ANNEX 12

PROGRESS REPORT ON IMPLEMENTATION OF AHCRS – MALAYSIA

Brief background

It was reported in the last ACC meeting that the implementation of Phase 1 of AHCRS is now running smoothly in Malaysia and there were no serious problems with the registration process.

The full GMP implementation locally for cosmetics manufacturers had been finalized and implemented effective 1 Jan 2006.

It was reported also that Malaysia is now in a state of readiness to engage in MRA with any countries within ASEAN that is ready for MRA implementation. In this respect, the Philippines, in the last ACC meeting had indicated their intent to have reciprocal recognition with Malaysia on product registration.

The outstanding problems as reported in the December 2006 progress report were as follows:

(i) The difference in classification of borderline products; these products are currently classified as pharmaceuticals in Malaysia but are cosmetics in other ASEAN countries.

(ii) There are some groups in the industry that are not ready for full implementation of the ASEAN Cosmetics Directives. This revolves around the requirement for PIF which will require the following information:

a. Safety data/ substantiation
b. Efficacy/ claims substantiation

These groups indicated that they are finding it difficult coming up with such documentations.

(iii) Implementation of the ASEAN Cosmetics Directives will create an open market and free movement of goods within ASEAN and this would open a flood gate for counterfeit and substandard products. Malaysia is studying the best mechanisms to ensure proper cosmetics control and enforcement of the requirements when we fully implement the ACD to avoid dumping of such products into the local market.

Ensuring the safety and quality of cosmetics can only be achieved through the join efforts by the regulators and industry through adherence to regulatory requirements and also through public education to ensure that products are used in accordance to their intended use.

Current Status

(i) Transposition of ASEAN Cosmetic Directive into National Legislation :

Malaysia has taken the necessary efforts for readiness to fully implement the ASEAN Cosmetic Directives by 2008. The amendments to the existing legislations have been initiated through Legal Advisor of the Ministry of Health and have been sent to the Attorney General for approval. The amendments will be gazetted for enforcement before end of this year.

(ii) Implementation of Notification Procedures.

The proposed date for implementation of the notification procedures is Jan 2007. Industry should be responsible for ensuring compliance of products with regulations before notifying the authority . The proposed ASEAN Notification template will be used for this purpose across all ASEAN countries. With the introduction of notification procedures , there will be no more requirement for submission of supporting documents such as label, GMP and CFS and other documents that are currently required for purpose of registration. A notification number will be issued after confirmation of payment of processing fees and the number will be used for purpose of importation and goods clearance at the entry points.

(iii) Good Manufacturing Practice

Consistent with the requirements of the AHCRS, the manufacturers of cosmetic products in Malaysia are subjected to GMP compliance. In terms of training, the authority with the cooperation of the industry had conducted several trainings on GMP to educate the local manufacturers to consistently produce quality cosmetic products {Please refer to attachment – Report on the preparation to implement GMP in Malaysia }

Since there will be no requirement for GMP certification amongst ASEAN countries after Jan 2008, Malaysia is of the opinion that ACC to keep a database of GMP compliant manufacturers in all ASEAN countries. This list is to be made available to NRA in each country.

(iv) Borderline products

Reclassification of borderline products (EPC products which are currently classified as pharmaceutical products in Malaysia) to cosmetics will ensure smooth adoption of the ASEAN Cosmetic Directives by the Malaysian authority as the classification of the products will be consistent with other ASEAN countries. In the last ACC meeting, it was agreed that ASEAN has a workshop on borderline products which was held in Jakarta

on March 15 – 18, 2006. It was agreed that such borderline products will be considered as cosmetics. This effectively resolves the problem of difference in classification by the respective countries. The authority recognizes that there is a need for amendment of existing legislations to allow for reclassification of the borderline products to cosmetic. Approach to be taken is to prepare proposal in order to reposition EPC claims which currently under OTC to be as cosmetic via supporting documents for claims justification (scientifically).

(v) PIF

The National authority with the support of the ASEAN Secretariat and the EU experts completed its training on PIF on May 17 & 18th to selected groups from the industry and the regulators. It has been decided that a full training workshop for the industry will be held in 3rd quarter of 2006 to familiarize and guide the industry on how to prepare the PIF. It is expected that with this training, the groups facing difficulty in preparing for the PIF documentation will be able to do so. This will facilitate the smooth execution of the transposition of the AHCRS.

(vi) MRA

In Jakarta last March, discussion on this was undertaken by Malaysia and Philippines. It was discovered that there are fundamental differences in the registration requirements of both countries:

a. Philippines, in conformity with the ASEAN requirement requires heavy metal test results while Malaysia does not have such requirement.

b. Malaysia requires full formula declaration whereas the Philippines does not.

c. Some categories of products do not require registration in the Philippines while Malaysia requires registration of all cosmetic products.

At this point of time, these issues remain unresolved. Malaysia plans to implement product notification process in Jan 2007 and is of the opinion that to go ahead with MRA will not bring much impact to both countries. In fact it may even cause complexity to our transition plan between registration and notification procedures.