The Administration's response to the submissions made by Deputations to the Bills Committee on the Patents (Amendment) Bill 2007

Item	Observations	The Administration's response
1. Submissions from the Medecins Sans Frontieres		
1.1	Support the proposal to empower the Director of Health (DH) to decide when to import a generic version of a patented medicine under a compulsory licence, after the Chief Executive has declared a period of extreme urgency.	Noted.
1.2	Support the proposal of limiting the period of prior negotiations, if required, between the patent proprietor and the generic medicine manufacturer to 28 days in order to avoid undue delay.	Noted.
1.3	Support the proposal of fixing a cap at 4% for the remuneration payable to avoid abuses in case of exports under a compulsory licence.	Noted.
1.4	Suggest providing a simplified and accelerated procedure for the export compulsory licence holder to alter the quantity of medicine to be manufactured and exported under the licence.	If the importing Member of the World Trade Organization ("WTO") is facing an extreme urgency, our proposed mechanism in the Patents (Amendment) Bill 2007 ("the Bill") has already provided for a simplified procedure for obtaining an export compulsory licence (e.g. prior negotiation with the patent proprietor for a voluntary licence is not required). We believe that where a larger quantity of a medicine is required for export, the process of issuing a fresh compulsory licence would not be unduly complicated or lengthy. If the importing WTO Member is not facing an extreme urgency, we consider it not appropriate to adopt a fast-track procedure, having regard to the needs for safeguarding the interests of the patent proprietor.

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2. Submissions from the Democratic Party		
2.1	The Bill introduces Clause 72B, which stipulates that "the Chief Executive in Council may by notice publish in the Gazette declare a period of extreme urgency whenever the Chief Executive in Council considers it to be necessary or expedient in the public interest to do so to address any public health problem or threatened public health problem in Hong Kong". However, what circumstances would be regarded as conditions warranting declaration of extreme urgency or threatened public health problem? When discussing the Bill, the Committee may wish to have in-depth discussion with the Administration as to what conditions would constitute urgent situations.	(i) If there is a public health crisis that may have profound impact on human lives or protection of public health, a situation of extreme urgency under the Patents Ordinance (Cap. 514) would arise. This would call for the application of s. 72C – 72I. (ii) The Doha Declaration states, among other things, that "Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crisis, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstance of extreme urgency." We envisage that a pandemic would be one of the situations where the Administration would consider declaring a period of extreme urgency.
2.2	Thailand's recent issue of "compulsory licences" for certain medicines has led to a series of disputes. If other poorer countries issue compulsory licences for similar reasons (i.e. for addressing persistent public health problems like AIDS rather than urgent situations like wars and infectious diseases) in future, would the Department of Health issue export compulsory licences as a matter of course?	(i) The amendments set out in the Bill are proposed mainly for the purpose of implementing a Protocol which is open to acceptance by WTO Members. By amending the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS Agreement") of the WTO, the Protocol facilitates Members' access to generic versions of patented pharmaceutical products when addressing public health problems. It is envisaged that beneficiaries may include some developing and least-developed countries which are afflicted with serious public health problems, especially those resulting from

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		HIV/AIDS, tuberculosis, malaria and other epidemics. Some WTO Members[1] have indicated that they would not make use of the system under the Protocol as importers, while 11 Members[2], including Hong Kong, have declared that they would not take advantage of the system as importers unless in situations of national emergency or other circumstances of extreme urgency. As for the remaining WTO Members, they may use the system for importing pharmaceutical products regardless of whether or not they are in situations of national emergency or other circumstances of extreme urgency. Upon enactment and commencement of the Bill, if certain WTO Members wish to import generic versions of patented pharmaceutical products under the framework of the Protocol for addressing public health problems and a Hong Kong manufacturer intends to make the products for export to those countries, the latter may apply for an export compulsory licence under the Patents Ordinance. The DH will decide whether the compulsory licence should be issued under the system as set out in the Bill. (ii) Under the proposed section 72K in the Bill, if a WTO Member intends to import a patented pharmaceutical product referred to in the Bill according to the mechanism under the Protocol when it is not faced with a national emergency, an applicant for an export compulsory licence in Hong Kong should, before applying for such a licence, make reasonable efforts to obtain authorisation from the proprietor of the patent concerned on reasonable commercial terms and conditions to make and sell for export the patented pharmaceutical product. The DH would consider granting the

