Business Facilitation Advisory Committee
Retail Task Force

Response to Concern of Trade in the Beauty Products/ Cosmetics/ Medicines Retail Categories

Purpose

To follow up on the discussion with representatives of relevant trade in October 2005, the Secretariat referred *RTF Paper 15 – Regulatory review of the beauty products/cosmetics/medicine retail categories* to the Department of Health (DH) for further study of improvement potentials. Upon the request of the department, the Secretariat drawn up some improvement proposals in November for reference by the Department. This paper outlines the response of the department to trade's concerns.

Response to trade's concerns

2. Trade's concerns, improvement proposals and responses of DH are summarized in the ***Annex***.

Way forward

3. Members are invited to give views on the responses of DH to trade's concerns.

Business Facilitation Advisory Committee Secretariat
January 2006

Annex

Trade's concern	Improvement proposal drawn by Business Facilitation Division for reference by Department of Health	Response by Department of Health
1. Lack of guidelines on beauty/ health products that need registration • Role and authority of Department of Health (DH) and Food and Environmental Hygiene Department (FEHD) are not clearly defined. • Food supplements made of uncommon herbs do not require registration, whereas common products with Omega 3 or evening primrose would have to register. • For health products, trade has to provide many supporting documents for DH to decide if product registration is required. This confirmation process takes an average of 3 to 6 months and no interim reply is given to an inquirer. The registration process takes another 6 months.	• DH to line up with FEHD to review the current arrangement on providing support service to retailers of beauty/ health products, including preparation of clear guidelines on the need/criteria for product registration. • To set performance pledge and specific supporting requirements for determination of whether a health product needs registration. • To give interim reply to an inquirer on the need for registering a product.	• DH will consider issuing self-explanatory guidelines for the trade and industry to determine by themselves if a product they intend to sell is a pharmaceutical product requiring registration.

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2. Long processing time of registration • For pharmaceutical products with new chemical entities, trade experiences that it takes much longer than the pledged time of 5 months. • Lack of transparency in the registration process.	• To re-engineer the registration process. A possibility is to apply varying degrees of evaluation for products. For products having been approved by competent regulatory agencies such as US FDA and Australian TGA, evaluation can be limited to verification which takes lesser time. In Singapore, the target processing time is 45 working days when the product has been approved by two or more such competent regulatory agencies. • To simplify procedures of legislative amendments required for products with new chemical entities. • To include specific supporting requirements for registration in application documents and guides.	• The performance pledge for registration is 5 months. For the past 5 years, over 90% of applications for registration have met this pledge. Those which do not meet the pledge are pharmaceutical products containing new chemical entities. • The reason for the pharmaceutical products with new chemical entities to take longer than 5 months to register is due to the need for LegCo to approve the relevant amendments to the Pharmacy and Poisons Regulations and the Poisons List Regulations. This takes time. However, DH has streamlined the procedures so that the delay is kept to a minimum.

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		• The registration requirements have been incorporated in the relevant guidelines which have been distributed to the importers and manufacturers and which have also been put on DH's website. The trade could provide further suggestions on how the guidelines could be improved.
3. Long processing time of re-registration • It takes a long time to "re-register" a product for minor changes such as product name or package size, while there is no change in formula or composition (CIFC). • Based on figures provided by trade, such re-registration could take 3 to 11 months. • Members of the Retail Task Force consider the pledge of 5 months too long for re-registration of products not involving CIFC.	• To adapt simpler procedures for re-registration of products without CIFC. • For products with CIFC, to limit checking only to attributes related to changes. • To establish separate performance pledges for re-registration of products with or without CIFC.	• Re-registration is not required for most minor changes, including change of package size. Only change of formula and change of name require re-registration. The reason of re-registering the latter is to avoid confusion by the public. DH will consider giving priority to processing applications for such re-registration.

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4. Restrictions on product ingredients • Common products such as hand cream, face wash, hand soaps and liquid soaps are subject to a 6-month registration process when they feature an anti-septic element. • There is no clear definition for anti-septic element. • A health product commonly sold in overseas countries could not be sold in Hong Kong if the preservative it contains is not in our approved list.	• To devise guidelines on the need for registering common products like hand wash/ creams, etc. • Alternatively, to issue a list of anti-septics that require registration. • To update approval list regularly for ingredient elements that can be sold with reference to other competent regulatory authorities.	• DH will consider issuing guidelines for the trade and industry to determine by themselves if the products they intend to sell are pharmaceutical products requiring registration.

