Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Clarifying the regulation of dietary supplements in Australia

Consultation paper

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About this consultation

Under the *Therapeutic Goods Act 1989* (the **Act**), the person who holds the listing of a medicine in the Australian Register of Therapeutic Goods (**ARTG**) (the **Sponsor**) is required to ensure that all therapeutic goods intended for inclusion in the ARTG comply with applicable standards. The standards include:

- a standard that is constituted by the matters specified in an order under section 10 that is applicable to the goods (also known as a ministerial standard or a Therapeutic Goods Order (**TGO**));
- default standards, being:
    - the British Pharmacopoeia (**BP**)
    - the European Pharmacopoeia (**Ph. Eur**.); and
    - the United States Pharmacopeia-National Formulary (**USP-NF**)
- a homoeopathic standard;
- an anthroposophic standard.

Issue 1

In some cases, the USP-NF contains monographs relevant to listed medicines that are not available in the other default standards, meaning that the USP-NF is the sole applicable quality standard.

However, there is currently a lack of legal clarity for Sponsors as to whether the requirements in the USP-NF for 'dietary supplements' (the type of goods regulated as listed medicines under the TGA's regulatory framework) are mandatory requirements for listed medicines supplied in Australia, because the USP-NF itself permits voluntary compliance for dietary supplements, based on whether or not a statement of compliance is included on the medicine's label.

This paper proposes to establish a new TGO that clarifies when the requirements in the USP-NF for 'dietary supplements' applies to listed medicines (Option 2).

Issue 2

International standards are developed for different regulatory frameworks and the requirements in the default standards might not always align or be achievable in the Australian context. Under the Act, there are currently mechanisms available by which Sponsors can request (by applying and paying for an application) a consent from the Secretary that would allow a Sponsor to supply therapeutic goods that do not conform with a standard applicable to the goods (other than by reason of a matter relating to labelling or packaging) or the Minister may, by legislative instrument, determine that specified monographs or specified statements in default standards are exempt (and therefore do not apply to certain therapeutic goods).

The consultation paper seeks specific details from stakeholders on whether they have any concerns with certain monographs, statements or notifications in the USP-NF that they consider are not in complete alignment within the Australian regulatory framework with a justification for their views.

Proposed options

The Options proposed to address the above issues are:

- **Option 1** – Status quo. Do not provide clarity on the applicability of requirements of the USP-NF for listed medicines.
- **Option 2** – Establish a new TGO clarifying the quality requirements for certain listed medicines.

We invite interested stakeholders to provide feedback by answering the questions in this consultation paper in the consultation hub by **15 January 2027**.

If you have any questions relating to this consultation, please email: nonprescriptionmedicines@health.gov.au.

Introduction

Medicines that are considered lower risk (due to containing low risk ingredients and making low level health claims) can be entered as 'listed' medicines on the ARTG and are suitable for self-selection by consumers without a prescription or a pharmacist's advice e.g. most vitamin and mineral supplements.

Listed medicines (identifiable by an 'AUST L' ARTG number on the medicine label), are not individually evaluated by the TGA before they are supplied in the marketplace. Instead, Sponsors must certify that their medicine meets all applicable requirements in relation to safety, quality and efficacy.

Sponsors of assessed listed medicines (identifiable by an 'AUST L(A)' ARTG number on the medicine label), like other listed medicines, self-certify that their medicine meets all applicable requirements in relation to safety and quality. However, unlike other listed medicines, the efficacy of an assessed listed medicine is pre-market evaluated by the TGA.

Under the Act, Sponsors are required to ensure that all therapeutic goods intended for inclusion in the ARTG comply with applicable standards. Ensuring product quality and labelling meets established standards supports the safety and efficacy of medicines supplied to the Australian public.

The standards include:

- a standard that is constituted by the matters specified in an order under section 10 that is applicable to the goods (also known as a ministerial standard or a Therapeutic Goods Order (**TGO**));
- default standards, being:
    - the British Pharmacopoeia (**BP**)
    - the European Pharmacopoeia (**Ph. Eur**.); and
    - the United States Pharmacopeia-National Formulary (**USP-NF**)
- a homoeopathic standard;
- an anthroposophic standard.

Legislation

- Subsection 10(1) of the Act provides an administrative power for the Minister to make a TGO determining that matters specified in the order constitute a standard for therapeutic goods or class of therapeutic goods identified in the order (whether or not those orders are the subject of a monograph in the BP, the Ph. Eur., the USP-NF, a homoeopathic pharmacopoeia or an anthroposophic pharmacopoeia). A TGO can modify or substitute the applicable default standards as appropriate.
- Under subsection 13(2) of the Act, if a TGO applies to a medicine and there is an inconsistency between the TGO and a default standard (such as statements or monographs from the BP, Ph. Eur. or USP-NF), the TGO takes precedence, i.e. the requirements in the default standard are disregarded to the extent of the inconsistency.
- Sections 14 and 14A of the Act provide mechanisms for the Secretary, in specified circumstances, to consent to import, supply or export of therapeutic goods that do not comply with an applicable standard.
- A legislative instrument made under section 3C of the Act allows the Minister to determine that specified monographs, or specified statements in those monographs, in the BP, Ph. Eur. and USP-NF are exempt in relation to specified therapeutic goods (sections 3C(1) and 3C(2) of the Act).