[1] These WTO Members include Australia, Canada, the European Union and its member states, Iceland, Japan, New Zealand, Norway, Switzerland and the U.S.

[2] These 11 WTO Members are Hong Kong China, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Singapore, Chinese Taipei, Turkey and United Arab Emirates.

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		export compulsory licence only if the applicant has failed to obtain the authorisation within 28 days. However, for cases where the WTO Member which intends to import a patented pharmaceutical product has declared that it is under national emergency or other circumstances of extreme urgency, the foregoing requirements would not apply. This is consistent with the requirements under the Protocol. As a WTO Member, Hong Kong has to comply with the requirements in implementing the Protocol. (iii) As regards the Democratic Party's reference to the Thai Government's recent issue of "compulsory licences" for three medicines, we understand that the medicines involved were manufactured in Thailand for local consumption. Hence, it does not relate to the import and export of medicines as envisaged under the Protocol.
2.3	When the proprietor of the patent at the exporting end is unable to recover the payment of the remuneration, the HKSAR Government, instead of the holder of the import compulsory licence, would pay the remuneration to the proprietor of the patent in Hong Kong. The HKSAR Government would use public funding for paying remuneration to the proprietor of the patent for importing the medicine to address the needs in Hong Kong. Given government subsidies and the lower cost of the medicine compared with patented medicine, importers and retailers would be able to make substantial profit. As such, the Government should consider imposing terms and conditions in	(i) Hong Kong has indicated that it would not use the system under the Protocol to import generic versions of patented medicines as an importer unless in situations of national emergency or other circumstances of extreme urgency. Where Hong Kong imports a pharmaceutical product under the Protocol, an obligation to pay remuneration to the proprietor of the patent in Hong Kong will arise only if adequate remuneration is not paid in accordance with the Protocol after all legal remedies to recover the payment of the remuneration at the exporting end have been exhausted. We expect that such circumstances will be extremely rare. Where such a situation arises, we consider it appropriate for the HKSAR Government to pay the remuneration to the proprietor of the patent in Hong Kong since the pharmaceutical product is used to contain an

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	the import compulsory licences to prevent stocking and price speculation by importers and retailers, a situation that would put public health at risk.	urgent public health problem in Hong Kong. (ii) The Bill provides a mechanism for preventing abuses of the import compulsory licensing system. Under section 72C, the DH may grant an import compulsory licence to importers whom he considers reputable and reliable. Besides, in granting an import compulsory licence to any person, the DH may impose any other terms or conditions as he thinks fit under section 72D(1)(c), having regard to the public health needs in Hong Kong in the period of extreme urgency, including measures that help prevent stocking and price speculation by parties involved in the supply chain.
2.4	For the export of pharmaceutical products, adequate remuneration shall be paid to the patent proprietor at the exporting end. It is believed that many countries with no manufacturing capacities in the pharmaceutical sector are poor and less developed countries. The amount of remuneration payable by them to the proprietor of the patent at the importing end may be lower. In addition, the remuneration payable to the patent proprietor by the Exporting Member would be determined having regard to the economic value of the use of the medicines to the Importing WTO Member. It is believed that there would be difficulties for a place to assess the economic value of the use of a non-patented medicine to another place. Also, there may be a number of importing WTO members afflicted with the same disease. This may further complicate the assessment of remuneration payable to the patent	The arrangement of paying remuneration to the patent proprietor at the exporting end as proposed in the Bill is made in accordance with the requirements under the Protocol. As a WTO Member, Hong Kong has to observe the requirements when implementing the Protocol.

