

**Business Facilitation Advisory Committee
Retail Task Force**

*Update on Improvement Measures in Response to Concern of Trade in the
Beauty Products/ Cosmetics/ Medicines Retail Categories - May 2007*

Purpose

The Secretariat circulated the *RTF Paper 31 – Update on Improvement Measures in Response to Concern of Trade in the Beauty Products/ Cosmetics/ Medicines Retail Categories – February 2007* to trade representatives for comment after the RTF meeting in February 2007. Seven representatives from pharmaceutical manufacturers of new chemical entities, distributors of generic pharmaceutical products, cosmetics and health food/supplement sectors responded. The trade generally noted that DH demonstrated some positive responses but they re-iterated some of the views raised by the trade in the past. The key ones and DH's relevant responses are summarized below –

Lack of guidelines on beauty/health products that need registration

- The health food industry opines that DH seems to have hesitation in establishing performance pledge for determining whether a health product needed registration. Also, the department has not addressed directly the concern that products like Omega 3 with vitamin E and wheat germ oil may require product registration. DH considers it premature to set up pledges before reviewing the effectiveness of the guidelines and it will consider the suggestions of the trade on products like Omega 3 and vitamin E with wheat germ oil in the context of producing the self-explanatory guidelines for determining if a product is a pharmaceutical product that requires registration.

Long processing time of registration

- Registering products containing vitamins/minerals and other herbal ingredients usually takes longer than 5 months. The health food industry is concerned about the difficulties in registering such products and would like to know why 10% of the application for product registration fell out of the pledged time of 5 months. DH has explained in the past that the products which do not meet the pledge are products containing new chemical entities which require amendments to Regulations by the LegCo.
- Distributors of generic pharmaceutical products also share the views of the health food industry on long processing time for registration.

Restrictions on product ingredients

- The health food industry suggests that vitamins, minerals and other health supplements be treated differently or excluded from pharmaceutical products that require registration. The cosmetics industry also suggests relaxing cosmetic products from registration. DH responds that the trade's views are being considered in the context of producing the self-explanatory guidelines for determining if a product is a pharmaceutical product that requires registration. Considerations include trimming of registration requirements for vitamins, minerals and some health supplements so as to speed up their registration process.

Advertising health/medical products

- The health food industry opines that Schedule 4 of the UMAO deprives consumers' right to know in purchasing suitable products to protect their health and demands for the revamping of the ordinance. It would also like to have more actual examples on the contravention of the UMAO on the internet for access by the industry. On the former, DH considers that its responses in the past have explained the department's position regarding the trade's concern. For the latter concern, DH will consider adding new examples when updating the department's guidelines on the UMAO.

Stability test requirement for registration and renewal of vitamins and supplement preparations

- The health food industry re-stated its request for exempting the stability test required of vitamin and mineral products. DH has responded that the Registration Committee of the Pharmacy and Poisons Board (P&P Board) has decided not to accede to the request because the stability of vitamin and mineral products are more problematic, and because the industry had been given over 5 years' grace period, and many traders have already spent the required resources to conduct and complete the tests.
- Distributors of generic pharmaceutical products suggest that vitamins, minerals and other health supplements be treated differently from pharmaceutical products that require registration. DH responds that the trade's views are being considered in the context of producing the self-explanatory guidelines for determining if a product is a pharmaceutical product that requires registration.

Implementation progress of other improvement measures

2. All of the trade's concerns, improvement proposals and the relevant responses/measures adopted by the DH are detailed in *Appendix I*. The latest update on improvement proposals and related implementation progress not mentioned in the above section are given below:

Long processing time of registration

- The trade has been invited to suggest how the application guidelines for registering pharmaceutical products should be improved, and DH is awaiting its response.
- Taking into account of Government's overall policy on controlling the size of the civil service, a bid for manpower increase will be made at the opportune time.

Long processing time of re-registration

- The DH will issue guidelines on re-registration requirements in Q3 of 2007.

Restrictions on dispensing prescriptions

- The legal advice concludes that it is legally in order to accept fax copies of amended prescriptions sent by doctors direct to pharmacies so that the patient does not need to ply between the doctor's office and the pharmacy for amendment of the original prescription on the presumption that doctors keep a copy of all the prescriptions they issue. Enquiries with doctors have revealed that they do not do so.

