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Cosmetics market regulation in Asian countries

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ABSTRACT: The purpose of this article is to give a comparative overview on the cosmetic market regulation in some key Asian countries and consequently it should facilitate the reader to properly understand main critical issues, differences and similarities of the related cosmetic regulations. In fact each legal system has different requirements but there is also a similar outline which consists of common rules and topics involving registration procedure, labeling, licensing, ingredients restrictions and product safety requirements. Therefore this article will try to show the reader some main issues of the cosmetic regulations throughout a very practical approach.

INTRODUCTION

Cosmetic products are subject to legislative regulatory requirements in almost every industrialized country, included Asian countries. A cosmetic can generally be defined as «any substance or preparation for human use for the purpose of cleansing, beautifying or altering the appearance commonly to include personal toiletry products (such as shampoos and lotion), beauty products and fragrances», certain cosmetics products (e.g. anti-dandruff shampoo) classified as cosmetics in some countries (e.g. as in the EU, China), in other countries may be regulated as Over-The-Counter drugs (as for instance in the USA) or Quasi-drugs (as in Japan).

JAPANESE COSMETICS REGULATION

Cosmetics regulation in Japan is based on different laws and ministerial ordinances consisting mainly of the *Pharmaceutical Affairs Law (PAL)* (1) Ministry of Health and Welfare *Notification N.331 of 2000*, which states the standard for cosmetics; but also on *Notification N.1339* from the Director-General of the Pharmaceutical Affairs Bureau, Ministry of Health and Welfare, October 9, 1980 for the Standards for Fair Advertising Practices of Drugs, Quasi-drugs, Cosmetics and Medical Devices.

In Japan, for legal purposes, cosmetics are divided into *quasi-drugs* and *cosmetics*. In the PAL quasi-drugs are defined as items that have a middle action in the body, and include



those stipulated by legislation and those designated by the MHLW. Quasi-drugs stipulated by law are for example products intended to prevent bad breath, body odour or heat rash; to promote hair growth, prevent hair loss, remove hair, or for the extermination of mosquitoes or fleas. Quasi-drugs that are designated by MHLW include for instance sanitary cotton, permanent wave solution, bath agents, products for improving chapped skin, dry skin, and itching, medicated cosmetics, therapeutic dentifrices, products for wound disinfection or protection, disinfection for soft contact lenses, etc..

Cosmetics are intended to use on the body, for cleansing, beautifying, or increasing the attractiveness of the body, for changing the appearance, and their actions on the body are mild. Although in Japan both are differentiated in legislative terms, there is no difference whatsoever between them in the microbiological context, and it's not properly clear the classification (2).

On the other hand, the major point of difference between Japan and other Asian countries in the regulation on cosmetics is that in the last decade Japan has eased the standards for cosmetics and has deregulated the cosmetics industry, so the old system of obtaining prior approval and licenses for products has been abolished in principle.

Instead, Japan, differently from China and Vietnam, has build an good example of a nation where costly pre-market registration procedures were replaced with manufacturer responsibility for product safety and with post-market surveillance (similar to the systems in the USA and EU) without compromising consumer safety.

At the first glance this system appears to be more relaxed than these of the other Asian counterparts, but the Japanese cosmetic industry has a high level system of quality, with the presence of industry guidelines and in fact depending on the cosmetic company some of the in-house standards are even more stringent than the voluntary industry code. By the way, a potential market player should bear in mind that deregulation doesn't mean that the existing system of approval and licensing for the manufacture, import, and sale of cosmetics doesn't remain

intact, but just that requirements for granting approvals and licenses are eased.

The Japanese government regulates the cosmetics industry through its Ministry of Health, Labour and Welfare (hereinafter MHLW) according to the *Pharmaceutical Affairs Law (PAL)* (3).

The PAL states that a person wishing to start marketing business for drugs, quasi-drugs, cosmetics, or medical devices must obtain a marketing business license depending on the type of business as well as persons wishing to establish a business for the manufacture of drugs, quasi-drugs, cosmetics, or medical devices must obtain a manufacturing business license in accordance with the manufacturing category (4).

MHLW has adopted a list of prohibited ingredients, a list of restricted ingredients, a positive list of UV filters and a positive list of preservatives. Other than these restrictions, the burden of ensuring product safety, as aforementioned, has been shifted to cosmetic manufacturers and importers. As such, any ingredient that can be shown to be safe may be used in a cosmetic product (5).

