Australian Government
Department of Health
Therapeutic Goods Administration

Reformatting Product Information

Frequently asked questions

Version 4.2, March 2020

TGA Health Safety Regulation

Contents

A new product information (PI) form was approved on 8 November 2017, with a commencement date of 1 January 2018. From this date, PI documents that must accompany relevant registration applications will need to be prepared in accordance with the format of this new form. The PIs for all marketed products will need to be in the new format by 31 December 2020.

A revised version of this form was approved on 8 March 2018 following amendments to the *Therapeutic Goods Act 1989* (the Act). The revised version includes updated references to the Act as well as updates to the form to improve its clarity and provide some additional instructions. These revisions do not change the form substantively from that which commenced in January 2018.

The TGA has developed the following Frequently Asked Questions to assist sponsors with reformatting their approved PI, or preparing a new PI in the required format.

For further information on the PI reformat you can contact the TGA: PI.reformat@health.gov.au.

General FAQs

Why is the PI being reformatted?

The TGA is changing the format of the PI document to ensure that the critical clinical information is more accessible within the document. TGA has developed the new format in consultation with health professionals and sponsors, who support its implementation. In addition, the new format has been developed to align with the formatting requirements of other international regulators, specifically the New Zealand medicines regulator Medsafe, and the European Medicines Agency.

What is changing in the PI format?

The key changes are:

- the content of the PI is being re-ordered to bring critical clinical information together at the front of the document
- the headings and subheadings have been updated to align with headings used internationally.

Some new subheadings have been added to facilitate the harmonisation of format with that used in New Zealand and Europe. Many currently approved PIs already include content that relates to these headings, for example the effects of the medicine on a person's ability to drive and use machines. For these medicines, this information will now be located in a standardised place in the PI. For medicines that do not currently include such information, standard text has been provided in the *Form for providing Product Information*, and can be inserted as part of the reformatting process.

An annotated version of the form has been prepared to indicate where new content has been added, including optional and mandatory standard text.

What has changed in the form approved on 8 March 2018?

A revised *Form for providing Product Information* was approved on 8 March 2018. The form was revised following recent amendments to the *Therapeutic Goods Act 1989* (the Act). The new instrument of approval provides updated references to the appropriate subsections of the Act, updated transition arrangements and some other editorial changes. There have also been a number of changes to the form, which are:

- Clarification that only clinically relevant physical and chemical characteristics should be included in Section 2. Other physical and chemical characteristics should be included in Section 6.7.
- Clearly indicating which subheadings are mandatory in Sections 4.4, 5.1 and 5.3.
- Addition of a new mandatory subheading has been introduced in section 4.8 – 'Reporting suspected adverse effects'.
- Clarifying that only the subheadings that are relevant to the product need to be included in Section 5.2. For example, a product administered intravenously would not require the 'absorption' subheading.
- Providing an alternative optional standard text for section 6.6 which is more relevant to products used in healthcare settings.
- Other minor editorial changes have been made which do not affect the interpretation of the form.

These changes are also highlighted in the annotated version of the form provided at the end of these FAQs.

I have already provided a reformatted PI to the TGA. Do I need to make further changes due to the March 2018 version of the form?

No. If you have already reformatted your PI you are not required to make further changes. However, it is recommended that you include the subheading 'Reporting suspected adverse effects' in section 4.8 at your next PI update.

Can I make other editorial changes to the PI during reformatting?

Reformatting is considered as:

- updating or adding headings to align with the new PI format
- adding optional standard text and mandatory standard text, including additional sponsor contact information in section 8as described in the*Form for providing Product Information*
- updating cross-references to include section number and updated heading, and updating table and figure numbers

Reformatting does not include other editorial changes such as re-ordering of information within a section, or rephrasing the approved content. These changes must be annotated on the PI, and requested with the appropriate application type (i.e. with a MEC application).

Updated When can I reformat my PI?

PIs can be submitted to the TGA in the new format now, for any application with a decision date after 1 January 2018. For Category 1 applications currently under evaluation, it is strongly recommended that the PI is reformatted as part of the current submission.

PIs accompanying Category 1 applications must be provided in the new format if they are submitted after 1 January 2018. In addition, Section 23 Category 3 applications and Section 23 Self-Assessable Requests must also be accompanied by a reformatted PI if submitted after 1 January 2018.

Reformatted PIs can also be submitted with any other application type related to that medicine, including minor variations, safety related requests, and applications to update medicine ingredient names. Reformatted PIs submitted with any other application type do not attract an additional fee.

