Creating the CMI summary page

Guidance for sponsors

Version 1.0, August 2020

TGA Health Safety Regulation

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Contents

Overview

Purpose

This document provides guidance about preparing the summary page for Consumer Medicine Information (CMI) documents. It is intended for sponsors of medicines supplied to the Australian market and other interested stakeholders.

Sponsors must ensure that CMI for medicines newly registered from 1 January 2021 comply with the applicable CMI template.

CMI for all previously registered medicines must adopt the new format by 30 December 2025. These requirements apply to all medicines that are required to have CMI, including prescription medicines and some non-prescription (over-the-counter) medicines, as established in Schedules 12 and 13 of the *Therapeutic Goods Regulations 1990*.

This document is intended to be a companion resource to the previously published guidance documents *Using the TGA CMI template - Guidance for sponsors* and *Consumer Medicine Information (CMI) – How to use the improved CMI template*. Those documents provide general information and guidance regarding the new templates and effective writing for consumers.

The advice in this document aligns with the feedback received from consumers during user testing of the new templates, and subsequent targeted consultation with key stakeholder organisations, including Medicines Australia, the Generic Biosimilar Medicines Association and the Consumer Healthcare Products Association.

General advice about producing the summary

We strongly recommend that you write the summary after finalising the content for the full CMI.

Sponsors remain fully responsible for creating the content in their CMIs and ensuring that they are effective. The template is designed to assist sponsors to create CMI documents that are shorter and better laid-out. The exact wording in the headings and the body text, including in the summary, is suggested rather than mandatory. Sponsors may change the wording in the headings and body text, including in the summary, for practical reasons or to maximise the effectiveness of the communication. However, the type of information indicated under each heading must be included in the same order in which it appears in the template.

> Sponsors can change the wording in either headings or body text in both the summary (if applicable) and full CMI. The templates outline the type of information required and the order in which it must be presented. However, sponsors can make changes for practical reasons or to improve effectiveness.

The key considerations when producing the CMI summary are:

• it should be no more than one page long

• it should contain the most critical information about the safe and effective use of the medicine

• the content should be clear and easy to understand.

The summary is designed to be provided with the full CMI and therefore is not required to be comprehensive. Based on user-testing feedback, if the information is too detailed it will be overly repetitive of the full CMI and consumers will be less likely to read it or find it valuable.

Each heading in the summary should match the heading in the full CMI to support document navigation.

> The summary is required to be one page and should only include the most critical information about the safe and effective use of the medicine. The summary is intended to only be supplied in conjunction with the full CMI and therefore does not need to be comprehensive.

Using this guidance document

The following guidance material is broken up into two sections:

- Prescription medicines, which relates to creating a summary using the *TGA Consumer Medicine Information (Prescription Medicine) Template*

- Non-prescription medicines, which relates to creating a summary (which is optional) using the *TGA Consumer Medicine Information (Non-prescription Medicine) Template*.

Each section includes an annotated copy of the summary page from the relevant template. This is followed by advice that is clearly numbered to indicate the part of the template to which it relates.

Please note that a summary is optional for non-prescription medicines, as indicated in that template. However, we encourage sponsors of non-prescription medicines to consider including a summary. Summaries were user-tested as part of the project to develop the revised templates and received very positive feedback from participants (see *Improved CMI usability evaluation report*).

> The one-page summary is optional for non-prescription medicines, but is still encouraged. The summary was user-tested with consumers and received very positive feedback.

Prescription medicine summaries

[medicine name]* ①

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details. [Include if applicable]

WARNING: Important safety information is provided in a boxed warning in the full CMI. Read before using this medicine. [Include if applicable] ②

1. Why am I using [medicine name]?

[Medicine name] contains the active ingredient [insert active ingredient]. [Medicine name] is used to ....

For more information, see Section 1. Why am I using [medicine name]? in the full CMI. ③

2. What should I know before I use [medicine name]?

Do not use if you have ever had an allergic reaction to [medicine] or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use [medicine name]? in the full CMI. ④

3. What if I am taking other medicines?

Some medicines may interfere with [medicine name] and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI. ⑤

4. How do I use [medicine name]?

- [Insert statement regarding dosage]
- [Insert statement(s) regarding device use / other important directions for use]

More instructions can be found in Section 4. How do I use [medicine name]? in the full CMI. ⑥