Impractical/Outdated requirements for pharmacy set-up

- Taking into account the feedback received from the pharmacists' associations, the P&P Board has decided that the address should remain in the pharmacist certificate but that pharmacists can choose to use any contact address other than home address.

Classification of drugs

- There have been proposals on the wording to be used to replace the word "poison" on pharmaceutical products. DH is consulting the Health, Welfare and Food Bureau on the proposals. The P&P Board will consider the proposals at its next meeting.

Way forward

3. Members are invited to note the progress made in implementing the improvement measures and give views on the latest responses/improvement measures adopted by the DH.

Position as at May 2007

| Trade's concern | Improvement proposal for reference by Department of Health | Updated response by Department of Health |
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| <p>1. Lack of guidelines on beauty/ health products that need registration</p> <ul style="list-style-type: none">• Role and authority of Department of Health (DH) and Food and Environmental Hygiene Department (FEHD) are not clearly defined.• 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. | <p>A. 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.</p> | <p>a1. Taking into account the views received from the trade and industry during the consultation, DH is revising the draft self-explanatory guidelines which the trade and industry can use 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. -Briefing sessions will be held to facilitate the trade's understanding of the guidelines. <i>[May 2007]</i></p> <p>a2. The guidelines will be updated on an as-and-when-required basis, taking into account new developments of the industry. <i>[June 2006]</i></p> |

| Trade's concern | Improvement proposal for reference by Department of Health | Updated response by Department of Health |
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| | B. To set performance pledge and specific supporting requirements for determination of whether a health product needs registration. | b. DH will review the effectiveness of the guidelines 6 months after the introduction. The guidelines are still to be finalized. <i>[May 2007]</i> |
| | C. To give interim reply to an inquirer on the need for registering a product. | c. DH will not issue interim replies since inquirers are mainly concerned with knowing the final decision of whether a product needs registration. Inquirers can contact the department for the latest position of their inquiries. <i>[June 2006]</i> |
| <ul style="list-style-type: none"> • Customs require classification letter from DH for clearance of health food / cosmetics at entry points. | <p>D. To maintain product inquiry services and issuing classification letter.</p> <p>E. To publish products that do not require registration on the web.</p> | <p>d. The requirement for classification letter was imposed by Customs and Food and Environmental Hygiene Departments in July / August 2006. DH has discussed with the relevant departments on the issue and has been informed that these departments no longer require classification letters for clearance of such products. <i>[February 2007]</i></p> <p>e. Same as (d) above.</p> |

| Trade's concern | Improvement proposal for reference by Department of Health | Updated response by Department of Health |
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| <ul style="list-style-type: none"> The draft guidelines do not provide a clear picture to the trade. | <p>F. To enhance communication with trade and refine the guidelines with input from the trade.</p> | <p>f. Taking into account the views received from the trade and industry during the consultation, DH is revising the draft guidelines with a view to, among other things, improving the clarity of the guidelines. The guidelines will be released in Q2 of 2007. <i>[May 2007]</i></p> |
| <ul style="list-style-type: none"> Food supplements made of uncommon herbs do not require registration, whereas common products with Omega 3 or evening primrose would have to register. | <p>G. To exclude food supplements such as products with Omega 3 with Vitamin E and Wheat Germ Oil from the registration requirement.</p> | <p>g. Suggestions for classifying vitamin / mineral as health food / supplement are being considered in the context of finalizing the self-explanatory guidelines under Item 1, a1 above. <i>[May 2007]</i></p> |

| Trade's concern | Improvement proposal for reference by Department of Health | Updated response by Department of Health |
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| <p>2. Long processing time of registration</p> <ul style="list-style-type: none"> • 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. • Classification and registration of cosmetics and health food take 6 and 9 months respectively. The process delays the time of consumer access and inflates the cost of products. | <p>A. 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.</p> | <p>a1. 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. <i>[June 2006]</i></p> <p>a2. Past records show that if the time for legislative amendment is not counted, the processing time is 2 to 3 months: not far from the 45 working days target set by Singapore. <i>[October 2006]</i></p> |