Reformatted PIs can also be submitted as a stand-alone application. Fees are waived for stand-alone applications to reformat PIs if submitted between 1 January 2020 and 31 December 2020, if no other changes are made. See Submission FAQs for more information.

Updated What are the transition arrangements?

The new PI format will be implemented with a 3-year transition period. PIs that are updated through an application to the TGA during the transition period should be provided in the new format. Reformatted PIs may also be submitted with other application types that do not seek changes to the PI. There will be no additional fee to 'bundle' the reformatting of the PI with another application type. See 'Submission FAQs' for further information on how to submit reformatted PIs to the TGA.

Reformatted PIs can also be submitted as a stand-alone application. Applications should be submitted as a Minor Editorial Change (MEC) through the TBS portal, using the PMMV (Prescription Medicine Minor Variation) E-Form. See the relevant 'Process Guidance' for further information about how to submit a reformatted PI to the TGA as a stand-alone application. Applications where the only variation made to the product(s) is to reformat the PI (as described

above) and no other editorial changes are made will be exempt from fees between 1 January 2020 and 31 December 2020. Applications where additional editorial changes are made at the same time as reformatting the PI will not be exempt from fees. See Submission FAQs for more information. Further information about fees is available on the TGA website.

Do I need to reformat the PI if the product is not marketed?

No. Only products that are marketed are required to be reformatted during the transition period. If you decide to market the product, the PI will need to be reformatted prior to marketing. However, you may reformat the PI of non-marketed products during the transition period if you choose to.

Do I need to update my Australian Specific Annex to the Risk Management Plan following reformatting a PI?

As the content of the PI is not changing as part of the reformat, there is no requirement to update the table in the Australian Specific Annex (ASA) that compares the wording in the PI and the Summary of Product Characteristics (SmPC). When the ASA is next updated, you should consider whether any revision is warranted to the content of the table with respect to the headings and subheadings referred to in the PI.

Including the PI in the packaging is a condition of registration for my product. Do I need to replace paper copies of the PI in the packaging prior to completion of the transition period?

No. It is acceptable for PIs in the old format to be phased out as sponsors exhaust stock of products that contain the PI in the old format. Following the PI being reformatted, new stock should have the new version of the PI included in the packaging.

Can I use the PI as a package insert in Australia and New Zealand?

The new PI format has been developed in consultation with Medsafe. The format of the PI aligns with the format requirements for the New Zealand Data Sheet. Sponsors should be able to use the Australian PI in the box of injectable products for Australia and New Zealand, if:

- the indications and dosing information align, and
- the content of the Australian PI also meets the requirements for use in New Zealand.

If additional content is required to meet NZ regulatory requirements, sponsors can seek to modify the Australian PI by submitting the appropriate application type to the TGA.

Updated Can I make changes to the PI other than those considered as formatting changes?

Yes. Any changes to PIs will require an application to the TGA, which may incur a fee. Applications for PI reformats can be bundled with another application, for example a Type F or J application, a safety-related request or a minor editorial change. These requests should be clearly indicated in the annotated version of the PI and the cover letter. Applications to reformat reformat a PI can be submitted as a stand-alone application. See Submission FAQs for more information. Further information about fees is available on the TGA website.

Submission FAQs

What is the legal declaration in the eForm and why must it be stated on the cover letter of all PI reformat applications?

To ensure that no unauthorised changes have been made to the PI, sponsors will be required to acknowledge a legal declaration in the TGA eform. You must also include the declaration in your cover letter to facilitate timely processing of the reformatting application. If your application does not use the TGA eform, please ensure you have included the declaration in your cover letter. The legal declaration is as follows:

I declare that:

where product information ("PI") is provided with this submission:

- *no amendments other than the amendments that are identified in the annotated version of the PI in Module 1.3.1.2 will be made to the PI;*
- *apart from any amendments to the content of the PI identified in Module 1.3.1.2, all content of the current PI approved under section 25AA of the Therapeutic Goods Act 1989 has been retained;*
- *any changes to the PI that do not relate to the submission are limited to:*
  - *changes to the text that are required as mandatory standard text or specified as optional standard text in the form for product information that was approved on 8 March 2018; and*
  - *changes to headings and cross-references that are necessary in order to comply with the form for product information that was approved on 8 March 2018.*

Note: Random audits of PIs that are reformatted to comply with the form for product information that was approved on 8 March 2018 will be undertaken to verify that no undeclared changes to content have been made.