5. What should I know while using [medicine name]?

Things you should do	• Remind any doctor, dentist or pharmacist [add other health professionals as appropriate] you visit that you are using [insert medicine]. • [Insert other relevant key point(s) e.g. monitoring of the condition / effectiveness of medicine]
Things you should not do	• Do not stop using this medicine suddenly (if relevant). • [Insert other relevant key point(s)]
Driving or using machines	• Insert relevant information regarding any warnings to consider before driving or operating machinery • [Insert other relevant key point(s)]
Drinking alcohol	• Insert relevant statement regarding drinking alcohol while using the medicine • [Insert other relevant key point(s)]
Looking after your medicine	• Insert storage details, in particular any formulation-specific storage details e.g. refrigerate do not freeze • [Insert other relevant key point(s)]

For more information, see Section 5. What should I know while using [insert medicine]? in the full CMI. ⑦

6. Are there any side effects?

[Include statement of common side effects, and serious side effects in particular that need to be noted.]

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

⑧

[medicine name]* 1

1. Medicine name

Replace '[medicine name]' with the brand name of your medicine and replace the '*' with a Registered symbol (®) if applicable.

The font and size of the heading were user-tested and found appropriate for consumers. As such, we recommend that you retain the formatting in the template. However, these characteristics are not mandated and can be changed for practical reasons or to improve effectiveness. For example, if your medicine's brand name is particularly long, you may wish to slightly decrease the font size to avoid having it run longer than a single line.

2. Special advisories

The template includes standard wording for situations where your medicine is subject to the Black Triangle Scheme or a boxed warning. If either is true for your product, delete '[include if applicable]' but otherwise retain the applicable wording <u>unchanged</u>. Otherwise, delete all non-applicable wording.

3. 'Why am I using [medicine name]?'

In the subheading, replace '[medicine name]' with the brand name of your medicine. However, the exact wording of the subheading is not mandated and can be changed for practical reasons, as long as doing so will not potentially create confusion for consumers. For example, if your medicine's brand name is particularly long, you may wish to replace '[medicine name]' with 'this medicine'.

In the body text, replace '[medicine name]' with the brand name of your medicine and replace '[insert active ingredient]' with the applicable details.

Summarise the approved indications for your product using Plain English. If you feel it is necessary to include a medical or technical term, this should be clearly but briefly defined in Plain English. Remember, while this information should include all relevant details, it does not have to be detailed or comprehensive. For example, a medicine that is used to treat a number of different cancers could including wording along the lines of: 'This medicine is used to treat certain types of cancer.'

In rare situations, your medicine may have a large number of varied indications and it would prove difficult or confusing to group similar types of indications or to include them all within a few lines of text. If so, you may consider including wording along the lines of: 'This medicine is used to treat a number of different conditions and illnesses (see the full CMI for more details). The most common uses are [insert details].'

4. 'What should I know before I use [medicine name]?'

In the subheading, replace '[medicine name]' with the brand name of your medicine. However, the exact wording of the subheading is not mandated and can be changed to 'this medicine' as long as doing so does not create confusion for consumers.

In the body text, replace '[medicine]' with the brand name of your medicine.

In this section, you should summarise any significant contraindications and/or precautions that apply to your medicine. In many cases, the suggested wording in bold, relating to other medical conditions, other medicines and pregnancy/breastfeeding, may adequately address these considerations. However, you may change this information or include additional information as you deem necessary for your product.

If your medicine is potentially habit-forming or addictive, it should be addressed in this section.

In rare situations, your medicine may have a large number of contraindications and/or precautions and it would prove difficult to include them all within a few lines of text. If so, you may consider including wording along the lines of: 'There are a number of circumstances in which a person should not use this medicine or may need to use caution. It is important to understand if these apply to you before taking [medicine] (see the full CMI for more details).'

5. 'What if I am taking other medicines?'

In the body text, replace '[medicine]' with the brand name of your medicine.

6. 'How do I use [medicine name]?'

In the subheading, replace '[medicine name]' with the brand name of your medicine. However, the exact wording of the subheading is not mandated and can be changed to 'this medicine' as long as doing so does not create confusion for consumers.

In the body text, replace the instructions presented in square brackets ([…]) with the indicated information, summarising important dosage information and other key directions for use.

An example of this type of information might be:

Follow all directions given to you by your doctor and other health professionals carefully including:

- how many tablets to take each day (the usual dose is 10 mg taken once a day)

- swallow the tablets whole with a full glass of water, do not chew or crush the tablets.

As per the template, it is recommended that this information be presented as dot points. However, you may present the information differently for practical reasons or to improve effectiveness.

7. 'What should I know while using [medicine name]?'

