quantitative and qualitative formulation, and quality standards of individual ingredients issued by the suppliers. The formulation table should only include the proprietary ingredient name, content, and quality standard.

10. Product packaging, patient information, and storage conditions:

Primary packaging refers to the packaging directly in contact with the drug product.

Secondary packaging refers to the first component opened by the consumer, and any additional wallets, pouches, blister lidding, etc. All should be briefly described.

All pack sizes proposed with the application should be listed.

All applicable shelf life and storage conditions should be entered using only the provided dropdown lists.

Any package types that are not applicable should have 'Not applicable' entered.

11. Production

Manufacturers:

The address of the actual site of manufacture should be provided.

GMP certification should be issued by a recognised authority as listed in the GRTPNZ. This is only required for related products intended to be taken internally. For other products some form of non-GMP certification is expected eg, ISO, client audits.

The site information should be completed for each individual manufacturing steps, even if a site conducts steps.

If a manufacturing step is not applicable to the application type 'Not applicable' should be entered in the name section.

DMF/Certificate of Suitability:

This information is only relevant if a DMF or Certificate of Suitability is available.

The DMF number refers to the number assigned to the DMF by Medsafe.

If the DMF number is not known, this field should be left blank. If supplying certificates of analysis as evidence of drug substance quality for a lower risk product, this section should be left blank.

Site responsible for batch release:

This should be the site holding documentation for batches released onto the New Zealand market and is not necessarily the testing site.

If the medicine is manufactured and packed overseas, the company should advise the name and address of the company who is importing the medicine into New Zealand. This site is termed the New Zealand site of batch release and is responsible for undertaking the duties described in section 42 of the Medicines Act 1981.

12. Provided information

Please indicate the section in which the documents specified on the NMA form can be found, so administration staff and the evaluators can quickly locate pertinent information in the dossier.