Updated Does the reformatted PI need to be submitted as an annotated and clean copy?

If the PI is only being reformatted, without any content changes other than those considered part of reformatting (updating headings and/or subheadings, updating numbering and cross-references of tables and figures, and inclusion of standard text), then an annotated copy is not required. However, clean copies of both your currently approved PI and the reformatted PI should be submitted.

If the PI is being reformatted as part of an application to make content changes to the PI, then the PI should be reformatted prior to any updates to the content. Following the reformatting process, 'track changes' should be turned on to create an annotated version that clearly identifies the proposed updates to the PI. Any changes to the original content of the PI should be tracked. If you are adding new information under the new mandatory subheadings (e.g information from the ARTG for section 6.1 list of excipient or section 6.5 Nature and contents of container), please ensure you tracked those changes. For these applications the following documents should be submitted: clean copy (old format, no changes), clean copy (new format, no changes), annotated copy (new format, tracked/annotated changes) and clean copy (new format, with proposed changes).

New I am reformatting the PI as a stand-alone application. How do I apply? How do I access the fee waiver?

Applications should be submitted using the online PMMV (Prescription medicine minor variation) e-form through the TBS portal. You will need to select the code 'PIME' for a minor editorial change (MEC) application. Please include the following text in the 'Comments Field' section and the cover letter of your dossier:

"This is a PI reformat only application for fee exemption."

As per standard billing processes, your company will still receive an invoice for the MEC application. We ask you to inform your billing department to withhold payment of this invoice as a subsequent credit note will be generated and provided to the sponsor which will nullify the invoice (i.e. the TGA will not be seeking payment of this invoice). If your organisation does proceed to pay an invoice and your application is eligible for a refund, this will be managed as per standard TGA process.

Your PI reformat only application will be subject to a filtering process to ensure all the PI changes proposed in your application comply with the Therapeutic Goods Regulations 1990, which enable the refunds and fee waivers to PI reformat only related applications. You will be notified if the fee waiver can be applied to your application. Once you have been notified, the application will proceed as per standard TGA processes.

You can still combine your PI reformat changes with your other minor variations applications. This type of application will not be subject to a filtering process, which can lead to possible delays.

New What changes are not considered part of a PI Reformat (and will incur a fee)?

Changes to the Therapeutic Goods Regulations 1990 came into effect in 1 January 2020, which enable refunds and waivers to be provided in relation to fees for PI reformat changes. The refunds and waivers will only apply in relation to requests expressly confined to PI reformat related changes. The refunds and waivers will not be extended to changes unrelated to PI reformat; these unrelated changes, will incur a fee and be progressed as per standard TGA processes.

Please see below for examples of unrelated PI reformat minor editorial changes that would therefore incur a fee:

- Changes to the corrections of the spelling in the PI, for example changing from frusemide to furosemide
- Addition of any new statements to the PI, unless the statements are mandatory or recommended standard statements. Example of mandatory or recommended statements include "No data available" or "In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging". For PI reformat standard texts, please see '*Form for providing Product Information*'
- Any changes to currently approved texts, for example:

  "A reduction in hair growth, hair shaft diameter and hair pigmentation is are seen"

If additional changes to the PI have been identified during the filtering process, you will need to pay the invoice as the fee waiver cannot be applied.

I am reformatting the PI as part of an application – how do I notify the TGA that the PI has been reformatted?

You can submit your reformatted PI as part of an application (for example Category 1, Category 3, Safety-Related Request). For all applications, the cover letter should clearly state that "we request to reformat the PI as part of the application". In addition, for minor variations submitted using the e-form, please include the request to reformat the PI in the comments section of the e-form.

How do I submit my reformatted PI in eCTD format?

Updated electronic Common Technical Document (eCTD) specifications will be available for use from 1 January 2018, with the current specifications available until 30 June 2018.

Under the current specifications (version 3.0), *Module 1.3.1.1 Product Information – clean* should contain the clean copy in the new format, which includes the proposed changes. The other PI documents should be placed in *Module 1.3.1.2 Product Information – annotated*; this should include copies of the approved PI in the old format, the reformatted PI without changes, and the reformatted PI with tracked/ annotated changes.

Under the new specifications (version 3.1), *Module 1.3.1.1 Product Information – clean* should contain the clean copy in the new format, which includes the proposed changes. *Module 1.3.1.3 Product Information – approved* should contain the currently approved PI in the old format. Copies of the reformatted PI without changes, and the reformatted PI with tracked/ annotated changes should be provided in *Module 1.3.1.2 Product Information – annotated*.

