Australian Government
Department of Health
Therapeutic Goods Administration

Market exclusivity for listed medicine ingredients

Listed medicines must only contain low risk ingredients. All ingredients available for use in listed medicines and requirements relating to their use are specified in the Therapeutic Goods (Permissible Ingredients) Determination (the Determination).

For a new ingredient to be included in the Determination, an applicant must submit a data package containing safety and quality data for evaluation.

*From **March 2018** successful applicants of a new ingredients approved for use in listed medicines have the option to have exclusive use of that ingredient.*

What is 'market exclusivity'?

Market exclusivity prohibits unauthorised sponsors from using an ingredient that has market exclusivity **(a protected ingredient)** in a medicine listed in the Register for a **2 year period**.

It is intended to reward the resources invested by **innovators** who research and develop new ingredients to be used in listed medicines. Protected ingredients can only be used in listed medicines by the ingredient owner and any other authorised sponsors.

Other sponsors can use the ingredient to develop a product and prepare a product for listing, however they cannot list or supply their product until the expiry of the 2 year exclusivity period.

Ingredients that are eligible for exclusivity

- ✓ Exclusivity will only be permitted for a **new listable ingredient** that has not been previously included in the Determination or used in registered medicines.
- ✓ Exclusivity may apply to **active or excipient** ingredients that can be used in **listed medicines** (including complementary medicines, sunscreens and oral health products).
- ✘ Exclusivity will not apply to applications submitted for a new role or a change to any existing ingredient requirements, e.g.:
  - change from excipient to active use
  - update the permitted level of use (e.g. 0.5% to 1%)
  - change the route of administration (e.g. from topical to oral use)
  - update the plant part, preparation method or purity
  - allow for a new strain of an existing species (e.g. LA-5 strain of Lactobacillus acidophilus)
- ✘ It will not be eligible if it is already included in the Determination or available for use in registered medicines, including under a synonym name.

Process for determining market exclusivity

1. An application is made for an eligible substance and the applicant 'opts in' for market exclusivity.
2. Within 5 business days, the TGA will acknowledge receipt of the application.
3. Valid applications for eligible substances are considered on a first in, first received basis.
4. TGA screens the application to verify that it meets the requirements for a valid application. The applicant is notified about the outcome of screening.
5. If the application is valid ,TGA will evaluate the submission dossier.
6. The TGA makes a decision on whether or not to recommend inclusion of the ingredient in the Determination and whether Market Exclusivity is applicable.
7. If the recommendation is accepted, the ingredient will be included in the Determination as soon as practicable. If the applicant opted in and is eligible for market exclusivity, they are granted 2 years exclusive use of that ingredient.
8. The applicant (the ingredient owner) may authorise sponsors to use the ingredient to list a medicine in the ARTG.

How market exclusivity works

- Market exclusivity is **optional** for successful applicants of newly approved ingredients. It is the responsibility of the sponsors to **'opt in'** at the time of making the application to ensure that the TGA puts the necessary administrative arrangements in place.
- The TGA will consider valid applications on a **first in, first served basis**. The TGA may provide informal advice to applicants about competing applications at the pre-submission or submission phase. However, ultimately the risk of submitting a competing application will sit with the ingredient applicant.
- The applicant that is granted exclusive use of a new ingredient (the ingredient owner), will be identified in the Determination by their **name and TGA client ID**. The exclusivity details will appear as a specific 'requirement' relating to the use of the ingredient in listed medicines (i.e. this will be **identified in Column 4** of the Determination).

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirement(s) applying to the ingredient in column 2
	Example ingredient	A,E	*Only to be used in a medicine where* ***[Applicant name] (Client ID 12345)****, who applied to have the ingredient included has given written authorisation to the sponsor of a medicine to include the ingredient in the medicine. This paragraph ceases to be a requirement for this ingredient after 30 June 2018.*

- The exclusivity period will start from the date the ingredient is included in the Determination and **end 2 calendar years later** (i.e. start 1 July 2018 and end 30 June 2020).
- At the end of the exclusivity period, the ingredient will become available for any sponsor to include in a listed medicine in the Register.

Using exclusive ingredients

- Ingredients that are subject to an exclusivity period will be **publicly viewable** via the Ingredients Table search on the TGA Business Services website and in the Determination. Ingredients will also be viewable in the Electronic Listing Facility (ELF) application form.
- An ingredient subject to an exclusivity period can only be used by the **ingredient owner and authorised sponsors** to list a medicine in the Register. Ingredient owners can grant access to use an exclusive ingredient to additional sponsors by submitting the "Authorisation to use an ingredient during the exclusivity period" form when the new substance application is made or after the ingredient is included in the Determination.
- New ingredients approved with an exclusivity period are **not** available for inclusion in Propriety Ingredients but **can** be used in registered medicines without authorisation from the ingredient owner.

How will the TGA ensure exclusive use of approved ingredients?

- The **Electronic Listing Facility** contains new rules to help ensure that only authorised sponsors are able to use a protected ingredient.
- Use of a protected ingredient within the exclusivity period without an approval from the ingredient owner would contravene the requirement relating to the use of the ingredient and **provide grounds to cancel the listing of the medicine** from the Register under paragraph 30(1)(e) of the *Therapeutic Goods ACT 1989*.
- The TGA will not **intervene or arbitrate disagreements** between sponsors, manufacturers or suppliers in relation to authorisation agreements or competing applications.

For more resources and further information go to:

https://www.tga.gov.au/publication/australian-regulatory-guidelines-complementary-medicines-argcm

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