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

Purpose

Subsequent to the RTF meeting in June, the Secretariat has circulated the *RTF Paper 22 – Improvement Measures in Response to Concern of Trade in the Beauty Products/ Cosmetics/ Medicines Retail Categories* to the trade for comment. Apart from the long lead time for registration of products with new chemical entities, the restrictions on advertising for medicine and some minor issues, the trade was generally pleased with the improvement measures put forward by the Department of Health (DH).

2. A review of the applications for registration of products with new chemical entities is being conducted to identify further room to shorten the processing time. The review findings will be presented to the Business Facilitation Advisory Committee for consideration.

3. Separately, the Secretariat has arranged a meeting between the trade and the Television and Entertainment Licensing Authority in August to discuss its concerns on medicinal advertisements. The meeting enhanced mutual understanding between the trade and the Authority on the subject.

4. Other minor issues were conveyed to the DH for consideration of further improvement opportunities. This paper presents the latest improvement measures adopted and the progress made by the DH in response to the concern of the trade.

Improvement measures and their implementation progress

5. The trade's concerns, improvement proposals and the relevant responses/measures adopted by the DH are detailed in ***Appendix I***. An update on the measures adopted and the implementation progress is given below:

Lack of guidelines on beauty/health products that need registration

- Draft guidelines originally planned for issue in August are still being consulted with the trade.
- DH intends to do away the inquiry service when the guidelines are considered effective.

Long processing time of registration

- The Pharmacy and Poisons Board (P&P Board) will prepare a new meeting schedule in order to avoid the delay caused by the LegCo's summer recess. The P&P Board will also increase the number of its meetings so as to shorten the waiting time for approval of drug registration.
- Negative vetting does not speed up the registration process (see ***Appendix II***).
- The Registration Committee (RC) will exempt drugs that have been tested by competent overseas authorities from local lab test.
- The RC, after a review, has decided that the requirement of two Certificates of Pharmaceutical Products (CPPs) should be retained in the interest of patient safety.
- The RC will accept official evidence of a drug's approval (e.g. certified true copy of the drug's registration certificate or approval letter) in lieu of the strict requirement for an original CPP.

Long processing time of re-registration

- DH will give priority to processing applications for re-registration involving minor changes such as product name.
- DH will issue guidelines on re-registration requirements.
- "Notification for minor changes" by the trade to replace "re-registration" would require legislative amendment. The Administration will introduce this amendment together with the revamping of the Pharmacy and Poisons Ordinance.

Restrictions on dispensing prescriptions

- The P&P Board will consider lifting some items (e.g. certain nicotine replacement) from the Poisons List at its next meeting.

Impractical/Outdated requirements for pharmacy set-up

- The P&P Board is consulting the pharmacists' associations on the proposal of removing the address from the pharmacist's registration certificate.

Classification of drugs

- DH will prepare a guide to pharmaceutical names on the chemicals covered by the Poisons List for distribution to pharmacy practitioners and posting on DH's website.
- The P&P Board will consider the proposals on the wording to replace "poison" 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 DH.

Business Facilitation Advisory Committee Secretariat
October 2006

Trade's concern	Improvement proposal for reference by Department of Health	Updated 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.	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.	a. DH is consulting the trade and industry on 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. b. The guidelines will be updated on an as-and-when-required basis, taking into account new developments of the industry. *[Same as at June 2006]*
	B. To set performance pledge and specific supporting requirements for determination of whether a health product needs registration.	c. DH will review the effectiveness of the guidelines 6 months after the introduction and do away the inquiry service when the effectiveness of the guidelines is proven.

