For discussion on
27 May 2002

Legislative Council Panel on Economic Services
Regulation of beauty products

Purpose

On the request of Members, this paper sets out the registration framework for beauty products which are defined as pharmaceutical products, discusses the need for a labelling system and outlines the arrangement for beauty products and services in certain overseas countries.

Registration of beauty products which are defined as pharmaceutical products

2. Under the Pharmacy and Poisons Ordinance (Cap 138) (PPO), "pharmaceutical product" and "medicine" mean any substance or mixture of substances manufactured, sold, supplied or offered for sale or supply for use in-

(a) the diagnosis, treatment, mitigation, alleviation or prevention of disease or any symptom thereof;

(b) the diagnosis, treatment, mitigation, alleviation of any abnormal physical or physiological state or any symptom thereof;

(c) altering, modifying, correcting or restoring any organic function,

in human beings or in animals.

3. Any products containing the above substance or making claims to have the effect of (a), (b) or (c) above are regarded as pharmaceutical products and subject to the controls imposed by the PPO. The following is a list of substances currently classified as drugs and products containing these substances are required to be registered as pharmaceutical products, albeit for cosmetic use -

(i) Zinc pyrithione, an antidandruff substance which may be used in shampoo or hair conditioner;

(ii) Selenium suphide, an antidandruff substance which may be used in shampoo;

(iii) Hydroquinone, a skin whitener which may be used in beauty cream;

(iv) Triclosan, an antibacterial substance which may be used in shampoo, shower cream, toothpaste and handwash, etc.;

(v) Salicylic acid, a dermatological agent which may be used in skin care cream or gel.

4. In accordance with the PPO, pharmaceutical products, including the substances listed in (i) to (v) above, must first be registered with the Pharmacy and Poisons Board (PPB) before they can be manufactured or sold in Hong Kong. In considering an application for registration, the PPB will consider the safety, efficacy and quality of the product concerned. In this connection, the importer / manufacturer is required to produce scientific documents to prove that the product is safe and effective for the claimed medicinal purpose. The importer / manufacturer is also required to provide details of the manufacture and quality control to show that the product is manufactured to an acceptable standard of quality.

Labelling Arrangement

5. The Government is not adverse to the idea of labelling. In fact, we have mandatory labelling requirements in current legislation for a wide range of products and for various purposes, such as to -

- denote restricted access by certain sectors of the community (e.g. age restriction for indecent articles);

- signify compliance with local regulatory requirements (e.g. the GU mark on approved gas appliances);

- provide descriptions of the product and instructions for use (e.g. food labels); or

- advertise a general advice from the Government (e.g. health warning on cigarette packets).

6. The Consumer Goods Safety Ordinance (CGSO) also contains provisions relating to product labelling. Pursuant to its "general safety requirement", consumer goods have to be reasonably safe having regard to all circumstances including "the use of any mark in relation to the consumer goods and instructions or warnings given for the keeping, use or consumption of the consumer goods" (s.4(1)(b)). Where the Commissioner for Customs and Excise has reasons to believe that the consumer goods are unsafe, the Ordinance also empowers him to require the manufacturer, importer or supplier of the goods concerned to modify them or their labelling, etc. so that they would comply with the safety requirements (s.10(b)).

Labelling of Beauty Products

7. In considering whether labelling of beauty products should be made mandatory, the following factors are relevant.

(A) The Need

8. There is no compelling health and safety reasons to impose further regulatory control on beauty products. Where these products fall under the definitions of food or pharmaceutical products, elaborate systems of safety control already exists under existing legislation. For other beauty products, existing provision under the CGSO should provide appropriate cover.

(B) The Usefulness

9. While it might have certain advantages, a labelling system, which requires stating the ingredients of the product, cannot be expected to eliminate all health risks associated with beauty products -

(i) beauty products often contain ingredients, the chemical expressions of which are hardly meaningful to the general public;

(ii) listing the ingredients of a product may help consumers stay away from certain ingredients if they so wish, but precedents indicate that it is not the labelled ingredients or intended content of the product that give rise to health risks : the problem arises from impurities or ingredients that should not have appeared in the product in the first instance. In the recent cases of facial cream with high mercury content, both products have clear labels of ingredients. It was our surveillance and enforcement systems that identified the hazards in these products, and worked to safeguard the interest of the public; and

(iii) it would be difficult to decide how much detail should be included in the labels, e.g. active ingredients only or all ingredients. Sometimes, it may be the other non-active ingredients that cause problems.