| Trade's concern | Improvement proposal for reference by Department of Health | Updated response by Department of Health |
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| | <p>B. To further increase the number of PPB meetings to more than 5 times a year.</p> <p>C. To adopt alternative means such as paper circulation instead of holding physical PPB meeting.</p> | <p>b. The Pharmacy and Poisons Board (P&P Board) has considered several options to reduce the waiting time for registration approval. It has decided to speed up the process further by approving the legislative amendments by circulation of papers instead of at meetings, and to increase the frequency of approvals from 4 times a year to 5 times a year with effect from 2007, and to time the approvals such that the process will not be delayed due to LegCo recesses. <i>[February 2007]</i></p> <p>c. Same as (b) above.</p> |
| | <p>D. To simplify procedures of legislative amendments required for products with new chemical entities, including exploring feasibility of negative vetting.</p> | <p>d. As regards negative vetting, HWFB has studied the option and has found that generally speaking, negative vetting takes more time to complete than positive vetting does. Therefore, negative vetting does not help speed up the registration process. <i>[October 2006]</i></p> |

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| | <p>E. To include specific supporting requirements for registration in application documents and guides.</p> | <p>e1. 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. Suggestions of the trade are still awaited. <i>[May 2007]</i></p> <p>e2. DH has been organizing seminars on pharmaceutical registration to help the trade understand the supporting requirements for registration. <i>[June 2006]</i></p> |
| | <p>F. To review the whole drug registration process with a view to speeding up the registration time and removing unnecessary regulatory controls.</p> | <p>f. The process had been reviewed twice. The proposal will be taken forward subject to the availability of resources. <i>[February 2007]</i></p> |

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| | <p>G. To accept third-party laboratory's analysis results so as to save the time of analyzing drug samples by the Government Laboratory.</p> | <p>g1. In September 2006, the Registration Committee (RC) under the P&P Board re-issued to the trade the criteria of accreditation of laboratories that can take up the role of drug sample analysis in lieu of analysis by the Government Laboratory, thereby shortening the registration time by 2 months. <i>[October 2006]</i></p> <p>g2. The RC has decided to exempt drugs that have been tested by competent overseas authorities from local lab test. <i>[October 2006]</i></p> |
| | <p>H. To review the current requirement of 2 CPPs (Certificates of Pharmaceutical Product) for drug registration.</p> | <p>h. The RC has reviewed the current requirement of 2 CPPs and has decided that in the interest of patient safety, the 2-CPP requirement should remain. <i>[October 2006]</i></p> |

| Trade's concern | Improvement proposal for reference by Department of Health | Updated response by Department of Health |
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| | I. To accept other forms of registration evidence in lieu of an original CPP. | i. The RC has also decided that in view of the industry's concern that overseas countries often took 1 to 2 months for a CPP to be issued upon application, the strict CPP requirement was relaxed such that other official evidence of a drug's approval, e.g. a certified true copy of the drug's registration certificate or approval letter, would be accepted. <i>[October 2006]</i> |
| | J. To make known the progress of application so that trade is kept in the picture. | j. DH upholds the principle of transparency for processing registration applications. An applicant can make inquiry on the progress of application at any time. A statement to this effect would be included in the application guidelines at the next round of review in mid 2007. <i>[June 2006]</i> |

| Trade's concern | Improvement proposal for reference by Department of Health | Updated response by Department of Health |
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| | K. To discuss with trade the issues with registering products containing vitamins/minerals and other herbal or natural ingredients. | k. Suggestions for classifying vitamin / mineral as health food / supplement are being considered in the context of finalizing the self-explanatory guidelines under Item 1, a1 above. Considerations include trimming of registration requirements for vitamins, minerals and some health supplements so as to speed up their registration process. <i>[May 2007]</i> |
| | L. To increase manpower for product registration. | l. Taking into account Government's overall policy on controlling the size of the civil service, a bid for manpower increase will be made at the opportune time. <i>[May 2007]</i> |

