

3.2 Allura red as an excipient in therapeutic products

Outcome

ACCM noted the lack of a definitive link between the ADRs and Allura Red AC in medicines on the ARTG and the ongoing TGA monitoring for safety of this excipient ingredient.

4. Guidelines on Levels and Kinds of Evidence to Support Claims

Nil items

5. Evaluation of New Substances

Nil items

6. Safety or Efficacy Reviews

Nil items

7. Registration Applications

Nil items

8. Regulatory Reforms

Nil items

9. Adverse Drug Reactions associated with complementary medicines.

9.1 ADRs associated with complementary medicines from 1 August to 31 October 2010

Outcome

ACCM noted the adverse events reported for complementary medicines from 1 August 2010 to 31 October 2010 .

10. Matters Referred from within TGA

10.1 Krill oil compositional guidelines

Outcome

In making the above recommendation:

- ACCM recognises that krill oil is an approved listable substance irrespective of whether the substance complies with the compositional guideline.
- Based on the presented data ACCM identified no safety concerns in either of the two compositional guidelines, providing the krill oil is identified and the solvents used are compliant with the requirements in the *British Pharmacopoeia*.
- ACCM recognises that different raw material processing methods may result in different constituent profiles in the final material. However, this is not uncommon in natural substances and is therefore not a strong argument for the existence of more than one compositional guideline. Further, ACCM noted that variations in the active constituent profile may be reflected in the final dosage instructions for the therapeutic product.
- Finally, ACCM also notes the possibility of a relevant monograph being included in a TGA recognised standard in the future and that this may impact on the need for a krill oil compositional guideline.

Action Items

- OCM to reinvestigate the role of compositional guidelines.

Recommendation 4.2

ACCM recommends to the TGA that the revised compositional guideline, which includes broader specifications, be adopted to control quality and safety of all solvent-extracted krill oils.

10.2 Summary of ACCM considerations to date

Outcome

ACCM noted the attached consolidated list of ACCM items considered, recommendations and action items from 2010.

Action Items

- ACCM to be presented the summary of ACCM considerations on a regular annual basis.