Trade's concern	Improvement proposal for reference by Department of Health	Updated response by Department of Health
	C. To give interim reply to an inquirer on the need for registering a product.	d. 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. *[Same as at June 2006]*
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.	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.	a.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. *[Same as at June 2006]*

Trade's concern	Improvement proposal for reference by Department of Health	Updated response by Department of Health
		b. 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. c. The Pharmacy and Poisons Board (P&P Board) has considered several options to reduce the waiting time for registration approval. It has decided to time its May meeting carefully so as to avoid the delay due to the LegCo's summer recess. It has also been decided to increase the number of meetings so as to further shorten the waiting time for registration approval.
	B. To simplify procedures of legislative amendments required for products with new chemical entities, including exploring feasibility of negative vetting.	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 (see elaboration at ***Appendix II***).

Trade's concern	Improvement proposal for reference by Department of Health	Updated response by Department of Health
	C. To include specific supporting requirements for registration in application documents and guides.	e. 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. *[Same as at June 2006]* f. DH has been organizing seminars on pharmaceutical registration to help the trade understand the supporting requirements for registration. *[Same as at June 2006]*

Trade's concern	Improvement proposal for reference by Department of Health	Updated response by Department of Health
	D. To accept third-party laboratory's analysis results so as to save the time of analyzing drug samples by the Government Laboratory.	g. 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. h. The RC has decided to exempt drugs that have been tested by competent overseas authorities from local lab test.
	E. To review the current requirement of 2 CPPs (Certificates of Pharmaceutical Product) for drug registration.	i. 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.

Trade's concern	Improvement proposal for reference by Department of Health	Updated response by Department of Health
	F. To accept other forms of registration evidence in lieu of an original CPP.	j. 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.
	G. To make known the progress of application so that trade is kept in the picture.	k. 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. *[Same as at June 2006]*

Trade's concern	Improvement proposal for reference by Department of Health	Updated response by Department of Health
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.	A. To adopt simpler procedures for re-registration of products without CIFC. B. For products with CIFC, to limit checking only to attributes related to changes. C. To establish separate performance pledges for re-registration of products with or without CIFC.	a. 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. b. DH will issue guidelines on re-registration requirements.
	D. To accept "notification for minor changes" instead of re-registration process.	c. 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.

Trade's concern	Improvement proposal for reference by Department of Health	Updated response by Department of Health
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.	A. To devise guidelines on the need for registering common products like hand wash/ creams, etc. B. Alternatively, to issue a list of anti-septics that require registration. C. To update approval list regularly for ingredient elements that can be sold with reference to other competent regulatory authorities.	a. 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. *[Same as at June 2006]*

Trade's concern	Improvement proposal for reference by Department of Health	Updated response by Department of Health
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	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.	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 *(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.		*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. *[Same as at June 2006]*

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	B. To allow dispensing of generic drug equivalent when a drug has been prescribed in brand name.	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. *[Same as at June 2006]*

Trade's concern	Improvement proposal for reference by Department of Health	Updated response by Department of Health
	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.	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. DH is actively seeking legal advice on the acceptance of fax copies of amended prescriptions sent by doctors direct to pharmacies.

Trade's concern	Improvement proposal for reference by Department of Health	Updated response by Department of Health
	D. To review the need for registering patients' personal particulars with reference to overseas practice.	d. 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. *[Same as at June 2006]* e. P&P Board will consider lifting the requirement for some items *(e.g. certain nicotine replacement)* from the Poisons List at its next meeting.

[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
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.	A. To review the requirements on physical set-up of pharmacy shop with a view to minimizing/updating the requirements. B. To examine critically the need for running water and drainage at pharmacy counter.	a. 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. *[Same as at June 2006]*
	C. 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)*.	b. 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. *[Same as at June 2006]*

Trade's concern	Improvement proposal for reference by Department of Health	Updated response by Department of Health
	D. To re-design the pharmacist's certificate to exclude the field "home address".	c. P&P Board is consulting the pharmacists' associations on the proposal of removing the address from the certificate of registration of pharmacists. Replies are still awaited from these associations.

Trade's concern	Improvement proposal for reference by Department of Health	Updated response by Department of Health
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.	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.
• 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.	B. To review the wording "poison" as a description for controlled drugs and consider using "prescription" instead.	b. P&P Board has received certain proposals on the wording to be used to replace the word "poison" and will consider them at its next meeting.

