Information for Sponsors-Proposed Changes to Validation Rules in the Electronic Listing Facility (ELF)-Fish Liver Oil

Dear Member,

The TGA's Office of Complementary Medicines has advised that currently in the Electronic Listing Facility (ELF) Vitamin A and Vitamin D are non-mandatory components of the following Listable ingredients:

- Code liver oil,
- Skipjack liver oil,
- Halibut liver oil,
- Pollack liver oil, and
- Shark liver oil

Both Vitamin A and Vitamin D are however included in Schedule 4 of *the Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP) with cut-offs to unscheduled of 3000 Retinol Equivalents (RE) / daily dose for Vitamin A and 25 micrograms / recommended daily dose for Vitamin D. Therefore, these ingredients should be mandatory components of fish liver oil ingredients when used in Listed medicines, as opposed to non-mandatory components. The OCM propose to correct this error by:

- Amending the ELF validation rules for the aforementioned ingredients to include Vitamin A and Vitamin D as mandatory components

These rules are based on the requirements for both substances as set out in the SUSMP and will correct the current rules in ELF. The proposed change to the ELF validation rules will take place on the **21 October 2011**.

The OCM has advised that they have written to Sponsors of products containing these ingredients to inform them of the situation and the changes to be made to the ELF validation rules and to ask them to add these components (if not already present) and the relevant Vitamin A warnings to the their product Listing (if appropriate). Changes can be made via the TGA's eBS system and there is no charge for making these updates.

The TGA has advised Sponsors that the labels of medicines containing the ingredient Vitamin A are required to include particular warning statements if the product is for the use in adults. These statements are outlined in the *Required Advisory Statements for Medicine Labels* (RASML). Sponsors are reminded to comply with these labelling requirements at the next print run, or within two years from the 23 September 2011.

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