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	proprietor. It should be more practicable to pay at the importing end the remuneration to the patent proprietor.	
3. Submissions from the Hong Kong Bar Association		
3.1	S.72E(1) of the Patents (Amendment) Bill ("the Bill") applies to the case where remuneration has been paid to the proprietor in the exporting member. It does not apply in the case where there is no applicable patent. S.72E(2) applies where a remuneration has not been paid to the proprietor of the patent, which works on the assumption that there is such a patent. It is suggested that a provision should be added to deal with the situation where there is no applicable patent in the exporting member.	(i) The Protocol seeks to provide a mechanism under which a WTO Member may manufacture and export the generic version of a patented pharmaceutical product to another WTO Member, without having to comply with the condition under Article 31(f) of WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS Agreement") which requires that the use of such generic products should be predominately for the supply of the domestic market. The Protocol also introduces a new Article 31 bis and an objective of paragraph 2 of such Article is to forestall the payment of double remuneration to right holders. Hence, the Protocol presupposes that there is an applicable patent in the exporting Member. (ii) Outside the context of the Protocol and the Bill, Article 28(1)(a) of the TRIPS Agreement obliges Hong Kong to confer on the local right holder certain exclusive rights including those of "offering for sale, selling, or importing". In the case of use of apatent without the authorization of the patent holder in Hong Kong, the right holder "shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization" as required under Article 31(h) of the TRIPS Agreement. This obligation would apply even if there is no applicable patent at the

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		exporting WTO Member. This scenario is covered under the existing Part IX of the Patents Ordinance (Cap.514) concerning government use of patented inventions[3]. The Government is obliged under s.71 of the Ordinance to compensate the patent proprietor in Hong Kong.
3.2	S.72E does not provide clearly for the situation where there are more than one relevant patent in the exporting member. Please advise whether s.72E(1) and s.72E(2) are applicable to the situation that the relevant patents are owned by different proprietors and that not all proprietors have been paid. There would be a situation that the paid patent is governed by s.72E(1) and the other patent(s) is/are governed by s.72E(2). This appears to be the proper interpretation and if so clearer drafting is preferable.	(i) If several patents are involved in one single generic medicine which is the subject of an import compulsory licence, we agree that both s.72E(1) and (2) will apply. That is to say, the paid patent is governed by s.72E(1) and the unpaid patent(s) is/are governed by s.72E(2). (ii) S.72E adopts expressions in the singular. In the light of s.7(2) of the Interpretation and General Clauses Ordinance (Cap.1), which provides that words/expressions in the singular include the plural, any proprietor of the patent can seek to claim remuneration under s.72E(2) if remuneration has not been paid to the proprietor of the patent granted in the exporting member. (iii) In view of the above, we consider it not necessary to amend s.72E to provide expressly for situations where there is more than one proprietor of patents.

[3] The existing Government use provisions (sections 68 to 72) in the Patents Ordinance give to the Government the right to use a patented invention without the need for any prior licence from the patent proprietor in periods of extreme urgency under specified conditions. The provisions apply to all type of inventions and are in line with Article 31 of the TRIPS Agreement. Unlike the Protocol which the Bill seeks to implement, the government use provisions are subject to the conditions that the use shall be predominantly for the supply of the domestic market of the WTO Member authorising such use (i.e., the majority of the product should not be exported) and that right holders should be paid adequate remuneration in the circumstances of each case.

