Q&A for ACD Workshop 26 August, 2010

Questions from Flyer		
	Question	Answer
1	What is the percentage of AHA not to be considered as cosmetic product?	Up to 10% of Lactic or Glycolic acids is allowed in general public products; 10-20% for products to be used by professionals only; above 20% the products can only be used by medical professionals;
2	Are cosmetic products allowed to contain ingredients of animal origin? If so, what are the additional document requirements for products with ingredients of animal origin.	Yes, but the company must have certification that the ingredients are free of Transmissible Spongiform Encephalopathy (Mad Cow disease); if the animal is pork, then a red symbol must be displayed in Malaysia and Indonesia
3	What is the status of mutual recognition? Will products notified in other ASEAN countries or in Europe be automatically allowed or notified in Singapore?	- The Mutual Recognition was only valid between 2003 and 2008. It is no longer applicable and was actually never used. Products must be notified in each ASEAN country. EU is a different part of the World and the ACD does not apply to EU. The EU regulation and the ASEAN one are similar.
4	For the product notifications been submitted by the local manufacturer/distributor, a) Should the retailer to re-submit a notification to HSA again? b) Should the retailer obtain a copy of notification from the local manufacturer/distributor and file in the PIF?	The company responsible for placing the product in the market (usually not the retailer) must have the PIF and notify the authorities; The retailer has to make sure that added labels (like price) do not hide mandatory information;
5	Is there a list of cosmetics which are notified to HSA, posted on website?	Yes;
6	Is this claim acceptable for a skincare cream? Control of production of Melanin to reduce the appearance of dark spots.	Yes provided the supporting evidence is in the PIF;
7	Products are purchased in a very small quantity for in house (Salon) use, are still considered as sale or supply requiring	Yes, whoever you are buying these from is the company responsible for placing the product in the market and must notify. If you are buying these from outside Singapore, then you are placing the product in the market and must notify

	notification, e.g. creams for face, tints for eyelashes.	and have the PIF;
8	Regarding Banned or prohibited ingredients checklist a) Is it can only be done manually by referring to a list? Item by item? b) Or is there a website where we can key in all the ingredients of a particular product and it prompts us if it contains prohibited substances.	This EU web site gives important information ingredient by ingredient: http://ec.europa.eu/consumers/cosmetics/cosing/ Some of the ingredient have a different status in EU and ASEAN; still manual search is important. A new web site giving all the info for formula (rather than searching by ingredient) is being developed; CTFAS members will be informed when it is live;
9	Acne is a skin disease and if my products have claims such as effective to prevent acne, which mean it is a drug? What about helps to prevent white or black heads?	Acne is not a disease; it is a normal consequence of oily skin. Any product claiming to "help prevent acne" is a cosmetic; "treatment of acne"is a drug claim;
10	a) Is essential oil used in beauty spa for massage considered a cosmetic product? If not, then what category should it belong to? b) If manufacturer has no GMP facility, can its products be imported and sold in Singapore?	a) Yes: it goes under: "Creams, emulsions, lotions, gels and oils for skin (hands, face, feet, etc.)" b) No: only products made in GMP facilities can be sold in ASEAN;
11	In Singapore it is understood that parallel import is allowed. a) How does parallel importer comply with PIF requirement? b) How is the enforcement of the ACD applied to the parallel importer?	a) Parallel importers have to declare themselves to HSA and get authorization; they can only import products that are already placed in the market by the appropriate company; b) The same way it is to any other importer: notification is mandatory and post market surveillance applies the same way;
12	What are the combination of Raw materials in cosmetic products as evaluated or found as carcinogenic or mutogenic by ACD? e.g. Nitrozone	The ACSB is tasked with insuring that non safe RM are not allowed in cosmetic products. When a RM is found to be carcinogenic, there is a review process;
13	a) How would HAS differentiate parallel	a) If labels are not on the product, the product is illegal whether it is a parallel import or not;

	imports / direct purchase from overseas if labels have been taken out? b) What should distributers do to ensure that they have carried out their responsibility to prevent shops / salons do not remove any of the labels?	b) Train and explain;
14	Do we need to include the health-related complaints that take place in all ASEAN countries in the PIF or just the health-related complaints that take place in Singapore? Because we also distribute our products to other ASEAN countries.	This is a company decision: you do what you want! The recommendation is to have all ASEAN complaints in one place in order to better understand how the product is perceived by consumers;
15	a) If authority found one or two labels missing on a product in a retail shop. Who should that authority fine, retailer or distributor?	a) If this is one or two products: they will probably take no action; if it concerns all products in one or two references, they will take action and probably send a letter to the "Company responsible for placing the product in the market"; b) Both are acceptable;

		Answer
	b) Must labels be printed on the packaging or paste with stickers?	
16	For example, a product made in USA but sold under Spanish Brand, company will be imported & distributed in Singapore. a) Is it acceptable to have the packaging done as " Made in USA Distributed by Spanish Company A Singapore Company B "	a) If the product is "made in the USA" then the label should read "made in the USA"; the name and address of the distributor in Singapore is mandatory any other additional information is not mandatory but not forbidden; b) EU is not a country; the country of origin must be on the packaging. "Made in EU" is not acceptable;

	b) Can we use "Made in EU"?	
17	If there is a use of biotical plant, do we have to use Latin name in the labeling or do we have to name the part of the plant use?	INCI name is mandatory: this is the Latin name; other information is not mandatory but can be used;
18	Since products manufactured by medical practitioner for use of patents are exempt from product notification, are the products therefore not required to comply with ASEAN labeling requirements?	- Ask HAS, this is specific to Singapore;
19	Is Hair shampoo or shower gel cosmetic product? Many such products now make claims to be therapeutic and even printed on the bottles. E.g. Relaxing, Distressing etc…. can this be allowed?	Yes, these products are cosmetics. "Relaxing or distressing" are not therapeutic claims;
20	a) According to Section of Part 2, method of analysis should include all the specifications for each ingredient, so must all these information corresponding to be collected? Besides, many methods are the same, such as appearance measurement, so should this information be kept repeatedly? b) How to judge the sufficiency of safety assessment? c) If shelf-life for products with more than 30 months, must be printing expiry date and manufacturing date?	a) This is needed only upon request by the authorities; no need to have in the PIF unless you are a manufacturer in which case it is part of GMP; b) The safety assessor is the judge; the authorities are controlling; the company placing the product in the market is responsible; c) If shelf life is less than 30 months, expiry date (or best before) must be printed; if more than 30 months either manufacturing date or expiry date must be printed;