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| <p>3. Long processing time of re-registration</p> <ul style="list-style-type: none"> • 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. | <p>A. To adopt simpler procedures for re-registration of products without CIFC.</p> <p>B. For products with CIFC, to limit checking only to attributes related to changes.</p> <p>C. To establish separate performance pledges for re-registration of products with or without CIFC.</p> <p>D. To consider views of trade on the issue.</p> | <p>a1. 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 has decided to give priority to processing applications for such re-registration. <i>[October 2006]</i></p> <p>a2. DH will issue guidelines on re-registration requirements in Q3 of 2007. <i>[May 2007]</i></p> <p>b. Same as (a1) and (a2) above.</p> <p>c. Same as (a1) and (a2) above.</p> <p>d. Same as (a1) and (a2) above.</p> |

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| | E. To accept “notification for minor changes” instead of re-registration process. | e. DH has written to the Department of Justice (DoJ) for advice on the need for legislative amendment in adopting “notification for minor changes”. The legal advice received was that legislative amendment would be required. Opportunity will be taken to accommodate “notification for minor changes” during the revamping of the PPO. <i>[October 2006]</i> |

| Trade's concern | Improvement proposal for reference by Department of Health | Updated response by Department of Health |
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| <p>4. Restrictions on product ingredients</p> <ul style="list-style-type: none"> • 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. • Cosmetics are very safe. The number of cosmetic products classified as pharmaceuticals should be minimized • Majority of health food / supplement products are imported from overseas. They contain vitamins and / or minerals for health protection, not for therapeutic use and are not considered as pharmaceutical products in the country of origin. • Food supplements and cosmetics unnecessarily classified as pharmaceutical products. | <p>A. To devise guidelines on the need for registering common products like hand wash/ creams, etc.</p> <p>B. Alternatively, to issue a list of anti-septics that require registration.</p> <p>C. To update approval list regularly for ingredient elements that can be sold with reference to other competent regulatory authorities.</p> <p>D. To conduct a meeting with the cosmetics and health food trade to listen to its views and answer questions on the classification of pharmaceutical products.</p> <p>E. To review the classification rationale and to relax the restriction on ingredients that need registration.</p> <p>F. To collaborate with trade to develop guidelines for classifying vitamin / mineral as health food / supplement in line with the international market.</p> | <p>a. Please refer to response under Item 1. At the focus group discussion with the trade in February 2006, 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. [June 2006]</p> <p>b. Same as (a) above.</p> <p>c. Same as (a) above.</p> <p>d. Cosmetics <i>per se</i> do not require registration, unless they contain drug ingredients or carry medical descriptions on their label or package. DH has consulted the trade on the criteria for classifying products, including both oral and non-oral ones, as “pharmaceutical products” which will / will not require registration in the context of finalizing the self-explanatory guidelines under Item 1, a1 above. Suggestions for relaxing the restriction on ingredients that need</p> |

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| <ul style="list-style-type: none"> Vitamin/mineral supplements do not make claims relating to diagnosis, treatment, mitigation or prevention of a disease or symptom. Health supplement does not fall into "pharmaceutical products". | <p>G. To provide the trade with a set of comprehensive guidelines encompassing both oral and non-oral products that need registration.</p> <p>H. To adopt a differential approach in drug registration.</p> | <p>registration are being considered in the context of finalizing the guidelines. Considerations include trimming of registration requirements for vitamins, minerals and some health supplements so as to speed up their registration process. <i>[May 2007]</i></p> <p>e. Same as (d) above.</p> <p>f. Same as (d) above.</p> <p>g. Same as (d) above.</p> <p>h. Same as (d) above.</p> |
| <ul style="list-style-type: none"> Difficulties in registering vitamin / mineral product that also contains herbal or natural ingredients. | <p>I. To discuss and share with trade, on DH's standard and procedures in evaluating products with mixed ingredients.</p> | <p>i. DH has been in discussion with the trade on registration issues, including the registration of vitamin / mineral products that also contains other ingredients with regard to the documentation required to substantiate the safety and efficacy of such products for registration approval in the context of finalizing the self-explanatory guidelines under Item 1, a1 above. Suggestions of the trade are being considered in the context of finalizing</p> |