3.3	Clarification should be made in s.72E so as to refer to remuneration having been paid in accordance with Article 31 bis in the Protocol and Article 31(h) of the TRIPS Agreement, or legislation made in pursuant thereto or in implementation thereof. The Protocol and the TRIPS Agreement would have to be implemented by local legislation in many exporting members.	Insofar as the payment of remuneration is concerned, WTO members' domestic laws are required to comply with the standards prescribed in Article 31 bis in the Protocol and Article 31(h) of the TRIPS Agreement. On reflection, we accept that it is possible that WTO members may have made adjustments in their domestic laws to cater for their own needs in addition to the standards stipulated in Article 31bis in the Protocol and Article 31(h) of the TRIPS Agreement. Adding a clause similar to that suggested by the Hong Kong Bar Association will make s.72E(2) clearer. We will make Committee Stage Amendments (CSAs) to the provision along the line suggested by the Bar Association.
3.4	Please state whether s.72I could help if there are disputes between the Director of Health ("the Director") and the proprietor as to whether all legal remedies have been exhausted for the purposes of s72E(2). It would seem that the proprietor may have to seek relief by applying for judicial review. This dispute does not seem to be covered by s.72I because it goes to entitlement to be paid, and not just quantum or apportionment. It may be desirable to expand s.72I to cover this situation.	(i) It is our policy intention that the court may also consider disputes regarding whether all legal remedies have been exhausted at the exporting member for the purposes of s.72E(2). In our view, this has already been covered in s.72I(6)(a). (ii) S.72I(6)(a) provides that the patent proprietor may apply to the court for review if he is aggrieved by the grant of an import compulsory licence. In this case, his grievance lies in the grant of an import compulsory licence which is unaccompanied by any arrangement relating to remuneration to him as the local patent proprietor. He can apply to the court for review under s.72I(6)(a) and establish his entitlement to remuneration by evidence showing that remuneration has not been paid at the exporting end and that all legal remedies to recover payment of the remuneration in the exporting end have been exhausted. (iii) In view of the above, we consider it not necessary to expand s.72I to cover disputes regarding the question of whether all legal remedies have been exhausted for the purposes of s.72E(2).

		(iv) Separately, the decision made by the Director in s.72E(2) is an administrative decision which may be subject to judicial review by the court on application based on the usual principles of administrative law.
3.5	It may not always be fair to have equal share of the remuneration under s.72E(5), although this would perhaps be practical, leaving it to the proprietors to apply to the court for a variation if desired, as it appears that the court can vary the apportionment under s.72I(7)(c). If this is the case, clarification may be preferable by making s.72E(5) expressly subject to a Court order to vary the apportionment (although this may not be absolutely necessary in view of s72I(6)(c)).	S.72I(6)(c) has expressly provided that the apportionment of the amount of remuneration under s.72E(5) may be reviewed by the court. We consider it not necessary to provide in s.72E(5) that the apportionment is subject to a Court order.
3.6	There may be gaps in s.72F(2). First, there may be no remuneration payable in Hong Kong because s.72E(1) applies and if so it is this fact that should be advertised or it is intended that in such a case there is no need to advertise. Second, under s.72E(2), where remuneration is payable to the proprietor in the exporting member, it would have been thought that the Director and the Hong Kong proprietor would not seek to agree on the remuneration in the expectation that the proprietor overseas will be paid. If it is not paid, then legal proceedings would have to be commenced in the exporting member to seek legal remedies, and only if all such legal remedies have been exhausted, the parties would then seek to agree.	(i) The notices under s.72F(1) and s.72F(2) would be issued at different points of time. (ii) After the grant of an import compulsory licence, the Director will give notice to the proprietor of the patent concerned in Hong Kong of the grant of licence and its terms and conditions, and advertise the above information in the official journal notice under s.72F(1). He would also make a notification to the TRIPS Council, specifying the names and quantities of the medicine(s) needed, confirming that Hong Kong has insufficient or no manufacturing capacities in the pharmaceutical sector for the medicine(s) in question, and that it has granted or intends to grant an import compulsory licence. There is likely to be a time lag before the relevant exporting WTO Member could be confirmed. There will inevitably be a further time lag