Issue 1: Lack of clarity as to whether compliance with the USP-NF is mandatory for listed medicines in Australia

The regulatory system for listed medicines requires compliance with applicable statements and monographs in the default standards. In some cases, the USP-NF has monographs that are not available in the other default standards, meaning that the USP-NF is the sole applicable quality standard.

There is currently a lack of clarity for Sponsors as to whether the requirements in the USP-NF for 'dietary supplements' (the type of goods regulated as listed medicines under the TGA's regulatory framework) are mandatory requirements for medicines listed in the ARTG and supplied in Australia.

The dietary supplement labelling requirement as presented in the USP-NF is a source of potential confusion among Australian medicine Sponsors and stakeholders, because:

- under the Act, the USP-NF is a default standard and compliance is mandatory for products included in the ARTG for supply in Australia (unless consent has been given under s 14/14A or an exemption or contradictory TGO applies) should there be statements or monographs that are relevant to the product; however,

- the USP-NF itself permits voluntary compliance for dietary supplements.

Part 3.10.20 of the USP-NF General Notices and Requirements provides the following criteria to determine if the USP-NF is applicable to dietary supplements and their ingredients:

> *'An article recognized in USP or NF shall comply with the compendial standards if the article is a […] dietary supplement, dietary ingredient, or other ingredient intended for incorporation into a dietary supplement and is labeled as conforming to the USP or NF.'*

Therefore, the USP-NF applies/does not apply to dietary supplements (or constituent ingredients) based on whether the labelling of the final good includes a statement that it conforms to the USP-NF (**USP-NF Citation**). That is, compliance with the USP-NF is only a requirement if the product includes a USP-NF Citation. Consequently, this can be interpreted to mean that compliance with the USP-NF is voluntary.

Under the TGA's ministerial standard, the Therapeutic Goods (Standard for Labelling of Non-Prescription Medicines (TGO 116) Order 2026 (**TGO 116**), an USP-NF Citation is not required on the label of listed medicines marketed in Australia. In addition, inclusion of such a statement on a medicine label in Australia would not be meaningful to consumers and could be a source of confusion.

This can lead to the situation where a Sponsor may contend that compliance with the USP-NF is not mandatory in Australia, as the labels of Australian products do not need to include the USP-NF Citation.

This is particularly undesirable where the USP-NF provides the only relevant quality standard for a listed good, as it could result in listed medicine sponsors/manufacturers having to determine their own quality criteria and/or listed medicines being supplied that are of insufficient quality.

Consultation

To address this issue, the TGA is proposing to clarify the circumstances in which compliance with the USP-NF is mandatory. The Option proposed in this consultation paper (Option 2) is that the TGA will create a TGO clarifying that compliance with applicable statements and monographs in the USP-NF is mandatory for listed medicines, unless there is an exemption from this requirement.

Issue 2: International monographs are developed for different regulatory frameworks

International standards are developed for different regulatory frameworks and the requirements in these standards might not always align or be achievable in the Australian regulatory context.

Under the Act, there are currently mechanisms available by which Sponsors can request exemption from a default standard or the TGA can permit exemptions on a delegate of the Secretary's own initiative, as described below.

Current legislative provisions for consent to import, supply or export therapeutic goods that do not comply with standards

Mechanisms available to Sponsors

Sections 14 and 14A of the Act provide mechanisms for the Secretary or their delegate, in specified circumstances, to consent to import, supply or export of therapeutic goods that do not comply with an applicable standard, including default standards.

Generally, these consent provisions are currently available to Sponsors to seek approval in individual cases where compliance with a particular standard cannot be achieved and where doing so would not adversely affect the quality of the goods or their inherent low risk status. They provide a discretionary pathway to address instances of non-compliance on a case-by-case basis, having regard to the particular circumstances of the goods and any relevant public health considerations.

Such applications are considered and subsequently approved for a finite period of time and are for individual products.

Mechanisms available to the TGA (as a delegate to the Minister)

A TGO can be made by way of a legislative instrument under section 10(1) of the Act to modify or substitute the applicable default standards, in part or in whole, as appropriate.

A legislative instrument under section 3C allows the Minister, to determine that specified monographs, or specified statements in those monographs, in the BP, Ph. Eur. and USP-NF are exempt in relation to specified therapeutic goods [sections 3C(1) and 3C(2) of the Act]. The Minister has previously made a section 3C instrument (see here: Therapeutic Goods (Exempt Monographs) Determination 2021 - Federal Register of Legislation). The provision under section 3C of the Act to exempt statements or monographs in default standards, is at the Secretary's own initiative and there is no pathway for industry to initiate this process.

