Business Facilitation Advisory Committee
Retail Task Force

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

Purpose

Subsequent to the RTF meeting with representative of the Department of Health (DH) in January, a focus group session was conducted in late February for the trade to discuss their concerns in detail with the department. The focus group session went through *RTF Paper 19 – Response to Concern of Trade in the Beauty Products/ Cosmetics/ Medicines Retail Categories* and discussed possible improvement measures for addressing trade's concerns. This paper presents the latest responses of the department to the concerns, the improvement measures adopted by DH and the progress made in implementing the measures since the focus group session.

Improvement measures and their implementation progress

2. Trade's concerns, improvement proposals and relevant responses/measures adopted by DH are summarized in the ***Annex***.

Way forward

3. Members are invited to give views on the responses/improvement measures adopted by DH.

Business Facilitation Advisory Committee Secretariat
June 2006

Annex

Trade's concern	Improvement proposal drawn for reference by Department of Health after the meetings with RTF and focus group session with trade	Response and improvement measures adopted 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 is preparing 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. The list of ingredients that must be registered will be included in the guidelines. The draft guidelines will be ready in June for trade consultation before issue in July/August. Where necessary, briefing sessions will be held to facilitate trade's understanding of the guidelines. • The guidelines will be updated on an as-and-when-required basis, taking into account new developments of the industry.

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		• DH will not issue interim replies since inquirers are mainly concerned with knowing the final decision of whether a product needs registration. • DH will review the effectiveness of the guidelines 6 months after the introduction.
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.	• 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 taking 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.

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	• To simplify procedures of legislative amendments required for products with new chemical entities, including exploring feasibility of negative vetting. • To include specific supporting requirements for registration in application documents and guides.	The Pharmacy and Poisons Board (P&P Board) is considering the following proposals for board meeting in order to speed up the registration process – 1. shortening the meeting cycle of P&P Board and its two committees *(i.e. Registration Committee and Poisons Committee)*; 2. reducing the time lapse between meetings; 3. re-scheduling meetings to avoid delay due to long breaks of the LegCo; and 4. conducting meetings upon receipt of applications for drug registration. • HWFB will explore the feasibility of negative vetting to expedite the inclusion of new chemical entities into the approved product lists, in the context of the major revamp of the Pharmacy & Poisons Ordinance.

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	• To accept third-party laboratory's analysis results so as to save the time of analyzing drug samples by the Government Laboratory. • To review the current requirement of 2 CPPs (Certificates of Pharmaceutical Product) for drug registration. • To accept other forms of registration evidence in lieu of an original CPP. • To make known the progress of application so that trade is kept in the picture.	• 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. DH noted that much registration delay was associated with the non-compliance of labelling requirements. The trade could provide further suggestions on how the guidelines could be improved. DH will improve its website and strengthen the application guidelines to help trade comply with the labelling requirements. DH is also organizing, on need basis, public seminars on pharmaceutical registration to help trade understand the supporting requirements for registration.

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		• In April, DH issued the criteria of accredited laboratories to the trade for sourcing acceptable laboratories that can take up the role of the Government Laboratory, thereby shortening the registration time by 2 months. • The Registration Committee (RC) under the P&P Board is reviewing the current requirement of 2 CPPs. • The RC is considering the proposal on accepting other forms of registration evidence in lieu of the original CPPs. • DH upholds the principle of transparency for processing registration applications. An applicant can make inquiry on the progress of application from time to time.

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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 adopt 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. • To accept "notification for minor changes" instead of re-registration process.	• 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. • DH has written to the Department of Justice (DoJ) for advice on the need for legislative amendment in adopting "notification for minor changes". The proposal will be presented to the P&P Board for consideration upon receiving DoJ's advice.

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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.	• Please refer to response under #1. At the focus group discussion with the trade in February, it was agreed that the proposed guidelines on determining the need for product registration would help trade determine if common products they intend to sell are pharmaceutical products that require registration.

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5. Restrictions on dispensing prescriptions • In countries such as Canada and New Zealand, items of a prescription can be dispensed at different pharmacies. Partial dispensing is, however, not allowed locally 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	• 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. Where legislative amendments are required for this to happen, an interim solution is to allow dispensing based on a fax copy of the	• 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. There will be risks in losing control over drugs that are prone to abuse *(e.g. dangerous*

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patient will have to go back to the doctor to amend an incomplete/ illegible prescription for the purpose. • 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.	amended prescription sent by the prescribing doctor to the pharmacy so that the patient does not need to ply between the doctor's office and the pharmacy for amendment of the original prescription. • To review the need for registering patients' personal particulars with reference to overseas practice.	*drugs).* When multiple items on a prescription must be taken together *(e.g. diuretics and potassium supplement – if diuretics are taken alone, it may lead to muscle cramps),* part-dispensing poses another type of risk and can be considered as a "misconduct" by the profession. While part-dispensing at different pharmacies is allowed in some provinces of Canada, it is still disallowed in developed countries such as the U.K.

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		• 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. DH is awaiting DoJ's advice on whether a fax copy of an amended prescription sent by the prescribing doctor to a pharmacy is acceptable for dispensing. Upon receiving the advice, the P&P Board will consider the proposal.

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		• 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. It acts as a deterrence against repeated buying of such drugs by abusers. • DH is considering lifting the requirement for some items *(e.g. certain nicotine replacement)*. Actual relaxation is to be agreed by P&P Board and subject to amendment of the current Pharmacy and Poisons Regulations under the Ordinance by HWFB.

[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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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. DH will consider alternatives put up by the trade, taking into account the physical constraints of the premises and level of cleanliness achievable. • It has never been a requirement that the prescribed form of pharmacy logo be in fixed dimensions and colours. DH will rephrase the relevant provisions when revamping the Pharmacy and Poisons Regulations.

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		• After much deliberation, DH concluded that the address appearing on pharmacists' certificates could serve as an additional safeguard to deter others from impersonation.
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	• To consider the adoption/inclusion of pharmaceutical names when classifying drugs and explore feasibility of including examples after the chemical names in the Poisons List. • 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.	• Pharmaceutical names are used in the classification of most drugs, the only exception being drugs which do not have pharmaceutical names. Legal advice is being sought on the feasibility of inclusion of examples after the chemical names in the Poisons List. • Draft drafting instructions have been issued to DoJ for amending the Pharmacy and Poisons Regulations to substitute the "poison" labelling requirement with other more meaningful requirements.

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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 cough syrups are being included into Part II under Cap 138.	• To update drugs in Part II under Cap 138 regularly with reference to control made on drugs by other competent regulatory authorities. • To amend the Antibiotics Ordinance to exclude some of the common skin ointments from prescription.	• 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. In view of other current issues, the Administration can only accord a low priority for revamping the Ordinance. • 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. • Micro-organisms can develop resistance to antibiotics and therefore antibiotics should be used with caution. It is not medically sound to exclude any antibiotics from prescription particularly at this time when there is world-wide concern about antibiotics resistance.

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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. Collection by inspector during routine inspection is not feasible as this will expose the inspector, who is carrying such drugs while on inspection duty, to security risks.

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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". 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 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. • To further shorten the waiting time for the interview.	• 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 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.

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		• DH opined that there is a need for the early employment of a pharmacist to perform pharmacy-related tasks such as handling of drugs delivered from manufacturers/suppliers. To facilitate the trade, DH has shortened the waiting time of interviewing the pharmacist from 2 to 4 weeks to within 1 week after lodgment of the application.
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. • To provide the trade information on the contravention made against the UMAO.	• 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. • Since February 2006, DH has begun providing details on the contravention made in warning letters issued to contravening companies.

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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.