Australian Government
Department of Health
Therapeutic Goods Administration

Streamlining proprietary ingredient categories

20 July 2021

Mixtures with an active ingredient

To help make the medicines application process more efficient, the TGA no longer allocates proprietary ingredient numbers (PI numbers) to ingredient mixtures that contain an active ingredient.

Ingredient suppliers can still sell these mixtures to sponsors intended for use in medicines, but details of the mixture will not be entered into the Proprietary Ingredients Table before the sponsor submits their application. Sponsors will instead select the individual ingredients into their application at the same time as they enter the rest of their medicines' formulation details.

Removing this redundant administrative step does not affect how TGA evaluates a medicine or existing Good Manufacturing Practice requirements for these products. It also does not change how ingredient information is displayed on labels or in the public summaries of medicines on the ARTG.

Where an ingredient mixture with an active ingredient already has a PI number:

- The PI number will remain visible in the Proprietary Ingredient Table if it is linked to a current ARTG medicine entry. A PI number is linked to an ARTG entry when the number or ingredient mixture name has been selected as part of the medicine formulation in TGA online application systems.
- We will write to ingredient suppliers of these mixtures to tell them that PI numbers will be inactivated where:
    - the ingredient mixture is not linked to a current ARTG entry, and
    - was entered into the Proprietary Ingredient Table **prior to 1 July 2020**. However, suppliers we contact will be given the option to tell us to keep the PI number active in the Proprietary Ingredient table.

We already inactivate historic PI numbers that are not linked to current ARTG entries as part of business as usual data integrity activities.

Non-specific PI categories

To improve the integrity of data held within TGA systems, we no longer allocate PI numbers to non-specific excipient mixtures. That is, those that do not clearly specify the purpose of the mixture.

Certain TGA medicine application systems rely on validation rules specific to the mixture's purpose (e.g. flavours, fragrances). Lack of a clear purpose for a mixture in the Proprietary Ingredients Table can result in the medicine application not validating.

Where a non-specific 'Excipient Mix' already has a PI number:

- The PI number will remain visible in the Proprietary Ingredient Table if it is linked to a current ARTG medicine entry.
    - Suppliers can also choose to update the purpose of their mixture to a more specific PI category. Such requests should be sent to TGAnames@tga.gov.au (mailto:TGAnames@tga.gov.au).
- We will write to suppliers to tell them their PI numbers will be inactivated where:
    - an Excipient Mix is **not** linked to a current ARTG entry, and
    - was entered into the Proprietary Ingredient Table **prior to 1 July 2020**. However, suppliers we contact will be given the option for a PI number to remain active in the Proprietary Ingredient Table. The purpose of these PI numbers will need to be clarified to remain active.

We already inactivate historic PI numbers that are not linked to current ARTG entries as part of business as usual data integrity activities.

When submitting a notification of a new proprietary ingredient (//www.tga.gov.au/form/notification-new-proprietary-ingredient), or requesting an update to the purpose of your mixture, select the 'type of proprietary ingredient' or purpose that most clearly describes the intended use in a medicine's formulation.

PI numbers can only have one purpose in the Proprietary Ingredient Table.

Existing ARTG entries that use PI numbers with an active ingredient or non-specific purpose in their formulation

PI numbers used in existing ARTG entries will remain active.

Sponsors **do not** have to make changes or update ARTG entries if they include PI numbers with these categories in their formulation.

Sponsors have the option to voluntarily update their ARTG entries to specify the constituent ingredients in the formulation instead of the mixture's PI number by making a correction to their entry. Standard fees and processes apply.

Sponsors who wish to use ingredient mixtures in their therapeutic goods that are no longer active in the Proprietary Ingredient table should enter the ingredient information into their registration or listing applications individually.

Consultation

We asked for feedback on the proposal to cease processing ingredient mixtures with an active ingredient ('Active premixes' and 'Active Herbal Extracts') and without a clear purpose (non-specific Excipient Mixes) in January - February 2021. We considered all feedback received during consultation before making a decision about this activity.

Thank you to everyone who provided feedback. The outcomes of the consultation and responses where consent has been given to publish the response is available through our consultation hub (https://consultations.health.gov.au/tga/streamlining-proprietary-ingredient-categories/).

GMP for mixtures that contain an active ingredient

This activity to streamline proprietary ingredient categories does not change GMP requirements for mixtures that contain an active ingredient.

The manufacture of mixtures in the Proprietary Ingredients Table that contain an active ingredient are considered to be a step in the manufacture of the finished product and a TGA Good Manufacturing Practice (GMP) licence or approval of the manufacturer may be required, unless exempt.

For more information see the TGA website including Manufacturing medicines (//www.tga.gov.au/manufacturing-medicines) which contains guidance specific to certain medicines, including listed and complementary medicines, under the 'GMP guidance' tab.

TGA proprietary ingredient processes

The TGA's proprietary ingredient processes are purely administrative:

- There is no legislative basis for entering a formulation into the Proprietary Ingredients Table and allocation of a PI number.
- When a mixture is entered into the Proprietary Ingredients Table we do not check whether the mixture's formulation meets specific regulatory requirements for use in therapeutic goods. For example, we do not check whether the manufacturer has or is required to have GMP licensing/approval or whether the formulation would meet listing requirements under 26BB of the Therapeutic Goods Act (https://www.legislation.gov.au/Series/C2004A03952). The sponsor of the therapeutic good is required to ensure that the goods comply with applicable GMP requirements.

For more information about using proprietary ingredient mixtures in therapeutic goods see notification of a new proprietary ingredient (//www.tga.gov.au/form/notification-new-proprietary-ingredient) and proprietary ingredient formulations and how they are used (//www.tga.gov.au/proprietary-ingredient-formulations-and-how-they-are-used).

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