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5. Restrictions on dispensing prescriptions • Partial dispensing is not allowed unless specifically stated in the prescription. Subsequently, this would: - refrain patients from partial filling of expensive prescription at different times; - restrict dispensing of refill prescription to the pharmacy that first dispensed prescription; and - confine dispensing of multiple items in a prescription to a single pharmacy. • When a drug has been prescribed in brand name, generic drug of a different brand cannot be used for dispensing, thereby depriving patients of choices. This is not the case in some countries such as the US. • Pharmacists cannot clarify details of a prescription with doctor over the phone. A patient will have to go back to the doctor to amend an incomplete/ illegible prescription for the purpose.	• To allow partial dispensing when the following criteria are met: - Doctor did not specify one time dispensing. - Total dispensed quantity does not exceed the prescribed quantity. - Dispensing is allowed within the treatment duration specified by doctor. • To allow dispensing of generic drug equivalent when a drug has been prescribed in brand name. • To legitimize clarification of prescription details over the phone between registered pharmacists and registered doctors. • To review the need for registering patients' personal particulars with reference to overseas practice.	• The principle of prescription dispensing is to ensure that it is dispensed correctly and in accordance with the instructions and intention of the prescribing doctor. The Pharmacy and Poisons Ordinance does not allow a prescription to be part-dispensed by different pharmacies. Partial dispensing is allowed, provided that the prescription is always dispensed by the same pharmacy. Allowing a prescription to be part-dispensed by different pharmacies will increase the risk of its being dispensed incorrectly *(dispensing one item more than once, missing out the dispensing of another item, etc.)*, potentially causing harm to the health of the patient. Such practice is also disallowed in developed countries such as the U.K.

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• There are privacy issues connected with patients buying Part I poisons as they have to record their personal particulars such as name & identity card number in a public register. The practice is not required in overseas countries such as the UK.		• According to regulation 9 of the Pharmacy and Poisons Regulation (Cap 138A), generic substitution is not allowed. Most generic drugs in Hong Kong are not proven to be "bio-equivalent" to the brand-named drug. This means that the two drugs are not exactly identical. If the prescribing doctor has specified a brand-named drug on the prescription, it is his intention that the patient should receive that drug. Dispensing a generic drug instead could result in the patient receiving a treatment which is not exactly identical to what the doctor has intended. Generic substitution is also not allowed in some developed countries such as the U.K. and Australia. However, in the U.S., it is commonly an insurance requirement to supply the cheapest drug which accounts for the possibility of generic substitution.

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		• The Regulations have laid down detailed requirements in relation to the writing of prescriptions. Incomplete prescriptions can be dangerous to the patient. When the pharmacist is doubtful about a prescription, he can always make telephone clarifications with the prescribing doctor. However, to protect the patient, the prescribing doctor and the dispensing pharmacy, any changes to prescriptions should be made by the original prescribing doctor in writing. • The Part I poisons [1] that require record-keeping during their sale are drugs liable to abuse (e.g. cough medicines containing codeine). The record-keeping requirement was introduced on the suggestion of LegCo members and other parties concerned about drug abuse in the community.

[1] By virtue of regulation 3 of the Pharmacy and Poisons Regulations (Cap 138A), these are drugs which are included in the First Schedule but excluded in the Third Schedule of the Regulations.

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		It acts as a deterrence against repeated buying of such drugs by abusers.
6. Impractical/ Outdated requirements for pharmacy set-up • Provision of running water and drainage at pharmacy counters. • Display of prescribed form of pharmacy logo of ***fixed*** dimensions. • Inclusion of home address in pharmacist's certificate which has to be displayed at conspicuous location.	• To review the requirements on physical set-up of pharmacy shop with a view to minimizing/updating the requirements. • To examine critically the need for running water and drainage at pharmacy counter. • To allow for replacing "fixed dimensions" pharmacy logo with "range of dimensions" to suit physical constraints of pharmacy shop *(e.g. restriction on logo size imposed by landlord will lead to a smaller, but still legible, logo)*. • To re-design the pharmacist's certificate to exclude the field "home address".	• The availability of running water and drainage in the dispensing room of a pharmacy is necessary, both because some dispensing operations require it *(e.g. the dispensing of oral antibiotic liquids which often require the making up of the liquid just before supplying it to the patient)*, and because the nature of work of a pharmacy requires a high level of hygiene at all times. • It has never been a requirement that the prescribed form of pharmacy logo be in fixed dimensions. DH will consider amending the Pharmacy and Poisons Regulations to rephrase the relevant provisions. • DH will consider amending the Pharmacy and Poisons Regulations to remove the address on pharmacists'

