Technical Alert

Changes to Propolis and Royal Jelly

Summary

A change has been made to the listed medicine application system that enables sponsors to enter propolis and royal jelly starting materials into the register in the same way as other ingredients by expressing the total parent ingredient and extract amounts.

What was the issue?

Due to previous IT limitations, sponsors were previously required to enter information about propolis or royal jelly preparations into the ARTG entry in a way that was not reflective of the true active ingredient.

Sponsors can now enter propolis and royal jelly starting materials into the register in the typical way. For example, when a medicine contains 100mg of a 5:1 propolis dry extract concentrate with 10% residual ethanol, previously sponsors had to enter this into the ARTG entry as:
Active: Propolis 500 mg
Equivalent: Propolis dry extract 100 mg
Excipient: Ethanol 10 mg

Sponsors will now be able to enter this ingredient as follows:
Active: Propolis dry extract 100 mg
Equivalent: Propolis 500 mg
Excipient: Ethanol 10 mg

Any residual solvents will still need to be entered as standard excipients.

Fee free transition period and how to make a change

The TGA is offering a **free** correction to listings with propolis and royal jelly ingredients. These changes cannot be made through the online form system.
Rather sponsors need to contact the TGA directly **before 31 March 2020**. If sponsors do not advise the TGA prior to this date, they will need to apply through the normal process for a section 9D(1)(a) variation.
Sponsors should email the AUST L numbers to the TGA, who will then switch the parent ingredient and the equivalent ingredient for free. Email this information to Complementary.Medicines@health.gov.au.

The TGA will notify affected sponsors with listed medicines containing propolis and royal jelly to advise them of the above arrangements, will also publish a notice on the TGA website.

A reminder about mandatory components

Propolis and royal jelly ingredients have specific requirements in Permissible Ingredients Determination. These requirements specify mandatory components that must be declared in the ARTG and have quantity restrictions (e.g. lead for propolis and 10-hydroxy-2-decenoic acid for royal jelly ingredients).

The TGA advises that if sponsors have not declared the quantity of these components in their ARTG entry, they should do so immediately. It is **free** to add these components to their ARTG entries through the online listed medicines application form.

The table below lists all propolis and royal jelly ingredients and their associated requirements under the Determination.

Ingredient Identifier	Ingredient Name	Purpose	Specific requirement(s)
59773	PROPOLIS	A, E	Lead is a mandatory component of Propolis. The concentration of lead in the medicine must be no more than 0.001%. When used topically, the medicine requires the following warning statement on the medicine label: -(PROP1) 'WARNING: Propolis may cause skin irritation. Test before use' When used for other than for topical, the medicine requires the following warning statement on the medicine label: – (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.'
104536	PROPOLIS BALSAM	A, E	Lead is a mandatory component of Propolis balsam. The concentration of lead in the medicine must be no more than 0.001%. When used topically, the medicine requires the following warning statement on the medicine label: -(PROP1) 'WARNING: Propolis may cause skin irritation. Test before use' When used for other than for topical, the medicine requires the following warning statement on the medicine label: – (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.'

104537	PROPOLIS DRY EXTRACT	A, E	Lead is a mandatory component of Propolis dry extract. The concentration of lead in the medicine must be no more than 0.001%. When used topically, the medicine requires the following warning statement on the medicine label: -(PROP1) 'WARNING: Propolis may cause skin irritation. Test before use' When used for other than for topical, the medicine requires the following warning statement on the medicine label: – (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.'
104538	PROPOLIS LIQUID EXTRACT	A, E	Lead is a mandatory component of Propolis liquid extract. The concentration of lead in the medicine must be no more than 0.001%. When used topically, the medicine requires the following warning statement on the medicine label: -(PROP1) 'WARNING: Propolis may cause skin irritation. Test before use' When used for other than for topical, the medicine requires the following warning statement on the medicine label: – (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.'
104539	PROPOLIS RESIN	A, E	Lead is a mandatory component of propolis resin. The concentration of lead in the medicine must be no more than 0.001%.

As these changes are a correction to the ARTG only, the TGA believe there should not be an impact on labels or manufacturing documents.

However members are encouraged to forward any identified issues to technical@cmaustralia.org.au for attention by the Committee Secretariat.

ENDS