Trade's concern	Improvement proposal for reference by Department of Health	Updated response by Department of Health
• 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.	C. To adopt easy-to-understand classification descriptions for drugs, using terms such as "general sales", "pharmacy only", "prescription only", "controlled drugs", etc.	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.
	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. *[Same as at June 2006]*

Trade's concern	Improvement proposal for reference by Department of Health	Updated response by Department of Health
	E. To amend the Antibiotics Ordinance to exclude some of the common skin ointments from prescription.	e. 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. *[Same as at June 2006]*
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.	A. To explore alternative disposal means such as flushing into toilets as commonly practised 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. *[Same as at June 2006]*

Trade's concern	Improvement proposal for reference by Department of Health	Updated response by Department of Health
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.	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.	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. *[Same as at June 2006]*
	B. To review the need for interviewing the pharmacy store manager in processing "Pharmacy Licence" application.	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 (the P&P Board) to ascertain the knowledge of the applicant in the operation of a pharmacy business, and his fitness to be issued a licence. *[Same as at June 2006]*

Trade's concern	Improvement proposal for reference by Department of Health	Updated response by Department of Health
	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. *[Same as at June 2006]*
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.	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. *[Same as at June 2006]*

Trade's concern	Improvement proposal for reference by Department of Health	Updated response by Department of Health
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.	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.	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. *[Same as at June 2006]*
	B. To provide the trade information on the contravention made against the UMAO.	b. Since February 2006, DH has begun providing details on the contravention made in warning letters issued to contravening companies. *[Same as at June 2006]*

Trade's concern	Improvement proposal for reference by Department of Health	Updated response by Department of Health
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.	A. To conduct thorough consultation with trade on proposed legislative amendments affecting the trade.	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. *[Same as at June 2006]*
	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.	b. 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. *[Same as at June 2006]*

Department of Health
October 2006

Appendix II

Elaboration on why "negative vetting" does not speed up the registration process

Generally speaking, the preparatory work for positive vetting and negative work is the same up till the finalization of the subsidiary legislation in question, i.e. the issue of the "blue", and its signature by the Chairman of the Pharmacy and Poisons Board.

Under the positive vetting procedure, the Secretary for Health, Welfare and Food has to serve a notice of motion (which includes the "blue") at least 20 days before a LegCo regular meeting. LegCo members vote on the subsidiary legislation in the form of a resolution. If it is passed, the subsidiary legislation will be gazetted two days afterwards. For the purpose of classification of new drugs, the legislation is usually commenced upon gazettal.

Under the negative vetting procedure, after the "blue" of the subsidiary legislation is released and signed, it is then sent for publication on the Gazette and then tabled before LegCo. Negative vetting does not have a built-in voting step. If LegCo members want to amend the legislation, it can do so by way of a resolution. If not, it is considered "passed" when the vetting period expires.

There is a 28-day initial vetting period after a piece of subsidiary legislation is tabled before LegCo. LegCo members can amend the legislation in every LegCo meeting during the period. Alternatively, members can by resolution extend the vetting period for another 21 days. In general, members must make any amendment before the 49-day period ends. Technically it is possible to commence a subsidiary legislation any time after gazettal. However, if the subsidiary legislation is drafted such that it is commenced before the 49-day period ends, there is a possibility that it is subsequently

amended by LegCo members with immediate effects. This will cause operational difficulties and perhaps attract public reactions. Government bureaux are strongly advised to schedule the commencement date after the full vetting period (the initial 28-day plus an extension of 21 days, i.e. 49 days). Commencement prior to the full vetting period requires strong reasons (e.g. pressing need to deal with emergency) and is subject to the careful scrutiny of LegCo. Hence, as a rule of thumb, negative vetting takes at least 49 days.

Health, Welfare and Food Bureau
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