In the subheading, replace '[medicine name]' with the brand name of your medicine. However, the exact wording of the subheading is not mandated and can be changed to 'this medicine' as long as doing so does not create confusion for consumers.

In the table, replace the instructions presented in square brackets ([…]) with the indicated information, if applicable. Delete any point and/or sections that are not applicable. For example, if there are no known serious interactions with alcohol, you do not have to include that information in this table. You may also add a section if it is important to the safe and effective use of your product.

Beware duplication of information between this section and other sections of the summary. If the information is already presented in another section, and that is the more appropriate section in which to address it, do not repeat those details in this table. For example, if there is a precaution to avoid taking the medicine while pregnant, it is important that the consumer understands this **before** they begin taking the medicine. While the potential to become pregnant may also be important while taking the medicine, and therefore is addressed in the corresponding section of the full CMI, it is not recommended to repeat that information here in the summary.

In rare situations, your medicine may have a large number of issues addressed in the corresponding section of the full CMI and you cannot effectively summarise them all in this table. If so, you may consider including wording before the table along the lines of: 'There are many important things to consider while you are taking this medicine. The most common and serious considerations are summarised below (see the full CMI for more details).'

8. 'Are there any side effects?'

As indicated in the template, you should include a summary of all common and serious side effects.

Common side effects are defined as those identified as 'common' in the 'Adverse effects' section of your medicine's Product Information (PI).

Serious side effects are defined as those for which a person should seek immediate attention, either from their doctor or – in very serious situations – a hospital.

Generally, as advised in *Consumer Healthcare Products Australia - Writing about Medicines for people: Usability guidelines for consumer medicine information. 3rd edition*, side effects should be grouped and prioritised in your CMI (and summary) by their seriousness, as indicated by the actions that the consumer needs to take. This is different to how they are handled in the PI, where adverse events are grouped by frequency (common, less common and rare).

If space permits, you may wish to include a reassuring statement in this section. For example: 'All medicines can have side effects. If they do occur, they are usually minor and temporary. Do not be alarmed by this list. You may not experience any of them.'

Summarise the known common and serious side effects for your product using Plain English. If you feel it is necessary to include a medical or technical term, this should be clearly but briefly defined in Plain English.

In some circumstances, it may be possible and helpful to group a number of potential side effects by type, such as 'stomach complaints', 'skin problems', or 'breathing issues'.

In rare situations, your medicine may have a large number of common and/or serious side effects and, after your best efforts, you are unable to include them all within the space available. If so, you may wish to list the most common and most severe side effects, including wording along the lines of: 'There are a number of side effects associated with this medicine. It is important to be aware of them so that you can identify any symptoms if they occur (see the full CMI for more details). The most common and serious side effects are [insert details].'

Non-prescription medicine summaries

[medicine name]* ①

Consumer Medicine Information (CMI) summary [optional]

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the full CMI. Read before using this medicine. [Include if applicable] ②

1. Why am I using [medicine name]?

[Medicine name] contains the active ingredient [insert active ingredient]. [Medicine name] is used to ....

For more information, see Section 1. Why am I using [medicine name]? in the full CMI. ③

2. What should I know before I use [medicine name]?

Do not use if you have ever had an allergic reaction to [medicine] or any of the ingredients listed at the end of the CMI.

Talk to your doctor or pharmacist if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use [medicine name]? in the full CMI. ④

3. What if I am taking other medicines?

Some medicines may interfere with [medicine name] and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI. ⑤

4. How do I use [medicine name]?

- [Insert statement regarding dosage]
- [Insert statement(s) regarding device use / other important directions for use]

More instructions can be found in Section 4. How do I use [medicine name]? in the full CMI. ⑥

5. What should I know while using [medicine name]?

Things you should do	• Remind any doctor, dentist or pharmacist [add other health professionals as appropriate] you visit that you are using [insert medicine]. • [Insert other relevant key point(s) e.g. monitoring of the condition / effectiveness of medicine]
Things you should not do	• [Insert other relevant key point(s)]
Driving or using machines	• Insert relevant information regarding any warnings to consider before driving or operating machinery • [Insert other relevant key point(s)]
Drinking alcohol	• Insert relevant statement regarding drinking alcohol while using the medicine • [Insert other relevant key point(s)]
Looking after your medicine	• Insert storage details, in particular any formulation-specific storage details, e.g. refrigerate do not freeze • [Insert other relevant key point(s)]

For more information, see Section 5. What should I know while using [insert medicine]? in the full CMI. ⑦

6. Are there any side effects?

[Include statement of common side effects, and serious side effects in particular that need to be noted.]