10. There are also suggestions that a label stating an expiry date and/or the name and address of the importer can help consumers make an informed choice, and may facilitate enforcement actions if the product is found to have adverse effect on public safety. However, -

(i) unlike food products, cosmetic products normally do not need to be consumed within a strictly defined timeframe. The case for making the labelling of an expiry date a mandatory requirement does not seem to be particularly strong; and

(ii) information on the name and address of the importer would not be useful for consumers who are dissatisfied with the product, as normally it is the retailer, rather than the importer, that a consumer would turn to. Such a labelling requirement may in fact work against consumer interest : it may deter parallel import, thereby limiting the choices to consumers at competitive prices; and the costs to the trade will inevitably be passed on to consumers.

11. Labelling is, nevertheless, a means for manufacturers or suppliers to provide more information to consumers. We welcome voluntary labelling and other efforts of information sharing. Market forces may also encourage manufacturers and suppliers to label their products, when informative labels are perceived as adding value to the product.

Overseas Arrangements

12. The arrangement for beauty products and services in overseas countries, vide **Annex**, are varied and sundry, developed presumably pursuant to local circumstances.

Conclusion

13. The CGSO, by virtue of its general safety requirement, imposes upon all importers, manufactures and suppliers the duty to ensure that the products for sale comply with reasonable national or international standards, thus providing "umbrella" protection for users of cosmetic products. Added protection is given in specific circumstances by the PPO and other legislative provisions.

14. One relevant consideration is that we do not have in Hong Kong a sizeable cosmetics production industry, the quality of which we wish to control and for such we have to draw up our own standards against which the products are to be tested. More importantly, in the cosmetic market, no particular product is indispensable and choices abound.

15. An effective way to help consumers make their purchasing decisions is to enhance consumer education and encourage dissemination of information. We see this as a more effective alternative to developing a set of specific legislative provisions for cosmetic products. The Consumer Council has made useful contribution in this regard and we look to it for continuous effort in this direction.

Economic Services Bureau
Health and Welfare Bureau
May 2002

Annex

Overseas Regulatory Framework for Beauty Products and Services

A. Beauty Products

	Japan	Singapore	Australia	New Zealand	United States	European Union
1. Relevant Legislation	• Pharmaceutical Affairs Law (this Law covers pharmaceuticals, quasi-drugs, cosmetics and medical devices)	• The Medicines (Cosmetic Products) (Specification and Prohibition) Order • The Medicines (Cosmetic Products) (Licensing) Regulations 1996 • The Medicines (Cosmetic Products) (Labelling) Regulations 1996	• Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulations	• No specific legislation regulating cosmetics/ beauty products • Any cosmetic product which claims to have a therapeutic effect is regulated under the Medicines Act 1981	• Food, Drug & Cosmetic Act	• EU Cosmetics Council Directive 76/768

	Japan	Singapore	Australia	New Zealand	United States	European Union
2. Definition of cosmetic products	• A substance with mild effect on the human body which is intended to be put on the human body for the purpose of cleansing, beautifying, enhancing the attraction, changing the appearance, or maintaining the skin or the hair healthy.	• Cosmetic products are classified into category I and category II products.	• A substance or preparation intended for placement in contact with any external part of the human body, including the mucous membrane of the oral cavity, and the teeth, with a view to altering the odours of the body; or changing its appearance; or cleansing it; or maintaining it in good condition; or perfuming it; or protecting it	• Medicines Act 1981 defines cosmetic as "any substance or mixture of substances used or represented for use for the purpose of beautifying, improving, protecting, altering, or cleansing the hair, skin, or complexion of human beings”	• Articles other than soap which are applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance	• Any substance or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition

	Japan	Singapore	Australia	New Zealand	United States	European Union
3. Registration/ Pre-approval	• No pre-approval requirement for cosmetic products • Manufacturers and importers of cosmetic products have to obtain a licence from the Ministry of Heath, Labour and Welfare	• Traders and manufacturers of the following products are required to get manufacturing /import licence and a product licence before the goods are imported and sold: – Eye and lip products – Oral and dental hygiene products including mouth refreshers and dentifrices	• No pre-approval requirement for cosmetic products except that products intended for therapeutic use including those which modify a physiological process (or treat or prevent disease) will fall within the ambits of The Therapeutic Goods Act 1989 and Therapeutic Goods Regulations, and must be included in the Australian Register of Therapeutic Goods	• No pre-approval requirement for cosmetic products except that distribution of cosmetic products with a therapeutic effect requires the prior consent of the Minister of Health	• No pre-approval requirement for cosmetic products except that the colour additives used in a cosmetic product must be approved by the relevant authority • A cosmetic company may voluntarily register its products with the Food and Drug Administration so that the latter can advise if the company is inadvertently using a prohibited colour additive or ingredient	• No pre-approval requirement for cosmetic products

