The Secretary
Scheduling Secretariat
GPO Box 9848
CANBERRA ACT 2601

Dear Secretariat

CHC Submission – Methylsulfonylmethane (MSM)

Thank you for the opportunity for the complementary healthcare industry to provide comment on the proposed scheduling of **Methylsulfonylmethane (MSM)** for consideration by the Joint meeting of the Advisory Committees on Medicines and Chemicals Scheduling (ACMS and ACCS).

The Complementary Healthcare Council (CHC) is the leading expert association exclusively committed to a vital and sustainable complementary healthcare products industry. We are unique in representing all stakeholder groups in the complementary healthcare industry; our members include importers, exporters, raw material suppliers, manufacturers, wholesalers, distributors, retailers, practitioners, consultants, direct marketers, multi-level marketers and consumers. The CHC is the principal reference point for members, government, the media, and consumers to communicate about issues relating to the complementary healthcare industry.

The CHC notes that the current proposal for MSM is in regard to its consideration for inclusion into Schedule 4 for human therapeutic use in concentrations greater than **1500 mg per dosage unit**. This consideration may also include methylsulfonylmethane for non-human use, mirroring the scheduling of dimethyl sulfoxide.

As a side note, the CHC recommends that the any reference to this substance be consistent with the TGA Australian Approved Name (AAN) - 'dimethyl sulfone' to reduce misunderstanding by sponsors.

The CHC provides the following comments for consideration:

The CHC acknowledges the proposal for MSM originates from the fact that a substance may be captured by another entry as a derivative of that substance. MSM can be prepared by oxidation of dimethyl sulfoxide (DMSO) with hydrogen peroxide which suggests that MSM could be classified as a derivative of DMSO and therefore captured by the schedule entries for DMSO.

The CHC notes that the provisions in Part 1 (2) (j) of the *Standard for Uniform Scheduling of Medicines and Poisons* (SUSMP) state that any other substance included in Schedules 1 to 6, at a concentration not exceeding 10 mg per litre or 10 mg per kilogram, unless that substance is also included in Schedule 7 or 8, **is excluded**. However, the monograph for MSM in the United States Pharmacopoeia has a limit of 0.1% (greater than the exclusion limits for inclusion into the SUSMP); the CHC assumes this is the reason behind the proposal for inclusion of an entry for MSM.

Noting the above, the CHC strongly **opposes** a new entry for MSM into Schedule 4 based on the following:

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- MSM has been evaluated and approved for eligibility as a Listable active ingredient with no daily dosage limit - refer to Listing Notice 2008 (No. 6). It should be noted that this substance was previously assessed by IJEACM[1] (refer to Item 3.5 April 2006 meeting). In addition, IJEACCM also evaluated DMSO (refer to Item 3.6 July 2006 meeting) where it was concluded that '*limited pre-clinical and clinical data suggests that oral and topical toxicity of DMSO is relatively low in humans, even after repeated administration'*. Both evaluations considered quality and safety of the substance for use as a listable ingredient. The collective outcome determined that there was **no safety basis for restricting MSM based on daily dosage.** The CHC therefore questions the justification for including a restriction on the substance.

- The Methylsulfonylmethane USP monograph (synonym dimethyl sulfone) specifies that '*not more than 0.1% of dimethyl sulfoxide is found, not more than 0.5% of any other individual impurity is found; and the sum of all impurities, including dimethyl sulfoxide, is not more than 0.2%*'.

As a proposed solution, the CHC recommends not including the proposed entry for MSM and instead suggests amending the entry for DMSO in Schedule 4 to exclude Dimethyl sulfone when compliant with the MSM (dimethyl sulfone) monograph in the USP.

The CHC would welcome the opportunity to discuss any matters relating to this submission and if you require further information please do not hesitate to contact me.

Yours sincerely

Kristy Tomas
Scientific and Regulatory Affairs Manager

19 January 2011

[1] IJEACCM was a Committee established under the proposed Trans-Tasman Harmonisation process which included representatives from the Therapeutic Goods Administration in Australia and Medsafe in New Zealand; all of which were technical and regulatory experts.