ACCM 4 Recommendations, outcome and actions

Item 2 Confirmation of Draft Minutes of ACCM 3 (3 September 2010)

Recommendation 4.1

ACCM confirms that the draft Minutes of its previous meeting ACCM 3 (3 September 2010), as amended, are a true and accurate record of that meeting.

Action Items

- OCM to investigate if the National Drugs and Poisons Scheduling Committee considered dermal absorption of cassia oil when the decision was made to include the substance in Schedule 4 of the SUSDP.
- OCM to consider obtaining external expertise in any possible future discussions in relation to probiotics and other substances derived from probiotics.

Item 3.1 Revised draft guidelines for assessing the safety of ingredients for use in listed medicines during pregnancy

Outcome

ACCM provided comment on the revised draft Guidelines for Assessing the Safety of Ingredients for Use in Listed Medicines During Pregnancy.

Action Items

- In general, the OCM should review the criteria for each category with the aim of presenting them in a positive rather than negative context.
- The OCM to investigate the disclaimer on the labels of supplements in the USA in relation to use in pregnancy.
- The OCM to explore the potential collaboration with other Government departments to develop a resource booklet for practitioners providing guidance on the use of complementary medicines in pregnancy.
- ACCM to reconsider the wording of any label advisory statement in relation to pregnancy for all/ selected Listed medicines.
- ACCM to be kept informed of the TGA's improved transparency project
- Specific changes to category 1 (clusters 1 and 2):
    - Remove 4th dot point '*No human or animal studies relevant to use during pregnancy have been conducted'*.
    - Include reference to the '*absence of biological plausibility'* in the 3rd dot point.
    - Amend 3rd dot point to start 'Human studies, *where undertaken,...*'
    - Add '*Pharmacological activity not known to be associated with ADRS'*.
    - Once the above changes are made, the first and second clusters can be combined.
    - Page 6, footnote 5: Add "*This should include a statement in relation to the quality assessment of the literature and may include doubts....* "

Item 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.

Item 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 .

10.1 Krill oil 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.

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.
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Action Items

- OCM to reinvestigate the role of compositional guidelines.

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 an annual basis.

11.1 Advisory Committee on Non-prescription medicines August 2010 minutes

Outcome

Members noted the Advisory Committee on Non-prescription medicines August 2010 minutes.

11.2 Advisory Committee on the Safety of Medicines 3rd meeting minutes

Outcome

Members noted the Advisory Committee on the Safety of Medicines 3rd meeting minutes.

11.3 Advisory Committee on the Safety of Medicines 4th meeting minutes

Outcome

Members noted the Advisory Committee on the Safety of Medicines 4th meeting minutes.

11.4 Medicines Safety Update No 5 bulletin

Outcome

Members noted the Medicines Safety Update No 5 bulletin.