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| | | <p>the guidelines. Considerations include trimming of registration requirements for vitamins, minerals and some health supplements so as to speed up their registration process. <i>[May 2007]</i></p> |

| Trade's concern | Improvement proposal for reference by Department of Health | Updated response by Department of Health |
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| <p>5. Restrictions on dispensing prescriptions</p> <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> - 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. | <p>A. To allow partial dispensing when the following criteria are met:</p> <ul style="list-style-type: none"> - 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. | <p>a. 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 (<i>dispensing one item more than once, missing out the dispensing of another item, etc.</i>), potentially causing harm to the health of the patient. There will be risks in losing control over drugs that are prone to abuse (<i>e.g. dangerous drugs</i>). When multiple items on a prescription must be taken together (<i>e.g. diuretics and potassium</i></p> |

| Trade's concern | Improvement proposal for reference by Department of Health | Updated response by Department of Health |
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| <p>A patient will have to go back to the doctor to amend an incomplete/ illegible prescription for the purpose.</p> <ul style="list-style-type: none"> • 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. | | <p><i>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. [June 2006]</i></p> |

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| | <p>B. To allow dispensing of generic drug equivalent when a drug has been prescribed in brand name.</p> | <p>b. 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. <i>[June 2006]</i></p> |

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| | <p>C. 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 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.</p> | <p>c. 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. As regards the acceptance of fax copies of amended prescriptions sent by doctors direct to pharmacies, although the legal advice received is that this is legally in order, it presupposes that doctors keep a copy of all the prescriptions they issue. Enquiries with doctors have revealed that doctors do not do so. <i>[May 2007]</i></p> |

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| | <p>D. To review the need for registering patients' personal particulars with reference to overseas practice.</p> | <p>d1. The Part I poisons¹ that require record-keeping during their sale are drugs liable to abuse (<i>e.g. cough medicines containing codeine</i>). 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. [June 2006]</p> <p>d2. At its meeting of 24.11.2006, P&P Board considered lifting the requirement for some items (<i>e.g. certain nicotine replacement</i>) from the Poisons List. The Board decided that the requirement might be lifted if the manufacturers concerned agreed to improve the labelling of these items such that smokers would know how to use them without professional guidance. The manufacturers have been informed thereof accordingly. [February 2007]</p> |

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.

| Trade's concern | Improvement proposal for reference by Department of Health | Updated response by Department of Health |
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| <p>6. Impractical/ Outdated requirements for pharmacy set-up</p> <ul style="list-style-type: none"> • Provision of running water and drainage at pharmacy counters. • Display of prescribed form of pharmacy logo of <i>fixed</i> dimensions. • Inclusion of home address in pharmacist's certificate which has to be displayed at conspicuous location. | <p>A. To review the requirements on physical set-up of pharmacy shop with a view to minimizing/updating the requirements.</p> <p>B. To examine critically the need for running water and drainage at pharmacy counter.</p> | <p>a. The availability of running water and drainage in the dispensing room of a pharmacy is necessary, both because some dispensing operations require it (<i>e.g. the dispensing of oral antibiotic liquids which often require the making up of the liquid just before supplying it to the patient</i>), 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. [June 2006]</p> <p>b. Same as (a) above.</p> |
| | <p>C. To allow for replacing "fixed dimensions" pharmacy logo with "range of dimensions" to suit physical constraints of pharmacy shop (<i>e.g. restriction on logo size imposed by landlord will lead to a smaller, but still legible, logo</i>).</p> | <p>c. 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. [June 2006]</p> |

| Trade's concern | Improvement proposal for reference by Department of Health | Updated response by Department of Health |
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| | D. To re-design the pharmacist's certificate to exclude the field "home address". | d. Taking into account the feedback received from the pharmacists' associations, P&P Board has decided that the address should remain in the certificate but that pharmacists can choose to use any contact address other than home address. <i>[May 2007]</i> |
| <p>7. Classification of drugs</p> <ul style="list-style-type: none"> 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. | A. 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. | a. Pharmaceutical names are used in the classification of most drugs, the only exception being drugs which do not have pharmaceutical names. The RTF Secretariat has identified funds for DH to engage a contract pharmacist to prepare a guide on the chemicals covered by the Poisons List. The guide would be distributed to the pharmacy practitioners and available under DH's website. The work to produce the guide is in progress. <i>[May 2007]</i> |

