Q&A for ACD Workshop March 2-3, 2010

	Question (Day 1 – 2 Mar 10)	Answers
1	Who keeps the PIF file?	The company who placed the product in the market should prepare before product launch and keep in the company for reference in case of HSA audit
2	Where to find International listing for notification of banned substances etc?	There is some international website e.g. FDA but around this region if you become CTFAS member, CTFAS will email blast any updates to the banned (prohibited) or restricted substances. This is a free web site for checking all ingredients: http://ec.europa.eu/enterprise/cosmetics/cosing/
3	If an event of notification, certain substance approved, along the way became not approved, how companies know the current status?	- HSA will email blast on banned or prohibited starting this year - CTFAS will update its members by sending a report after each ASEAN meeting
4	If Implementation by Spring Jan 2011, are the rest of ASEAN countries will be implementing the same day?	- All ASEAN countries already started implementation except Indonesia - Notification in each member country is required - Implementation Jan 2008 not 2011 but grace period is 3 years, thus Jan 2011 is the full implementation for all ASEAN countries
5	Cosmetic products cannot carry medicinal & theoretic claims can list examples?	Those claims with treatment or cure in intent are not allowed for cosmetics. Examples would be “cure acne”; “prevent cancer”, etc.
6	Cosmetic products are defined external usage; can denture cream be classified as cosmetics? Also cleansing tablets for denture?	Denture cream and Cleansing tablets for dentures are not cosmetics. Please refer to HSA for proper classification
7	GMP not mandatory if supplier do not have GMP certificate?	Supplier has to confirm compliance to ASEAN GMP Guidelines in the manufacture of products, there is no need for certification. Compliance is mandatory!
8	If we have market in Malaysia and they had done the PIF, can companies outside of Singapore use their PIF for submission in Singapore? And we only will bring in if required by authorities.	Yes but the PIF does not need to be submitted; authorities when auditing have to come to the address on the label to audit the PIF
9	Product labeling specific names of countries is necessary, can EU be acceptable?	EU is not a country, must state the country name
10	If substance under cosmetic for use by the doctor under the prohibited list, can they be allowable?	Doctors are under a different regulation for the products they make or use directly or prescribe. This has to be checked with HSA
11	If consumer buys, anyway to find out whether compliance or call here to check on notification by these companies?	Product notified are listed under HSA website

12	Labeling requirement for small size, have to comply?	Yes, all immediate packaging must comply; Ingredients listing & instruction for use can be on leaflet
13	Adverse reporting? a) If customer were to report such complaints but the products were by parallel importers b) If complaints relating to quality must record?	a) Document the feedback - Let HSA know - Ask customer to go to parallel importer b) Must record in your complaint system, don't need to be recorded in the PIF
14	As a retailer, how to ensure suppliers' compliance?	Retailers are not responsible unless the product is under their name in which case they are a company placing the products in the market. As such they need to have PIF, a letter from the manufacturer on GMP compliance. Under ASEAN agreement, the roles of each party can be defined as follows: ** Primary Manufacturer : Manufacturing Secondary Manufacturer : Bulk & filing Assembler : Put sticker Distribution / Retailer : Sell
15	For instance, when a customer (pregnancy) birth defect occurs, how?	If the product is intended to be used during pregnancy (e.g. stretch marks cream), there must be substantial safety data to support before the product is launched. Otherwise, a disclaimer should be used instead or no reference to pregnancy should be made. For general cosmetics, it is impossible for the consumer to prove that a birth defect can be associated with cosmetics.
	Question (Day 2 – 3 Mar 10)	**Answer**
1	What is the rationale if durability less than 30 months, keep the stability reports and don't need to show/mandatory for more than 30 months?	Expiry date is mandatory on the packaging if the durability is less than 30 months; otherwise companies can put either the manufacturing date or the expiry date.
2	Are there any guidelines to the microbial and heavy metal limits for a finished product?	Yes: Mercury 1 ppm; Lead: 20 ppm; Arsenic: 5 ppm Micro limit: 500 cfu/g for products for children under 3 years, eye area or mucous membrane; 1,000 cfu/g for all others
3	Any Control for Authority?	Yes, authorities do control products taken from the market place
4	How to define a mild formulation?	- Depends on safety assessment - usually with hypo allergic test
5	By when the PIF be due?	Before doing the notification
6	How to define soap free?	Soap is the product of the reaction of a fatty acid with a strong base. The absence of this is "soap free"
7	How to measure SPF in ACD?	In Vitro - no International Standard In Vivo – Most use US or EU SPF Standard; some Australian standard There is no ASEAN standard