Therefore, the following is a summary of the scheme of examinations for the approval of Quasi-drugs and Cosmetics according to the Japanese regulation:

- **Cosmetics:** items indicating all ingredients are exempted from application for approval and just need notification to prefectural governors required on individual items after acquiring manufacturing/marketing approval. Items containing ingredients not required for indication shall be approved by MHLW based on equivalency evaluation and examination for approval conducted by the Pharmaceuticals and Medical Devices Agency
- **Quasi-drugs:** new quasi-drugs shall be approved by the MHLW based on equivalency evaluation and examination for approval conducted by the Pharmaceutical and Medical Device Agency. Items which meet approval standards have to be approved by a prefectural governor. Other items shall be approved by MHLW based on equivalency evaluation and examination for approval conducted by the pharmaceuticals and Medical Devices Agency;

Furthermore must be taken into consideration the *Standards for Fair Advertising Practices of Drugs, Quasi-drugs, Cosmetics and Medical Devices*.

Notification from the Director-General of the Pharmaceutical Affairs Bureau, Ministry of Health and Welfare, October 9, 1980 (6) set a bunch of rules that aims at rationalizing the advertisements of drugs, quasi-drugs, cosmetics and medical devices, while preventing them from becoming falsified or exaggerated.

A person who puts advertisements of drugs, quasi-drugs, cosmetics and medical devices, shall make efforts to relay accurate information so that users can use the product concerned properly, and there are specific advertisement rules related to names, to the manufacturing method, to the effect or efficacy, performance and safety, with the aim of protecting the customer and the fair competition practice.

VIETNAMESE COSMETICS REGULATION

The cosmetics sector in Vietnam is continuously developing but, regrettably, the sale of cosmetics and beauty products is largely uncontrolled and is plagued by a wide range of fake, mislabelled, and smuggled products. This is one of reasons why Vietnamese Government is tightening control over imported and locally made cosmetics. In order to filter out low quality cosmetic product, the Vietnamese Government has imposed a series of legal measurements. These measurements are product registration, product testing, imposing tax, and advertising regulation.

Actually, the process of product registration is complex and often confusing to a foreign company. In this moment the main normative reference is represented by the Decision No.

48/2007/QD-BYT dated 31 December, 2007 promulgating Regulation on control over cosmetic. This Decision replaces regulations on export-import cosmetic on the Circular No. 06/2006/TT-BYT dated on 16 May 2006, regulations on information, advertisement directly effecting people' health attached to the Decision No. 2557/2002/QD-BYT dated 4 July 2002 and regulations on labelling cosmetic directly effecting people's health on Circular No. 14/2001/TT-BYT dated on 26 June 2001.

According to Decision No. 48/2007/QD-BYT, organizations and individuals can only introduce their cosmetic to

the market after approval and announcement by Vietnam Pharmacy Management Department (Ministry of Health) and take full responsibilities on those products' safety and efficiency. Organizations, individuals named on dossiers of cosmetic announcement must own Business Registration Certificate, including function of cosmetic trade (7).

Besides, during the custom processing companies are required to produce the original testing certificates for the imported cosmetics. The certificate must be issued by the producer. Once the products are imported, the cosmetic companies need to register their products with the Vietnam's Ministry of Health (MOH). The Ministry of Health requires cosmetic importers to provide at least three samples of each new product in order to examine its safety.

Before new regulations, cosmetics products have been monitored by four ministries. The Ministry of Industry kept control over the production, the standards of the products should be registered at the Ministry of Science and Technology, while the Ministry of Health controls the quality of the products, and the Ministry of Trade watched post sale activities. Presently, the Ministry of Health is the only state management authority over cosmetics products. In the past, state management authorities only kept control over five categories of cosmetics that may affect human health and represented by different kinds of face creams and shampoos. However, currently, all kinds of cosmetics are put under the strict control of the Ministry of Health. Moreover, from January 1, 2008, cosmetics companies must have the GMP (good manufacturing practice) certificate to be eligible to continue their production. The set regulation aims to strictly control the quality of cosmetics. The products available on the market must not contain substances that may harm human health, for example heavy metal residues, or industrial chemicals.

There are 230 chemicals listed as prohibited substances in making cosmetics products. The following items are some of those classified as cosmetics that directly affect human health and welfare and are required to be registered for quality assurance purposes with the MoH for distribution and circulation within Vietnam: products applied to the skin being creams, liquids, solutions, gels and oils, face masks (except for products not containing any chemical substance), all substances with a colour foundation (in the form of liquid, paste or powder), make-up powders, powder used after showering, hygiene powders, hygiene soaps, deodorant soaps, perfumes, hygiene scents and fragrances, products used when showering and washing, hair removal products, deodorant products for the body and anti-perspiration deodorants, hair care products, (such as: hair colouring products, hair colour removal products; hair waving products, products to stretch and set hair; permanent wave products;



hair cleansing products; hair nourishing products; hair beauty products) and others.