Further information on submitting a reformatted PI in eCTD format separately from an application will be provided when available.

Technical FAQs

Does my PI need a title on the first page?

Yes – your current title should be retained at the top of the PI. It is recommended that this title include the terms 'Australian Product Information', followed by the tradename and name of the active ingredient in brackets. It is considered best practice to also include the dose form when practical (for example 'tablets', 'solution for injection').

Where should my boxed warning be located?

If your PI has a boxed warning its location should be the same in the reformatted PI. For example:

- if the boxed warning is currently located prior to the name of the medicine in the current PI, it should be located above Section 1 in the reformatted PI; or
- if it is currently located in the contraindications section, it should remain in the contraindications section (Section 4.3)

Do changes to headings and subheadings constitute 'content change'?

No. Adding or updating the text of headings and subheadings to align with the new form is considered to be part of the reformatting process. Similarly, updating references within the text to align to new headings and/or subheadings is not considered to constitute a 'content change'.

Do I need to update cross-references in my PI?

Yes. Following the reformatting process, you should ensure that the tables and figures in your PI are labelled in chronological order, and update the references to these tables and figures within the PI text. In addition, any cross-references to headings and subheadings should be updated to reflect changes to the wording of these heading and subheadings. The updating of these cross-references is not considered to be a content change. Cross-references to other sections of the PI should include the section number. It is considered to be best practice to include both the section number and section heading in the cross-references.

Is the inclusion of standard text considered 'content change'?

No. Inclusion of either the optional standard text or mandatory standard text in line with recommendations in the *Form for providing Product Information* is not considered to constitute a change in the content of the PI.

How do I include electronic bookmarks in my reformatted PI?

A PI template has been prepared by the TGA to assist sponsors in reformatting their PI, or preparing new PIs. There are two versions of the template – one for products included in the black triangle scheme, and one for other products. The templates contain the appropriate bookmarks for headings and subheadings. It is recommended that sponsors use the template to ensure appropriate headings and bookmarks are included in the PI. The templates can be found on the TGA website. The bookmarks should be retained during the pdf conversion. This can be done by selecting the appropriate preferences for the software you are using.

For example, in the 2010 version of Microsoft Word, this is done in the 'Acrobat' tab, by selecting 'preferences' then the 'bookmarks' tab and checking the 'convert word headings to bookmarks' box.

Are the fonts and formatting in the PI template provided by the TGA mandatory?

No, the fonts included in the PI template are indicative only.

Sections 1 to 3

Section 1 – What information should be included under Name of the Medicine?

Only the Australian Approved Name(s) of the active ingredient(s) should be included in this section. Do not include trade names.

Updated Section 2 – Where should I list the excipients?

For reformatted PIs, the full excipient list included under 'Description' in the current PI can be retained in Section 2, and the optional standard text 'Refer to Section 2' should be included in Section 6.1.

For new PIs and those PIs being reformatted as part of an application to update the PI, excipients with 'known effect' should be listed in Section 2, and the full list of excipients included in Section 6.1. Excipients with 'known effect' are those included in Schedule 1 of TGO 91 or 92 (noting that the content of these schedules is the same). When listing excipients with known effects, please include the sub heading, 'Excipients with known effect', in section 2.

Section 2 – What information should I move to section 6.7?

Information such as physiochemical properties (for example, colour of the Active Pharmaceutical Ingredient), solubility and pKa values should generally be moved to section 6.7 unless the information is of such clinical importance that it should be retained in this section.

Sections 2 and 3 – Can I combine these sections if I am reformatting an approved PI?

For PIs being reformatted, it is acceptable to combine these sections with the following heading: '2 AND 3 QUALITATIVE AND QUANTITATIVE COMPOSITION AND PHARMACEUTICAL FORM'. It is recommended that this approach is only used if the current PI content contains the required information together in one statement. Wherever possible, it is considered best practice to separate these sections.

Section 3 – What is meant by 'pharmaceutical form should be described by the AAN' in Note 5?

The dose form used to describe your product in Section 3 should be the same as that used in your application to register the product. The approved terminology for dose form can be found in the Code Tables (see Where to find the approved terminology).

Section 4

Section 4.4 – Do I need to add information on use in hepatic and renal impairment?

No. However, if your current precautions include information on use in hepatic or renal impairment the content should be relocated to align with the order. Please also ensure you update the renal and hepatic subheadings to reflect the *Form for providing Product Information*.