| Trade's concern | Improvement proposal for reference by Department of Health | Updated response by Department of Health |
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| <ul style="list-style-type: none"> 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. | <p>B. To review the wording "poison" as a description for controlled drugs and consider using "prescription" instead.</p> | <p>b. P&P Board has received certain proposals on the wording to be used to replace the word "poison". DH has consulted the HWFB on the proposals. The P&P Board will consider them at its next meeting. <i>[May 2007]</i></p> |
| <ul style="list-style-type: none"> 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. | <p>C. To adopt easy-to-understand classification descriptions for drugs, using terms such as "general sales", "pharmacy only", "prescription only", "controlled drugs", etc.</p> | <p>c. To revamp the classification of drugs, a revamp of the Pharmacy and Poisons Ordinance is required. The Administration considers that the current PPO is functioning well, but will review it from time to time, taking into account proposals from the trade and having regard to other legislative amendment suggestions and their priorities. <i>[October 2006]</i></p> |

| Trade's concern | Improvement proposal for reference by Department of Health | Updated response by Department of Health |
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| | D. To update drugs in Part II under Cap 138 regularly with reference to control made on drugs by other competent regulatory authorities. | d. 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. <i>[June 2006]</i> |
| <ul style="list-style-type: none"> The PPO revamp issue has been hovering since the mid 1980s, yet there is no sign of action in the foreseeable future. | E. To take prompt and firm initiative to work out a road map for revamping the PPO. | e. HWFB will revamp the PPO taking into account the other legislative priorities. <i>[February 2007]</i> |

| Trade's concern | Improvement proposal for reference by Department of Health | Updated response by Department of Health |
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| | F. To amend the Antibiotics Ordinance to exclude some of the common skin ointments from prescription. | f. 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. <i>[June 2006]</i> |
| <p>8. Disposal of expired/ damaged drugs</p> <ul style="list-style-type: none"> 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. | A. To explore alternative disposal means such as flushing into toilets as commonly practiced in overseas countries and collection by inspectors on their routine inspection. | a. 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. <i>[June 2006]</i> |

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| <p>9. Licensing requirements</p> <ul style="list-style-type: none"> • 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. | <p>A. 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.</p> | <p>a. 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. <i>[June 2006]</i></p> |
| | <p>B. To review the need for interviewing the pharmacy store manager in processing “Pharmacy Licence” application.</p> | <p>b. 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 (<i>the P&P Board</i>) to ascertain the knowledge of the applicant in the operation of a pharmacy business, and his fitness to be issued a licence. <i>[June 2006]</i></p> |

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| | C. To further shorten the waiting time for the interview. | c. 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. <i>[June 2006]</i> |
| <p>10. Pharmacists' attendance at shop</p> <ul style="list-style-type: none"> 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. | A. To review the requirement of pharmacist's attendance in suiting the needs of the community and facilitating trade. | a. This requirement will be reviewed during the revamping of the Pharmacy and Poisons Ordinance. <i>[June 2006]</i> |

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| <p>11. Advertising health/medical products</p> <ul style="list-style-type: none"> 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. | <p>A. 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.</p> | <p>a. 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. <i>[June 2006]</i></p> |
| | <p>B. To provide the trade information on the contravention made against the UMAO.</p> | <p>b. Since February 2006, DH has begun providing details on the contravention made in warning letters issued to contravening companies. <i>[June 2006]</i></p> |
| | <p>C. To conduct a meeting with the trade to listen to it's views and answer questions on UMAO.</p> | <p>c. DH has been holding numerous meetings with the trade on UMAO to listen to their views and answer questions. Such meetings will continue as and when required. <i>[February 2007]</i></p> |

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| | D. To provide actual examples on the contravention on the internet for the industry to learn from the mistakes. | d. The DH guidelines on the Undesirable Medical Advertisements Ordinance are updated about once a year, when new examples will be added to the existing ones. <i>[May 2007]</i> |
| <ul style="list-style-type: none"> • The restriction on the advertising of pharmaceutical products was unfair and outdated as compared with the United States. • Schedule 4 was lately added to the ordinance to restrict health claims. Regardless of the presence of scientific evidence, a product's legitimate functions cannot be revealed through product label or advertisement. The change deprives consumers' right to make an informed decision on using the product. | E. To revamp the ordinance in meeting the health needs of today's society, in particular, the advent of aging population and deteriorating health amongst the younger generation. | <p>e1. The UMAO is intended to protect the public from being induced by advertisements to seek improper self-medication or treatment. <i>[February 2007]</i></p> <p>e2. Schedule 4 was added in response to the call for enhanced regulation of health products against improper health claims. The Schedule will come into effect after the registration of proprietary Chinese medicines has been completed. <i>[February 2007]</i></p> |