	Japan	Singapore	Australia	New Zealand	United States	European Union
4. Labelling Requirements	• Name and address of the manufacturer /importer • Product name • Manufacturer's serial number • List of ingredients • Expiry dates (for certain products)	• Name and address of the manufacturer /importer • Product name • Batch reference • List of ingredients • Precautions to be observed in use, if any	• List of ingredients • Precautions to be observed in use, if any	*[Only apply to cosmetic product with a therapeutic effect]* • Name and address of the manufacturer /importer • Product name and nature • Batch number • Expiry date where appropriate • Precautions to be observed in use, if any	• Name and address of the manufacturer /importer • Product name • List of ingredients	• Name and address of the manufacturer /importer • Nominal content • Product function • Batch number of manufacture • List of ingredients • Precautions to be observed in use

	Japan	Singapore	Australia	New Zealand	United States	European Union
5. Other Safety Requirement	• Japan Cosmetic Industry Association has compiled voluntary guidelines entitled "Guidance for Cosmetic Safety Evaluation"	• Cosmetic products shall not contain any prohibited or restricted substances beyond permissible limits	• No information	• No information	• Cosmetic products shall not contain any prohibited or restricted substances	• Cosmetic products shall not contain any prohibited or restricted substances • must not cause damage to human health when applied under normal or reasonably foreseeable conditions of use • Manufacturer/ importer shall keep information on composition, effect, and proof of the effect claimed for the product readily accessible to the authorities

	Japan	Singapore	Australia	New Zealand	United States	European Union
6. Enforcement Agency	• Ministry of Heath, Labour and Welfare	• Cosmetic Control Unit of the Health Sciences Authority under Ministry of Health	• Australian Competition and Consumer Commission	• New Zealand Medicines and Medical Devices Safety Authority	• Food and Drug Administration	• Relevant authorities in Member States

B. Beauty Services

	Japan	Singapore	Australia	New Zealand	United States	European Union
1. Relevant Legislation	• The Beauticians Law	• No dedicated legislation regulating beauticians and business establishment providing beauty services	• No dedicated legislation regulating beauticians and business establishment providing beauty services	• No dedicated legislation regulating beauticians and business establishment providing beauty services	• Each state will have its own practices and usually has legislation regulating beauticians and business establishment providing beauty services	• No dedicated legislation regulating beauticians and business establishment providing beauty services • Individual member States may have slightly different practices
2. Scope of regulation	• Persons who beautify people's appearances using such methods as perming and dressing the hair, and applying make-up and business establishments providing such services	• Not applicable	• Not applicable	• Not applicable	• The relevant legislation usually covers persons and business establishment providing natural hair styling, esthetics, cosmetology and nail specialty services	• Not applicable

	Japan	Singapore	Australia	New Zealand	United States	European Union
3. Licensing requirements/ general practices	• Beauticians are licenced. To obtain a licence, a person should have finished high school, completed relevant courses in a beautician's school designated by the Ministry of Health, Labour and Welfare • Business establishment providing beauty services is not licenced but the owner has to notify the local governor of the location, facility, names and information of the management and staff before commencement of business	• Beauticians and business establishment providing beauty services are not licenced, but relevant licensing requirements will come into play if the importation, selling or dispensing of controlled drugs or products as stated in section A3 above are involved.	• Beauticians and business establishment providing beauty services are not licenced. Nevertheless, a beautician usually possesses formal qualifications in beauty. The National Beauty Training Package, offered at vocational training colleges throughout Australia, is a training program nationally recognized	• Beauticians and business establishment providing beauty services are not licenced. Nevertheless, a beautician usually completes a six-month full-time or a one-year part time course at a beauty school	• Persons engaged in hair styling, esthetics, cosmetology and nail specialty services are licenced. Different qualifications are required for different services • In New York State, a person applying for a licence for different types of services has to complete the respective hours of relevant courses set out below and pass the respective examinations – <u>Example</u> - nail specialty: 250hrs - esthetics: 600hrs - hair styling: 300hrs - cosmetology: 1000hrs	• Individual member States may have slightly different practices