Section 4.4 – Are the headings 'Use in the elderly', 'Paediatric use' and 'Effects on laboratory tests' mandatory?

Yes – these headings were required in the previous form, and remain mandatory in the new form. If your approved PI does not include these headings, the following options are available:

i. If there is no information available related to these headings then 'no data available' may be added.

ii. If information is available in another section of the PI, a cross reference may be added (for example, 'See Section 4.2 Dose and method of administration')

iii. If the PI contains an already approved statement regarding these headings, then the approved text may be replicated under these headings.

Any new text included under these headings should be indicated as a change in the annotated version of the PI.

Section 4.7 – Do I need to add information on effects on ability to drive and use machinery?

If your current PI includes a statement on effects on ability to drive and use machinery, it should be relocated to Section 4.7. If there is a major effect of the medicine on the ability to drive and use machinery then this information should also be included as a precaution, with a cross-reference between sections 4.4 and 4.7. If you do not currently have a statement on these effects, you have two options:

i. the optional standard text '*The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration*' can be added, or

ii. you can apply to add the information as a Safety Related Request, or as part of a Category 1 application. Submission of the currently approved European Summary of Product Characteristics (SmPC) would be considered sufficient evidence to support the addition of the statement that is in the SmPC. For an SRR, it is appropriate to select the application type as one not requiring evaluation of data.

Section 4.8 – Is the content of the adverse effects section changing?

No, the content must still comply with the Australian requirements specified in the *Form for providing Product Information*.

Please note that there is a new requirement to include the mandatory statement on how to report adverse events in this section under the subheading 'Reporting suspected adverse effects'.

Section 5

Section 5.1 – What information should be included under the Clinical Trials heading?

The entire content included under the current Clinical Trials heading should be relocated to Section 5.1, under the subheading 'Clinical Trials'. This should be located after the statements under the 'Mechanism of Action' subheading.

Section 5.2 Are the headings 'Absorption', 'Distribution', 'Metabolism' and 'Excretion' mandatory?

The subheadings of 'absorption', 'distribution', 'metabolism' and 'excretion' in section 5.2 are not mandatory. You should use these headings if they are relevant to the pharmacokinetics of your product.

Section 5.3 – The carcinogenicity statement contains clinical information – where should it be located?

If there are clinical statements under the carcinogenicity subheading currently included in the precautions section, then the entire carcinogenicity statement (clinical and nonclinical findings) should be included in Section 4.4 'Special warnings and precautions for use', with a subheading of 'Carcinogenicity'. In this situation, the carcinogenicity subheading should be retained in section 5.3, but the following text should state 'refer to Section 4.4 Special warnings and precautions for use'.

Section 5.3 – Do I need to add information on preclinical safety data when I reformat my PI?

No. The information currently under the subheadings *Genotoxicity* and *Carcinogenicity* should be relocated to section 5.3.

Section 6

Section 6.1 – Where should I include information on excipients?

For reformatted PIs, the full excipient list included under 'Description' in the current PI can be retained in Section 2, and the optional standard text '*Refer to Section 2*' should be included in Section 6.1.

For new PIs and those PIs being reformatted as part of an application to update the PI, excipients with 'known effect' should be listed in Section 2, and the full list of excipients included in Section 6.1. Excipients with 'known effect' are those included in Schedule 1 of TGO 91 or 92 (noting that the content of these schedules is the same).

Section 6.2 – Do I need to add information on incompatibilities?

No. The optional standard text '*Incompatibilities were either not assessed or not identified as part of the registration of this medicine*' can be used under this heading if no information is currently included in the approved PI.

Section 6.3 – Do I have to add information on shelf life?

It is recommended that sponsors include the optional standard text '*In Australia, information on the shelf life can be found on the public summary of the ARTG. The expiry date can be found on the packaging*' under this heading. It is not recommended to include the actual approved shelf life (such as 12 months or 48 months) in the PI as this may change over time.

Section 6.4 – Do I need to include additional information on special precautions for storage?

No. The information on storage conditions included in the current PI should be relocated under this subheading.

Section 6.6 – Do I need to add information on special precautions for disposal?

No. The optional standard text '*In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy*' or '*In Australia, any unused medicine or waste material should be disposed of in accordance with local requirements*' can be used if your current PI does not include disposal information. Please choose the standard text most appropriate for the type of medicine, considering other factors such as the dosage form. For example, liquid cytotoxic medicines should not be disposed of at the local pharmacy.

Sections 7-10

Do I have to add an email address, phone number and/or website address to section 8?