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| <p>12. More communication with trade</p> <ul style="list-style-type: none"> • 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. • The trade is not normally involved at the drafting stage for legislation amendment. Opinion of trade is heard as formality and mostly not accepted. | <ul style="list-style-type: none"> A. To conduct thorough consultation with trade on proposed legislative amendments affecting the trade. B. To improve communication with trade at the outset of devising new control measures targeted at retailers as well as manufacturers. C. To set up regular discussion forum with the trade. | <ul style="list-style-type: none"> a. 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. <i>[June 2006]</i> b. Same as (a) above. c1. 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. <i>[June 2006]</i> |

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| <ul style="list-style-type: none"> • When regulation amendment is for urgent public health protection, the Administration does not consult trade, make the criteria for determining the urgency transparent nor provides explanation for urgency. • Many regulations imposed and enforced by DH are related to cosmetics. Yet, the cosmetic trade seldom has the opportunity to communicate with DH | | <p>c2. DH is considering the practicability and effectiveness of holding business liaison group meeting with the trade in the light of communication mechanisms currently in place. <i>[February 2007]</i></p> |

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| <p>13. CPP requirement for registration of generic drugs manufactured outside Hong Kong</p> <ul style="list-style-type: none"> Locally based traders that wish to appoint overseas manufacturers to produce generic drugs are not able to have the drugs registered in Hong Kong for sale | <p>A. To waive the CPP requirement for registration of generic drugs produced by qualified overseas manufacturers for locally based traders.</p> <p>B. To waive the CPP requirement for registration of vitamin/mineral and cosmetic products.</p> | <p>a. The CPP was promulgated by the World Health Organization. It is evidence that the product concerned is subject to monitoring by the health authority which issues it. It is an international practice among health authorities that a product must have a CPP from the country of origin before other countries will approve it. The consensus is that the health authority of each country is responsible for monitoring the products it manufactures, so that other countries importing the product can rely on the work of the country of origin to check the quality, safety and efficacy of the product. <i>[February 2007]</i></p> <p>b. Suggestions for waiving the CPP requirement for registration of vitamin/mineral and cosmetic products are being considered in the context of finalizing the self-explanatory guidelines under Item 1, a1 above. <i>[May 2007]</i></p> |

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| <p>14. Stability test requirement for registration and renewal of vitamins and supplement preparations</p> <ul style="list-style-type: none"> Suppliers are not able to come up with the test data stipulated in the 22 September 2000 or the 17 December 2001 notices as these are not required by the suppliers' local health agencies. The cost for stability test ranges from \$38,000 to \$173,000. The high cost of the mandatory requirement will push existing vitamins and supplements out of the Hong Kong market and pose a significant barrier to product introduction. Vitamin/mineral products are not classified as pharmaceutical products in overseas countries. Stability test is not critical for vitamin/mineral products that simply play the role of nutrition supplementation and is not available in the country of origin. | <p>A. To grant exemption to all pharmaceutical products marketed in Hong Kong prior to enforcement of the additional requirement.</p> <p>B. To treat vitamins, vitamin with mineral supplements and other health supplements as a separate category of product other than the "pharmaceutical product" and to apply less stringent registration requirements for them with reference to advanced countries, e.g. USA.</p> | <p>a. The Registration Committee of the Pharmacy and Poisons Board has considered this proposal from the trade and has decided that the stability test requirement cannot be exempted, because the stability of such products are more problematic, and because traders have been given over 5 years' advance notice to conduct the tests, many of whom have already spent the required resources to conduct and complete the tests. <i>[February 2007]</i></p> <p>b. Suggestions are being considered in the context of finalizing the self-explanatory guidelines under Item 1, a1 above. <i>[February 2007]</i></p> |

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