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI. ⑧

[medicine name]*   1

1. Medicine name

Replace '[medicine name]' with the brand name of your medicine and replace the '*' with a Registered symbol (®) if applicable.

The font and size of the heading were user-tested and found appropriate for consumers. As such, we recommend that you retain the formatting in the template. However, these characteristics are not mandated and can be changed for practical reasons or to improve effectiveness. For example, if your medicine's brand name is particularly long, you may wish to slightly decrease the font size to avoid having it run longer than a single line.

2. Special advisory

The template includes standard wording for if your medicine is subject to a [boxed warning](#). If so, delete '[include if applicable]' but retain the rest of the wording <u>unchanged</u>. Otherwise, delete this wording.

3. 'Why am I using [medicine name]?'

In the subheading, replace '[medicine name]' with the brand name of your medicine. However, the exact wording of the subheading is not mandated and can be changed for practical reasons, as long as doing so will not potentially create confusion for consumers. For example, if your medicine's brand name is particularly long, you may wish to replace '[medicine name]' with 'this medicine'.

In the body text, replace '[medicine name]' with the brand name of your medicine and replace '[insert active ingredient]' with the applicable details.

Summarise the approved indications for your product using Plain English. If you feel it is necessary to include a medical or technical term, this should be clearly but briefly defined in Plain English. Remember, while this information should include all relevant details, it does not have to be detailed or comprehensive.

In rare situations, your medicine may have a large number of varied indications and it would prove difficult or confusing to group similar types of indications or to include them all within a few lines of text. If so, you may consider including wording along the lines of: 'This medicine is used to treat a number of different conditions and illnesses (see the full CMI for more details). The most common uses are [insert details].'

4. 'What should I know before I use [medicine name]?'

In the subheading, replace '[medicine name]' with the brand name of your medicine. However, the exact wording of the subheading is not mandated and can be changed to 'this medicine' as long as doing so does not create confusion for consumers.

In the body text, replace '[medicine]' with the brand name of your medicine.

In this section, you should summarise any significant contraindications and/or precautions that apply to your medicine. In many cases, the suggested wording in bold, relating to other medical conditions, other medicines and pregnancy/breastfeeding, may adequately address these considerations. However, you may change this information or include additional information as you deem necessary for your product.

If your medicine is potentially habit-forming or addictive, it should be addressed in this section.

In rare situations, your medicine may have a large number of contraindications and/or precautions and it would prove difficult to include them all within a few lines of text. If so, you may consider including wording along the lines of: 'There are a number of circumstances in which a person should not use this medicine or may need to use caution. It is important to understand if these apply to you before taking [medicine] (see the full CMI for more details).'

5. 'What if I am taking other medicines?'

In the body text, replace '[medicine]' with the brand name of your medicine.

6. 'How do I use [medicine name]?'

In the subheading, replace '[medicine name]' with the brand name of your medicine. However, the exact wording of the subheading is not mandated and can be changed to 'this medicine' as long as doing so does not create confusion for consumers.

In the body text, replace the instructions presented in square brackets ([…]) with the indicated information, summarising important dosage information and other key directions for use.

It is recommended that this information be presented as dot points. However, you may present the information differently for practical reasons or to improve effectiveness.

7. 'What should I know while using [medicine name]?'

In the subheading, replace '[medicine name]' with the brand name of your medicine. However, the exact wording of the subheading is not mandated and can be changed to 'this medicine' as long as doing so does not create confusion for consumers.

In the table, replace the instructions presented in square brackets ([…]) with the indicated information, if applicable. Delete any point and/or sections that are not applicable. For example, if there are no known serious interactions with alcohol, you do not have to include it in this table. You may also add a section if it is important to the safe and effective use of your product.

Beware duplication of information between this section and other sections of the summary. If the information is already presented in another section, and that is the more appropriate section in which to address it, do not repeat those details in this table. For example, if there is a precaution to avoid taking the medicine while pregnant, it is important that the consumer understands this **before** they begin taking the medicine. While the potential to become pregnant may also be important while taking the medicine, and therefore is addressed in the corresponding section of the full CMI, it is not recommended to repeat that information here in the summary.

In rare situations, your medicine may have a large number of issues addressed in the corresponding section of the full CMI and you cannot effectively summarise them all in this table. If so, you may consider including wording before the table along the lines of: 'There are many important things to consider while you are taking this medicine. The most common and serious considerations are summarised below (see the full CMI for more details).'

8. 'Are there any side effects?'

As indicated in the template, you should include a summary of all common and serious side effects.