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		certificates.
7. Classification of drugs • Classification of drugs in the pharmacy and poisons schedule is only in chemical names whereas both the public and pharmacists are more familiar with pharmaceutical names. • The term "poison" as a description for medicines causes confusion and uneasiness to patients. The term is misleading as some of the controlled drugs are mild in nature. In other countries, the description has been replaced with "prescription" for a long time. • Classification descriptions such as "Part I Schedule I" and "Part II" drugs are difficult for consumers' understanding. In the UK, drugs are classified into "general sales", "pharmacy only", "prescription only", "controlled drugs", etc. • Control for drugs is becoming more stringent than most countries. Common drugs like medicated skin ointments and	• To consider the adoption/inclusion of pharmaceutical names when classifying drugs. • To review the wording "poison" as a description for controlled drugs and consider using "prescription" instead. • To adopt easy-to-understand classification descriptions for drugs, using terms such as "general sales", "pharmacy only", "prescription only", "controlled drugs", etc. • To update drugs in Part II under Cap 138 regularly with reference to control made on drugs by other competent regulatory authorities.	• Pharmaceutical names are used in the classification of most drugs, the only exception being drugs which do not have pharmaceutical names. • Action is being taken to amend the Pharmacy and Poisons Regulations to substitute the "poison" labelling requirement with other more meaningful requirements. • To revamp the classification of drugs, a revamp of the Pharmacy and Poisons Ordinance is required. The Administration is looking for an opportunity to do this. • Hong Kong always follows the international trend in terms of the control of drugs in respect of their mode of sale. For example, "Part II" drugs are equivalent to "general sales" drugs in the U.K.

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cough syrups are being included into Part II under Cap 138.		
8. Disposal of expired/ damaged drugs • Disposal of expired/ damaged drugs has to be made via service providers approved by EPD. For dangerous drugs, their disposal has to be done at DH's Nam Cheong Office. The trade considers the requirements rigid when compared to other countries.	• To explore alternative disposal means such as flushing into toilets as commonly practised in overseas countries and collection by inspectors on their routine inspection.	• Unwanted drugs are chemical wastes. Their disposal must follow the requirements of the Waste Disposal Ordinance in order to ensure an adequate level of protection of the environment. Disposal of dangerous drugs at DH office is an option and not a requirement.
9. Licensing requirements • Business Registration Certificate (BRC) as a pre-requisite for application of registration as authorized sellers of poisons ("Pharmacy Licence") is not in line with common business setups that only require business registration within one month upon business commencement. • Trade has to employ a pharmacist when applying for a "Pharmacy Licence".	• To review the pre-requisites for application of "Pharmacy Licence", including the need to obtain BRC and the attendance of pharmacist during the processing time of licence application. • To review the need for interviewing the pharmacy store manager in processing "Pharmacy Licence" application.	• The Pharmacy and Poisons Ordinance defines a pharmacy as a business. The pharmacy licence is therefore issued to the business, as identified by the business registration certificate. Licence applicants are advised to obtain the business registration certificate as early as possible. • The need for the early employment of a pharmacist is being reviewed.

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During the 6 to 8 weeks processing time, pharmacist has to be present at the shop that is either under fitting-out or that could not sell pharmaceutical products. • Both the pharmacist and store manager are required to attend an interview before "Pharmacy Licence" is granted. Trade is not clear about the purpose of interviewing the store manager and considers that waiting time for the interview is long.	• To further shorten the waiting time for the interview.	• The Ordinance also requires that a licence should only be issued to a "fit and proper" applicant. The interview is a means for the licensing authority *(the Pharmacy and Poisons Board)* to ascertain the knowledge of the applicant in the operation of a pharmacy business, and his fitness to be issued a licence.
10. Pharmacists' attendance at shop • The requirement for a pharmacist to be present at a pharmacy shop for at least two thirds of its trading hours during Monday to Friday deems to intervene business operation and that the two thirds criteria also deem arbitrary. It is suggested that the attendance be aggregated as a weekly requirement such that attendance on Saturday could contribute to the aggregated number of required attendance hours.	• To review the requirement of pharmacist's attendance in suiting the needs of the community and facilitating trade.	• This requirement will be reviewed during the revamping of the Pharmacy and Poisons Ordinance.

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11. Advertising health/medical products • There is no guideline or advisory service for application of the Undesirable Medical Advertisements Ordinance. Without such services, trade would sometimes break the law unintentionally.	• To devise mechanism/service for helping health/medical product traders and the advertising industry comply with UMAO, including the issue of clear guidelines on the subject.	• DH has drawn up guidelines to assist the trade to comply with the Undesirable Medical Advertisements Ordinance. These guidelines were released in November 2005 and have been put up at the DH website.
12. More communication with trade • Trade opines that there is limited communication with relevant regulatory authorities, particularly when new control measures are introduced. It would like to be appropriately and sufficiently consulted before the Administration makes legislative amendments affecting the retail business. It wishes to be informed also of measures directed at manufacturers so that it can help reinforce compliance by manufacturers.	• To conduct thorough consultation with trade on proposed legislative amendments affecting the trade. • To improve communication with trade at the outset of devising new control measures targeted at retailers as well as manufacturers. • To set up regular discussion forum with the trade.	• The Pharmacy and Poisons Board has always consulted stakeholders before making any amendments to the law, except where the amendment is deemed necessary for urgent public health protection purposes. • Various sectors of the trade and industry have been writing to the Board or its committees to express their views and suggestions. The Board has always responded to them. The trade and industry are encouraged to continue doing so.