Consultation

To determine the challenges a Sponsor might have in complying with the USP-NF, the TGA is requesting stakeholders to provide details of statements or monographs that may not be applicable in the Australian context, together with supportive information for this assertion and in addition, proposed amendments/omissions from the default standards (refer to question 3).

Important: Information from interested stakeholders is being sought for information-gathering purposes to assess the suitability of existing mechanisms for addressing these issues and to determine whether further consideration may be required. This should not be interpreted as indicating any proposed TGA position, decision or outcome.

Proposed options

This consultation proposes to clarify the circumstances in which compliance with the USP-NF is mandatory for Sponsors of listed medicines. Consideration of other standards are not in scope of this consultation.

Options are provided below.

Option 1: Status Quo

Do not provide clarity on the applicability of requirements of the USP-NF for listed medicines.

Reasons for this option:

- Retains the ability for listed medicine(s) sponsors to interpret that compliance with an applicable quality requirement of the USP-NF is not mandatory in circumstances where a monograph or notification is not considered applicable or achievable in the Australian regulatory context.

Reasons against this option:

- Does not establish a legislative basis for compliance with the USP-NF default quality standard and therefore hinders the TGA's ability to take any regulatory action if a specific medicine is found to be demonstrably non-compliant with this quality standard (and potentially of sub-standard quality).
- Does not provide consumers with assurances that all listed medicines are meeting applicable quality standards.
- Fails to reduce confusion around medicine labelling, particularly regarding the presence or necessity of the USP-NF Citation.
- Maintains legal ambiguity for Sponsors about when and how the USP-NF applies to listed medicines.
- Prevents Sponsors from confidently complying with USP-NF quality requirements without citing it on the product labels.
- Leaves inconsistencies across the Australian supply chain regarding the legislative application of USP-NF standards.
- May reduce regulatory consistency and competitive neutrality by enabling different approaches to compliance with applicable USP-NF requirements for comparable ingredients and products.

Option 2: Establish a new TGO clarifying the quality requirements for certain listed medicines.

Establish a new TGO that, at a minimum, specifies that the matters outlined in the TGO for the dietary supplements or ingredients are to be treated as requirements of any of the default standards applicable to such goods—regardless of whether those goods are labelled as conforming to that standard. As such, the position in 3.10.20 of the USP-NF General Notices and Requirements would be disregarded under subsection 13(2) of the Act to the extent of any inconsistency.

Sponsors are also encouraged to provide details of statements or monographs that may not be applicable in the Australian context, together with supportive information for this assertion and in addition, proposed amendments/omissions from the default standards.

Reasons for this option:

- Removes the ability for Sponsors to interpret that compliance with an applicable quality requirement of the USP-NF is not mandatory.
- Reduces confusion around medicine labelling, particularly regarding the presence or absence of the USP-NF Citation.
- Clarifies the legal application of USP-NF to listed medicines, removing ambiguity for Sponsors.
- Enables enforcement action when a medicine does not meet required quality standards, supporting listed medicine safety and efficacy and consumer confidence in these products.
- Allows Sponsors to comply with USP-NF quality requirements without needing to cite USP-NF conformance on product labels.
- Aligns all parties in the Australian supply chain under consistent legislation regarding the use of USP-NF standards.
- Establishes a transparent legislative basis for compliance with the USP-NF default quality standard and therefore enables the TGA to take any regulatory action if a specific medicine is found to be demonstrably non-compliant with this quality standard (and potentially of sub-standard quality), providing greater assurances to consumers that all listed medicines meet applicable quality requirements.

Reasons against this option:

- Unless an exemption is obtained, Sponsors may be considered non-compliant to a quality requirement of the USP-NF that they may consider is not relevant or achievable in the Australian regulatory context.
- There may be an increase in regulatory burden as Sponsors need to apply for exemptions under section 14 of the Act where a quality requirement of the USP-NF is not relevant or achievable in the Australian regulatory context.
- Some products may no longer be supplied in the market where these are not able to meet the applicable quality standards.
- Does not give consideration to differences in international and the Australian regulatory frameworks.

Consultation questions

These questions can be answered in the TGA Consultation Hub.



1. Which is your preferred Option?

   Option 1

   Option 2

2. Please provide details of why this is your preferred Option.

3. Are you aware of any USP-NF monographs, general chapters, notices or specific requirements that may be difficult to apply or achieve within the Australian regulatory framework?

   If so, please provide:

   a. Detailed scientific explanation why this is the case and substantiate your statements with evidence.

   b. Proposed amendments to make it applicable in the Australian regulatory context.

4. Is this proposal likely to increase regulatory burden? If so, please provide details.

5. Do you have any other comments or feedback on the proposal?

Version history

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