Common side effects are defined as those identified as 'common' in the 'Adverse effects' section of your medicine's Product Information (PI).

Serious side effects are defined as those for which a person should seek immediate attention, either from their doctor or – in very serious situations – a hospital.

Generally, as advised in *[Consumer Healthcare Products Australia - Writing about Medicines for people: Usability guidelines for consumer medicine information. 3rd edition](#)*, side effects should be grouped and prioritised in your CMI (and summary) by their seriousness, as indicated by the actions that the consumer needs to take. This is different to how they are handled in the PI, where adverse events are grouped by frequency (common, less common and rare).

If space permits, you may wish to include a reassuring statement in this section. For example: 'All medicines can have side effects. If they do occur, they are usually minor and temporary. Do not be alarmed by this list. You may not experience any of them.'

Summarise the known common and serious side effects for your product using Plain English. If you feel it is necessary to include a medical or technical term, this should be clearly but briefly defined in Plain English.

In some circumstances, it may be possible and helpful to group a number of potential side effects by type, such as 'stomach complaints', 'skin problems', or 'breathing issues'.

In rare situations, your medicine may have a large number of common and/or serious side effects and, after your best efforts, you are unable to include them all within the space available. If so, you may wish to list the most common and most severe side effects, including wording along the lines of: 'There are a number of side effects associated with this medicine. It is important to be aware of them so that you can identify any symptoms if they occur (see the full CMI for more details). The most common and serious side effects are [insert details].'

Example summary page

Atorvastatin

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Atorvastatin?

Atorvastatin contains the active ingredient atorvastatin. Atorvastatin is used to lower high cholesterol levels. It can also be used to reduce the risk of having a heart attack or stroke in certain patients.

For more information, see Section 1. Why am I using Atorvastatin? in the full CMI.

2. What should I know before I use Atorvastatin?

Do not use if you have ever had an allergic reaction to Atorvastatin or any of the ingredients listed at the end of the CMI.

Do not use if you have active liver disease.

Do not use if you are pregnant, intend to become pregnant, or are breast-feeding.

Talk to your doctor if you have any other medical conditions or take any other medicines.

For more information, see Section 2. What should I know before I use Atorvastatin? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Atorvastatin and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Atorvastatin?

Follow all directions given to you by your doctor and other health professionals carefully including:
* how many tablets to take each day (the usual dose is between 10-80 mg taken once a day)
* swallow the tablets whole with a full glass of water, do not chew or crush the tablets
* your agreed diet plan.

More instructions can be found in Section 4. How do I use Atorvastatin? in the full CMI.

5. What should I know while using Atorvastatin?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using Atorvastatin. • Keep all doctor appointments so that your condition and treatment can be effectively monitored. • Some self-help measures relating to weight, exercise, alcohol and smoking may assist your condition. • Stop taking it and contact your doctor immediately if you become pregnant.
Things you should not do	• Avoid drinking large quantities of grapefruit juice, as doing so increases the chance of side effects.
Drinking alcohol	• Avoid drinking large quantities of alcohol, as it may increase the chance of liver problems.
Looking after your medicine	• Keep your tablets in the blister pack until it is time to take them. • Store in a cool dry place where the temperature stays below 25°C and keep out of reach of children.

For more information, see Section 5. What should I know while using Atorvastatin? in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If they do occur, they are usually minor and temporary. Do not be alarmed by this list.

Common but usually mild potential side effects include muscle and joint pain/weakness; constipation, diarrhea and other stomach effects; heartburn and indigestion symptoms; urine infection; headache; stuffy, runny or bleeding nose; and rash.

Serious potential side effects that require medical attention include yellowing of the skin/eyes and dark urine; feeling weak, tired and excessively thirsty, and passing more urine; breathing problems; allergy symptoms; chest or unexpected muscle pain; sudden severe headache (possibly with other symptoms); and severe blisters/bleeding of lips, eyes, mouth, nose or genitals.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI

Atorvastatin 1

Further information and resources

The following websites, publications and resources are available to assist sponsors:

- [TGA website](#)

    - *[Using the TGA CMI template - Guidance for sponsors](#)*

    - *[Consumer Medicine Information (CMI) – How to use the improved CMI template](#)*

    - [Black Triangle Scheme](#)

    - [Boxed warning guidance](#)

- *[Writing about Medicines for people in: Usability guidelines for consumer medicine information. 3rd edition](#)*

- *[Australian Digital Transformation Agency, Content Guide - advice on how to write in plain English and create well-structured, accessible content](#)*

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Pharmacovigilance and Special Access Branch	August 2020