



Kristy Roberts
<policy@chc.org.au>
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To "Michelle.McLaughlin@tga.gov.au"
<Michelle.McLaughlin@tga.gov.au>
cc

Subject CHC concerns re permitted cholesterol claims

Hi Michelle,

As per our discussion on Friday, I am following up with an email regarding the outcomes from the CMEC meeting about endorsed cholesterol claims for Listed medicines. The CHC has been contacted by members who have been advised by staff within the TGA that only the wording that has been endorsed by CMEC can now be used on labels i.e. any wording which deviates from the approved claims will not be permitted as they refer to a serious condition.

The CHC is very concerned about this as 1) it limits the claims which can be made on any product designed for maintaining normal cholesterol levels in healthy people; 2) it has always been standard practice that similar wording to the claims can be made as long as they are 'kept within the spirit' of the approved wording and 3) there are a substantial number of products which refer to cholesterol for their claims which would have different wording to the approved CMEC wording which will have a significant impact on industry.

The CHC acknowledges that reference to cholesterol is a concession for industry as it is a serious condition however only permitting the exact wording of the endorsed claims to be used on labels appears to be unfair when similar wording could be used which is in 'keeping with the spirit' of the approved claim. The CHC is aware of many products (specifically) which refer to cholesterol – some

examples of their claims include:

- To assist in the maintenance of normal healthy cholesterol levels
- Maintaining healthy normal cholesterol and triglyceride levels
- Maintain normal healthy cholesterol levels
- Aids/assists in the maintenance of cholesterol health
- May help maintain normal/healthy cholesterol levels
- May help maintain cholesterol within the normal/healthy range and improve the HDL/LDL ratio
- Helps to support normal cholesterol levels in people with a healthy lifestyle and diet.
- XXXX may help to maintain normal cholesterol levels and help to maintain the health of the heart
- May support normal blood cholesterol levels, which may assist in maintaining a healthy heart.
- It boosts the level of fibre in the diet and thus may help to maintain normal cholesterol levels.
- Helps lower triglyceride levels in healthy subjects
- May help increase HDL (good) cholesterol in healthy subjects
- May assist in the management of cholesterol health
- Helps lower LDL cholesterol and triglyceride levels in healthy subjects
- Helps maintain healthy cholesterol levels in healthy subjects
- Helps maintain healthy triglyceride levels
- Supports healthy blood triglyceride levels
- Helps maintain healthy LDL: HDL cholesterol ratio in healthy subjects.

The CHC asks that the TGA accept claims for Listed medicines that are within the spirit of the approved claims for cholesterol and not expect exact wording to be used.

If you would like to discuss this matter further please do not hesitate in contacting me. I look forward to your response.

Kristy Roberts
Scientific & Technical Manager
Complementary Healthcare Council
PO Box 104
Deakin West ACT 2600
Ph: (02) 6260 4022
Fax: (02) 6260 4122
Mobile: 0438 890 889
Email: policy@chc.org.au
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