It is recommended that you include contact details such as an email address, phone number and/or website address to section 8. This information assists users of the PI to communicate with sponsors, such as in the case of adverse event reporting.

Sections 9 and 10 – I have added a new tradename which has resulted in a new ARTG entry for my medicine. Which section does the date of approval for the new tradename go in?

This type of change is viewed as a revision to the approved PI. Therefore, the date in Section 9 should be the date the medicine was first entered into the ARTG, and the date of approval of the new tradename should go in Section 10.

Updated Section 10 – What information should be included in the 'Summary table of changes'?

The table should have two columns with the headings 'Section changed' and 'Summary of new information'. Only the number of the section that has been changed should be entered in the first column. A brief description of the change should be included in the second column. Safety related changes to the PI may be retained in the table even after a subsequent PI update. If your PI is for a New Chemical Entity, you do not need to include a table.

An example of how the table could be presented is shown below:

Section changed	Summary of new information
ALL	PI reformat
4.1	New indication for use in children aged 6 years and over added
4.2	Dosing information added for use in children
4.4	Precaution for use in children updated
5.1	Clinical trial section updated with paediatric trial outcomes
8	Updated sponsor details
10	New tradename added

FAQs – generic and biosimilar medicines

Can I reformat my PI prior to the innovator?

Yes. The content of the PI is not changed as part of the reformatting process. Therefore it is acceptable for the PI of generic and biosimilar medicines to be in the new format prior to the innovator reformatting.

The innovator has reformatted their PI – do I have to update the PI for the generic product within 30 days?

Not unless safety-related changes were included in the innovator's PI at the time of reformatting. Inclusion of a safety-related change can now be identified from the information in the *Summary table of changes*, located in Section 10 of reformatted PIs.

I am submitting an application for a new generic or biosimilar medicine – does the PI have to be in the new format?

Yes, applications to register a new medicine must be accompanied by a PI in the new format. To prepare a PI for a new generic or biosimilar medicine, the content of the innovator's PI should be provided under the headings of the new form. Where information is missing, the relevant optional standard text may be included.

Where should the statement on biosimilarity be placed?

The statement that '***[Biosimilar product name]*** *is a biosimilar medicine to* ***[Reference medicine name]****. The evidence for comparability supports the use of* ***[Biosimilar product name]*** *for the listed indication[s]*' should be located in section 1, after the name of the active ingredient.

FAQs – applications including a new PI

Can I use the European SmPC instead of the Australian PI?

No. The Australian PI must conform to the format described in the *Form for providing Product Information*. While the headings and format of the PI generally align, there are some differences in the presentation of information. For example, the form describes the preferred presentation of adverse effects information.

What information should be put in Section 10 for a new PI

For new PIs, the heading '10 Date of revision' should be included in the PI, and the statement 'not applicable' can be included under the heading. It is not necessary to include the summary table of changes for a new PI, but this table must be included following any revision to the PI.

Can I use the optional standard text in the *Form for providing product information*?

PIs being prepared for new products should contain information under each heading and subheading. The suitability of the text under each heading will be considered as part of the registration process. In some sections, the optional standard text may be considered acceptable, such as the inclusion of:

- '*In Australia, information on the shelf life can be found on the public summary of the ARTG. The expiry date can be found on the packaging*' in section 6.3 Shelf life, or
- '*In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy*' in section 6.6 Special precautions for disposal.

Please note the new form contains the following mandatory standard text which must be included in your PI:

- '*Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at www.tga.gov.au/reporting-problems*' in Section 4.8 Adverse effects (undesirable effects), and
- '*For information on the management of overdose, contact the Poisons Information Centre on 13 11 26 (Australia)*' in Section 4.9 Overdose.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	TGA	2 June 2011
V2.0	Updated to reflect new product information form	TGA	20 November 2017
V2.1	Updated to clarify when reformatted PIs can be submitted	TGA	22 November 2017
V2.2	Updated to include new and revised FAQs, and the PI templates revised to include standard text	TGA	16 January 2018
V3.0	Updated to include new and revised FAQs, revised templates to reflect the form approved on 8 March 2018, and to include the sponsor checklist	TGA	10 April 2018
V4.0	Updated to include new and revised FAQs	TGA	4 January 2019
V4.1	Updated to include additional information about the transitional arrangements	TGA	6 August 2019
V4.2	Updated to include new and revised information, including Submission FAQs relating to accessing the fee waiver for applications for PI reformatting only in 2020	TGA	6 March 2020

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
https://www.tga.gov.au

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