

## PROGRESS REPORT ON IMPLEMENTATION OF AHCRS – MALAYSIA

Further to our progress report in June 2005, the implementation of Phase 1 of AHCRS is now running smoothly in Malaysia. Besides the mandatory requirements for all cosmetics to be registered with the local authority, Malaysia has also implemented the requirements for local manufacturers to comply with GMP requirements with full GMP implementation to take effect from 1 Jan 2006. The experiences gained during the past 3 years are valuable to the regulators and industry alike. The authority has gained more knowledge on the cosmetics industry, the products and its players, while the industry is familiarizing itself to the requirements of the AHCRS especially in preparation for full implementation of Phase 2 of the AHCRS when control of cosmetics products is very much via self regulation by the industry.

Malaysia is always looking forward to having MRA with other ASEAN countries that are already implementing Phase 1 of the AHCRS however, until to-date, we have not received any indication from other countries of their interest to enter into MRA with Malaysia.

The time has come now for us to prepare for effective implementation of Phase 2 of the AHCRS (Notification) and the local authority have already had several discussions with the industry on the possibility of implementing the notification process earlier than Jan 2008. Of course, as reported earlier, we will need to review existing legislations with the view to amend, if necessary, to ensure smooth transition to Phase 2 of the AHCRS. Nevertheless, we noted from our several dialogs with the industry that there are some groups in the industry that are apprehensive with implementation of Phase 2 mainly due to the need to develop product information file (PIF).

While Malaysia prepares for full implementation of the AHCRS, the local authority feels the need to highlight that there are some personal care and oral products that are currently classified as pharmaceuticals in Malaysia but are mainly classified as cosmetics in the region. The local industry is expected to submit a further proposal for reclassification of this category of products to cosmetics. Amendment of existing legislation may be necessary if these products are to be reclassified to cosmetics.

In terms of trainings, the local authority, with the cooperation of the industry had conducted several seminars to educate the industry on the requirements of the ASEAN Cosmetics Directives and GMP. We plan to have more activities in the future to further educate the industry on AHCRS and a series of nationwide seminars will be organized prior to the implementation of Phase 2 of the AHCRS.

We acknowledge that post-marketing surveillance activities would be gaining increasing importance when Malaysia fully adopts the ASEAN Cosmetics Directives. Therefore, Malaysia has been actively participating in all the EU-ASEAN trainings for PMS by sending representatives from the regulatory agency and the industry who will then become trainers for the industry.

Finally, both the local authority and industry agree that a mechanism is needed to ensure that the local markets are not besieged with substandard, counterfeited or parallel imported products especially after the implementation of Phase 2 of the AHCRS.