As far as labelling is concerned, the label of cosmetic must meet all conditions on cosmetic labelling of ASEAN Cosmetic Agreement. More exactly, the following particulars are some of those that shall appear on the outer packaging of cosmetic products or where there is no outer packaging, on the immediate packaging of cosmetic products: the name of the cosmetic products and its function, instructions on the use of the products, full ingredient listing (the ingredients shall be specified by using the nomenclature from the latest edition of standard references, botanicals and extract of botanicals should be identified by its genus and species), country of manufacture, the name and address of the company or person responsible for placing the product on the local market, the contents given by weight or volume, the manufacturer's batch number, the manufacturing date or expiry date of the product in clear terms (e.g. month/year), other special precautions to be observed in use and registration number from the country of origin (manufacture) of the country of registration (8).

The taxation is another factor which directly affects the cosmetic importing into Vietnam. There are two types of tax: Import tax and Value Added Tax (VAT). The VAT for cosmetic is 10 percent which is the same with that of other commodities. In an attempt to reduce inflation rate, on August 3, 2007 the Vietnam's Ministry of Finance had issued two Decisions No. 69/2007/QD-BTC and No. 70/2007/QD-BTC to reduce cosmetic tax from 50 percent to 30 percent.

Lastly, the regulation on cosmetic advertisement is another concern. Purpose of the regulation is to confirm that the advertisement's content is in line with product's quality. Cosmetic trading establishments in Vietnam in desire of advertising the products have to submit the dossiers to Department of Health at the local level where the headquarter of announcement organizations or individuals is located. The content of advertisement must fit documents on safety and efficiency of the cosmetics. Therefore, all the advertising messages for pharmaceuticals, agri-chemicals, cosmetics and toiletries are to be registered and approved from the government before being broadcast. The content of advertising message is approved by the Ministry of Culture and Information. Consumers are entitled to being informed of cosmetic, complaining, denouncing and requiring cosmetic trade establishment to compensate for losses caused by using cosmetics which are produced unsafely and qualitative (9).

CHINESE COSMETIC REGULATION

China has a quite complicated system for registration of cosmetic products (10). Any importer shall in the first place apply for registration of its cosmetic products to get a certificate for marketing which can be of two types depending on importing non-special purpose cosmetics or special purpose cosmetics (11).

Since September 1, 2008 the certificate must be granted by the State Food and Drugs Administration (SFDA) which, before the products can be lawfully distributed in Chinese market, will be responsible for the acceptance of the application for hygiene license of imported cosmetics, China-made special cosmetics and new ingredients of cosmetics. After the registration process, certification of labelling for manufactured and also for imported cosmetic



products shall be applied from PRC's Administration for Quality Supervision and Inspection and Quarantine (AQSIQ) before they are imported into China. Therefore, the approved certificate and number registered by SFDA and certification of labelling plus stickers attached to imported cosmetic products are necessary documents that cosmetic exporter shall obtain when exporting any of its cosmetic products into China.

Besides this two main governmental agencies in charge of registration of imported cosmetics (SFDA and AQSIQ), other non-governmental organizations are also required to be involved in the registration process, including cosmetic sanitation inspection institution in national level appointed by the Ministry of Health (MOH) and the agent representative of an importer.

The general registration process (as shown in the flow chart attached) can be simplified and summarized in four steps: to prepare samples of imported cosmetic, apply and submit them to inspection institution; to prepare documents and files for a Cosmetics Safety and Quality Test performed by an institution or organization appointed by MOH (12); to apply to SFDA for the registration and to obtain approved certificate. The required application documents and files for either imported cosmetic for special purpose and/or ones for non-special purpose are almost the same except for some item, as described below.

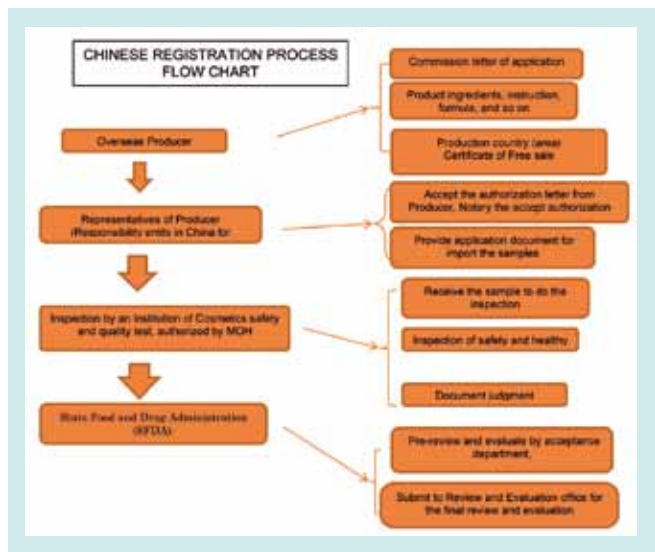
The Registration Documents for non-special purpose cosmetics are:

- The imported non-special-purposed cosmetics recordation form;
- Formula of cosmetics;
- Quality standard for cosmetics (enterprise standard);
- Inspection report issued by an inspection institution designated by the MOH;
- Original package of cosmetics (including label); package in design (including label) if planned to use special package in China;
- Free sale certificate of cosmetics in the manufacture country (region) or the country (region) of origin;
- Instruction book;
- Authorization letter, legalization and notary, submitted by the agent of cosmetic exporter, if use agent;
- Other information necessary for recordation;
- Plus: several pieces of sealed samples, amount depends on the nature of the cosmetics;
- Further documents needed for special purpose cosmetics registration are:
 - For special using, like hair growing, body fitness, breast beauty, should supply special effect ingredients name and effective ground;
 - Producing process brief and flow chart;
 - Several pieces of sealed samples, amount depends on the nature of the cosmetics;

After the submission of application, the SFDA will inspect the quality and performance of the product including all the documents you submitted. It will take 4-5 months for non-special purpose cosmetic and 8-9 months for special purpose cosmetics to get the final certificate

The Chinese laws specify that maximum time taken to review and evaluate imported cosmetics is eight months. According to local experiences, actual length for such process ranges from 2 months to eight months. For special purpose cosmetics, a committee under SFDA is scheduled to convene to review and evaluate only 6 times a year in February, April, June, August, October and

December. For non-special cosmetic, could be review and evaluate any time upon the submission.
 About the cosmetics import tariffs, China continues to adjust import tariffs in compliance with WTO Requirements. As China joined the WTO, import tariffs have been gradually lowered to the levels of 15-22 percent, plus 17 percent VAT and 8 percent CT for skin care products, and 30 percent CT for colour cosmetics in 2003. China further reduced import duties on cosmetics to about 10 percent by 2005. Although starting from August 2007, under a new rule, duties on luxury goods, including cosmetics, are raised by 10 to 30 percent, the current tariff bound rates is declined, effective from January 1, 2008, import tariff bound rate for the non-special skin care and hair care, the level declined to 6.5 percent, and 10 percent for the colour cosmetics, and 15 percent for the special hair care or nail care.



TAIWANESE COSMETIC REGULATION

The lack of formal diplomatic relations between the Republic of China on Taiwan with Taiwan's trading partners appears not to have seriously hindered Taiwan's rapidly expanding commerce. Actually, Taiwan is a very open country with very low custom duties. Indeed, for consumers and importers of cosmetics Taiwan's accession to the WTO in January 2002 has been beneficial mainly from the point of view of duties and taxes. Import duties range from zero to 15 percent on a cost, insurance and freight (CIF) basis. The Taiwanese tariffs are based on the Nomenclature of the Harmonized system of Name and Codification of Goods. Where the HS code/tariff number is known, tariff rates can be obtained by searching the websites of the Taiwan Directorate General of Customs, Ministry of Finance. Where the classification is not known or clear, Taiwanese importers can help and if necessary write to the relevant authorities to get a formal determination or opinion. Import duties on many types of cosmetics are being progressively reduced, some down to zero. There are two categories of cosmetics for regulatory purposes: common/general and medicated. The Taiwan Department of Health (DOH) has different requirements for registration under each category. The product claims and the ingredients are the key factors that determine which category a particular cosmetic will be classified under. Shortly, import licences issued by the Board of Foreign Trade are required for all imported cosmetics-related products.



All medicated cosmetics must also be registered and approved by the Department of Health (DOH) prior to sale (13). In regard to the issue of cosmetics import, the main regulatory frame is provided by the "Statute for Control of Cosmetic Hygiene". In accordance with this law "essential information such as the name and address of the manufacturer; the name of the cosmetic; the number of license/permit; the ingredients, usage, weight or volume, and the lot number or the manufacturing date shall be indicated on the label, leaflet and/or package of the cosmetic for sale. In addition, the storage instruction and the expiration date shall also be indicated on the label, leaflet and/or package of those cosmetics which have been designated by the central competent authorities as per its public notice". If the size of the package is too small to be marked or labelled, information required shall be incorporated in the leaflet accompanying the product (14).