8	If due PIF in Malaysia, must we submit PIF to Singapore Authority?	If the Authorities in one country audit the PIF in their country, they have to come to the address mentioned on the packaging. You never give the PIF away
9	Lacking of information on cosmetic ingredient, educating CASE will make them understand?	Will inform CASE
10	In regard to cosmetic product notification. Can we just provide the restricted or allowable limit ingredient in % but not all the other active ingredients?	No need percentage in Singapore; in other ASEAN countries (except Indonesia and Vietnam) only the percentage of restricted ingredients must be on the notification form. In Vietnam the full formula is required while Indonesia has not implemented the ACD
11	Water resistances SPF Claim, how to substantiate?	There is a SPF water resistance test which the manufacturer can have performed by a recognized laboratory
12	Must have human origin ingredients testing?	Ingredients of human origin are not allowed
13	How to differentiate what is primary or secondary function?	Primary function is one with the immediate intent such as Anti dandruff shampoo: Washing of hair is the primary and anti-dandruff function is the secondary
	Question **(Day 2 – 3 Mar 10 Panel Discussion)**	**Answer**
1	Are baby wipes under cosmetics?	All wipes are under cosmetic
2	Human origins growth factor under cosmetic?	- Human origin ingredients are not allowed in cosmetic
3	a) A Distributor company selling preventive measure for in grown toe nail product. Is this a cosmetic product? b) Do we need to apply for product notification / product registration with HSA? c) The company after applying GDP, do the company need to apply any other license from HSA? d) If the company is in the process of applying GDP. Can the company continue to sell this product while waiting for approval?	a) For external application, Yes; the claims have to be cosmetic not medicinal b) Pdt notification, no need registration c) No certification for GDP is required, just comply with the regulation d) Since this is a self certification, not an approval by Authorities, it is important that the company comply before the notification
4	Do we need to have the word “net weight” or “net volume” on the packaging on the cosmetic? Or is it fine to just have the weight / volume on the packaging e.g. xx ml / xx g?	Weight or volume must be on the packaging there is no requirement for the words “net weight” or “net volume”
5	Under the European Directive product shows 6M, meaning use product for 6	The EU regulation is different: it requires the PAO if the durability is more than 30 months; the expiry date if the

	month after opening. Asian Directive asks for manufacturing expiry date …. If product has MFG 01.01.2010, EXP 01.01.2013. How is the user to know to use product for 6 month after opening only rather than for all 3 years as indicated by MFG/Expiry Date?	durability is less than 30 months ASEAN regulation requires the expiry date if durability is less than 30 months (same as EU) but requires manufacturing or expiry date if more than 30 months
6	Are beauty products shampoos or creams with ingredients derived from human placenta (amniotic fluid) banned in Singapore /ASEAN?	Yes, all ingredients of human origin are banned in all ASEAN (as well as EU, China and many other countries)
7	If our head office is in Malaysia and they have the PIF, can they photocopy the PIF and send to us upon HSA request for audit?	Yes
8	a) Do HSA audit the warehouse? b) Is auditing of warehouse done routinely? E.g. once a year?	a) Yes b) Up to their schedule
9	What are the consequences should an auditor claimed a warehouse to be disorganized/messy? Will grace period to correct the warehouse be given?	This is up to the Authorities to decide
10	During the audit of GMP & GSP of the warehouse, will it be done by HSA or persons specialized in logistics & warehousing? Will the fault discovered be a positive one or just a warming for corrective actions to be taken, assuming it's a first audit?	The audit will be done by HSA the outcome of the audit is up to the Authorities to decide
11	How / who determine the product expiry date? (Please repeat the format of expiry date coding)	Usually companies do an accelerated stability test to determine the durability of the product. The format must be day-month-year or month-year
12	Does ACD requirement considered containers used to fill the cosmetic products as part of the compliance? What if containers production involved nitrosamine substance? E.g. metal can for aerosol or hair spray	Packaging is not under the ACD requirements. The formation of nitrosamines on contact between the product and the packaging must be avoided; this is mentioned in Annex 3
13	If myself made the product and been practice for 10 years. And we going to market out (small volume), what steps to get about? Who do we find to do "clinical trial" / Lab test?	Company making decision to sell in the countries must comply: Ingredients must comply with the Annexes; Products must be notified; PIF must be ready: this include GMP compliance and safety assessment Labeling and claims must be compliant
14	Retailer selling fragrance needs notification?	The products need to be notified. If the retailer buys the fragrances from a company in Singapore, that company must notify
15	For eye care cosmetic product, do we need to notify the HSA full active	No need percentage but all ingredients must be on the notification, no percentage required.

	ingredients or just the restricted or maximum allowable limit ingredient in percentage?	
16	Pigments used in eyebrows embroidery and tattoo, are they classified as cosmetic?	Yes if the products are temporary tattoos. For permanent tattoos (require needle) the products are not cosmetics (usually they are considered as drugs as they are injected)
17	Is Liposome (as ingredient) classified as cosmetic if the function is served as cosmetic?	Yes
18	Companies introduce products for doctor usage, who submit?	The Company
19	a) Any other license beside GDP for HSA b) How small retailers of perfume and cosmetics can comply with these regulations? c) If they have products of their shops complying all the conditions except importer or distributor's name stickers on them?	a) No license needed self regulation. b) Retailers have to make sure they buy from companies that do comply c) This is a mandatory requirements; if there is no address label on the packaging the products are illegal and HSA might recall them
20	With implementation of ACD is it true, no need product registration?	Yes
21	As a distributor (who requests documents from brand), what should we do if: a) HSA requests to do heavy metals test on our products b) Test results comes back with small content of Arsenic c) Principal / Brand says products does not contain Arsenic What should we do?	Discuss with HSA the test results and keep your product in the market if the Arsenic content is lower than 5 ppm. If higher than 5 ppm the product is not complying;
22	For retailers, while focus on manufacturing & distributor, what are retailer's stand points?	- Don't put price sticker on the mandatory labeling - taking in products, storage on or off the shelves - GSP
23	If Products contained prohibited substance from suppliers, how should the retailer deal with them?	Retailer can decide not to sell