

Technical Alert

New Condition of Listing for Krill Oil - Effective 30 June 2015

Dear member,

The TGA has informed CMA that effective 30 June 2015, a new condition of listing will be imposed on medicines containing the ingredient *Euphausia superba* (Krill) Oil.

Under section 28 of the *Therapeutic Goods Act*, a new condition of listing will be imposed on all new and existing products containing the ingredient *Euphausia superba* (Krill) Oil, requiring a label advisory statement with the words to the effect of: 'Contains crustacean shellfish' or 'Derived from seafood'.

Safety concern associated with *Euphausia superba* (Krill) Oil

Medicines containing krill oil have the potential to induce severe allergic symptoms in susceptible individuals, such as those with seafood allergies. TGA advise that there are a number of adverse events in the database associated with krill oil, including a number related to allergic reactions. Further, the TGA highlight that consumers may not be aware that *Euphausia superba* (Krill) are crustaceans and there is currently no mandatory advisory statement to alert consumers to the presence of this potential allergen.

Labelling requirements and practice for seafood source ingredients

Currently, some medicines that include ingredients sourced from seafood such as glucosamine, chitosan, 'concentrated omega-3-triglycerides-squid' and 'squid oil' are included in the Required Advisory Statements for Medicine Labels (RASML) and are required to carry the following label advisory statement: 'Derived from seafood'. Other medicines with ingredients such as fish, shark and shrimp are not required to carry a seafood label warning statement because the ingredient name clearly identifies the source as seafood.

Other products, such as foods are required to declare the presence of seafood ingredients. In relation to foods, Food Standard 1.2.3 'Mandatory Warning and Advisory Statements and Declarations' requires the declaration of the presence of crustaceans (specifying the specific type of crustacean), fish and fish products on food labels.

While there is currently no mandatory label advisory statement for medicines including krill oil as an ingredient, it is noted by TGA that 40% of krill oil medicines included on the Australian Register of Therapeutic Goods (ARTG) have a 'Derived from seafood' statement included in their medicine entry.

Why are TGA imposing a new condition of listing?

TGA consider that a label advisory statement on krill oil medicines is required because:

- adverse allergic events associated with krill oil are occurring
- krill oil, particularly when listed as the Australian Approved Name *Euphausia superba*, may not be identified by susceptible consumers as a seafood product

- other therapeutic products including seafood derived ingredients have the requirement to carry advisory statements
- it is consistent with current industry best practice, given that 40% of products already have a label advisory statement included in their ARTG entry.

Advice from the Office of Best Practice Regulation, in relation to requiring a label advisory statement for krill oil medicines, is that the regulatory impact on industry is likely to be minor given there is only a small number of affected products and 40% of products are already complainant. Therefore, OBPR have advised the TGA that a Regulatory Impact Statement is not required.

In considering options for imposing a label advisory statement to mitigate consumer risk in the short term, a new condition of listing is the preferred approach as this can be implemented in a timely manner, under current legislation and with minor regulatory impact for industry.

Implementation plan for new condition of listing

In the coming weeks the TGA will be writing to sponsors of affected products advising of the intention to impose a new condition of listing on all products containing krill oil. A statement will also be included on the eBusiness Services.

The new condition of listing will be imposed on **30 June 2015** and sponsors will be notified in writing prior to this time.

Sponsors are encouraged to update

The TGA and CMA appreciate that industry values both the safety of its consumers and the reputation of their businesses and it is anticipated that sponsors of existing krill oil products will elect to include an advisory statement on the label of their medicine prior to the new condition of listing being imposed.

Sponsors may wish to consider:

- Updating their medicine label at the earliest opportunity; or
- Over sticking existing labels with the advisory statement if amendment of the labels is not feasible in the short term.

The label advisory statement may be words to the effect of: 'Contains crustacean shellfish' or 'Derived from seafood'. Please note that the 'Derived from seafood' statement can be included on the ARTG entry with no associated fee.

What will happen after the condition of listing is imposed?

After the condition of listing is imposed, krill oil medicines that do not include the label advisory statement can be cancelled from the ARTG under subsection 30(2) (c) of the Act. In the future, consistent with other like products, TGA intend to include the required advisory statement for krill in RASML.

If you have any questions or require further information please contact Emma Burchell on 02 6260 4022 or email emma.burchell@cmaustralia.org.au