In case of importation of any cosmetic containing medical, poisonous or potent drug(s), the competent health authorities shall examine and test the products, this is why it must be submitted to them an application stating the name and content of raw materials, the name of colorant used, and the usage of the cosmetic, accompanied by the label, leaflet, samples, package, container, certificate of analysis and relevant supporting documents, together with the payment of license/certification fee and examination fees. After an import license is issued by the central competent authorities the cosmetic may be imported.

Instead, in the event of importation of any cosmetic not containing any medical, poisonous or potent drug(s), an application stating the information above shall be submitted to the central competent health authorities but only for its reference and file, except for those cosmetics for which submission of the foregoing application is exempted (15).

Besides, "a seller of cosmetic colorants may commence the business operation only after obtaining a business license from the competent health authorities" (16).

For manufacture of cosmetics containing medical, poisonous or potent drugs, the producer shall submit an application stating the name and content of raw materials, the name of colorant(s) to be used, and the purpose of manufacture to the central competent health authorities for its examination and approval (17). In addition, for manufacture of such cosmetics it is necessary to obtain the license and to retain and station at the factory a licensed pharmacist to supervise the dispensation and manufacturing process (18).

For manufacturing cosmetics not containing medical, poisonous or potent drugs, the applicant shall submit to the competent authorities the information above for products' examination and reference, except for those cosmetics for which submission of the foregoing application is exempted by the central competent authorities (19).

For importing samples of cosmetics, an application stating therein the name, ingredients, quantity and usage thereof,

accompanied by relevant supporting documents shall be submitted to the central competent health authority for issuance of a certificate (20)

As far as advertisement is concerned "no obscene, immoral, false or exaggerate advertisement may be published or publicized in newspapers, publications, advertising leaflets, or on broadcasting, slides, motion pictures, television and other mass communication media for promoting the sale of cosmetics. Before publicizing or advertising any cosmetic


product, the manufacturer or dealer shall first submit to competent health authorities for its approval all the text, pictures


and/or oral statements contained therein; and shall subsequently present the approval letter or certificate to the mass communication institutions concerned for their examination" (21). Another important issue to consider is represented by the import restrictions. More exactly all cosmetics, skincare and toiletries and ingredients that make use of the tissue of ruminants from countries affected by mad cow disease or foot and mouth disease are banned. This applies to both finished products and bulk ingredients from such countries. Currently those affected in this way are Great Britain, Canada, Ireland, France, Switzerland, Portugal, the Netherlands, Belgium, Luxembourg, Liechtenstein, Denmark, Spain, Germany and Italy. If a product does not contain tissue of ruminants from such countries it will not be banned (22).

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3. Law No.145 established August 10, 1960 and amended in 2005.
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5. Standards for Cosmetics published on <http://www.mhlw.go.jp/english/topics/cosmetics/index.html> accessed 23 September 2009.
6. PAB Notification N.1339.
7. Ministry of Health, "Decision No. 48/2007/QD-BYT", on promulgating Regulation on control over cosmetics, 31 December 2007.
8. ASEAN cosmetic association, "ASEAN Cosmetic Labeling Requirements", issued by ASEAN COSMETICS ASSOCIATION.
9. Ministry of Health, "Circular n. 06/2006/TT-BYT", on Regulation on Export-Import Cosmetic issued by Ministry of Health on May 16, 2006.o.06/2006/TT-BYT of May 16, 2006, Guiding the Import and Export of Drugs and Cosmetics.
10. Ministry of Health, "Regulations on Cosmetics Hygiene Supervision", (MOH Regulation; Order No. 3; promulgation date: 1989-11-13, effective date: 1990-01-01.
11. Special-purpose cosmetics means these for the education of cosmetics hair, hair, perm, hair removal, beautiful breasts, bodybuilding, deodorant, beauty cream, sunscreen cosmetics. Non-special cosmetics products are in addition to infertility hair, hair, perm, hair removal, beautiful breasts, bodybuilding, deodorant, beauty cream, sunscreen cosmetics nine categories of special purpose other cosmetics.
12. At present, there are three such organizations authorized by MOH to exercise such performance which are first the *China Center for Diseases Control and Prevention* (CCDCP) at the Institute for Environmental Health and Related Product Safety; second the *Shanghai Center for Diseases Control* (CDC) at the Environmental Health Section and last the *Guangdong Center for Diseases Control* (CDC) at the Public Health Research Institute. Consider that the test normally takes 2-6 months while costs vary depending on the types and complexity of the products.
13. New Zealand Trade Development Centre, *Market Profile for Cosmetics/Skincare/Toiletries in the Taiwan Market*, Taipei, February 2009.
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