	In the meantime, the import compulsory licence would have been granted and probably run its course and expired. It is envisaged that there shall be no advertisement in the meantime until agreement (or the failure to agree). As s.72F(2) seems to assume that there would always be one of two situations; agreement of remuneration or failure to agree, but there will be cases of no remuneration payable or a suspension period. If it is intended that advertisement is required only in the two situations as stated in s.72F(2), this should be made clearer.	before the local patent proprietor can establish whether remuneration has been paid at the exporting end, and if not whether all legal remedies have been exhausted at that end. (iii) We consider it not necessary to state in the official journal under s.72F(1) the remuneration issue. Under the Protocol, the payment of remuneration to the patent proprietor should as a general rule be handled at the exporting end. We trust this point should be clear to the patent proprietor in Hong Kong as this is one of the primary features of the compulsory licensing system under the Protocol. (iv) As regards the advertisement of the "suspension" period, there are practical difficulties in implementation. It is neither practicable nor appropriate for the Director to advertise the suspension period, given that he cannot ascertain exactly at what time all legal remedies to recover payment of remuneration in the exporting member will have been exhausted. (v) The need to issue a notice under s.72F(2) will only arise if the local patent proprietor has established that no remuneration has been paid at the exporting end after the exhaustion of all legal remedies over there, and when an agreement has been reached under s.72E(2) or no such agreement could be reached. We envisage that such a scenario should be extremely rare. When this scenario arises, the main purpose of the Director advertising a notice in s.72F(2) is to provide a reference date for any aggrieved parties who may wish to make application to the court for a review under either s.72I(2) or s.72I(6)(c). The Director will only be required to advertise in the official journal under s.72F(2) when he is satisfied that no remuneration has been paid to the patent proprietor at the exporting

		end after the exhaustion of all legal remedies over there, and after negotiation with the local patent proprietor on the remuneration amount has been undertaken. (vi) On reflection, we consider that it may be desirable to improve the wording in s.72F(2) so as to make it clear that the notice under s.72F(2)(a) should be made as soon as practicable after an agreement has been reached between the Director and the proprietor of the patent concerned granted in Hong Kong under s.72E(2)(a), and the notice under s.72F(2)(b) should be made as soon as practicable after the failure to reach the agreement under s.72E(2)(a). We will propose CSAs to that effect.
3.7	There does not appear to be any provision under s.72Q for the court to vary the apportionment of the amount of remuneration where there is more than one patent in relation to the patented pharmaceutical product mentioned in s.72M(1)(b)(v). S.72Q(2)(c) does not seem to be wide enough to cover this.	Under s.72Q(2)(b), the court in a review may confirm, vary or cancel a term or condition of the export compulsory licence imposed under s.72L. As the apportionment of the amount of remuneration is expressed as a term of an export compulsory licence in s.72M(1)(b)(v), s.72Q has already included a provision for the court to vary the apportionment of remuneration.
4. Submissions from the Hong Kong Association of the Pharmaceutical Industry (HKAPI)		
4.1	The Government is requested to benchmark its Avian Flu Responsive Alarm System as an example of how to put objective measures and a clear definition around key processes in a state of "extreme urgency."	(i) The Administration would consider declaring a state of extreme urgency in a wide range of emergencies that may arise. Flu pandemic is only one of the situations. (ii) A situation of extreme urgency under the Patents Ordinance (Cap. 514) will arise when there is a public health crisis that may have profound impact on human lives or health condition that calls for the application of s.72C – 72I.

		(iii) The Doha Declaration states, among others, that "Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crisis, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstance of extreme urgency."
4.2	An independent statutory body should be established, with a balanced membership, to advise the Chief Executive-in-council prior to any state of "extreme urgency" being declared. An important role for this body would be to reference recommendations and guidance from other international health bodies.	There is a well-established mechanism for the Chief Executive in Council to make decisions on important policy issues, including protection of public health. The Government will take into account the advice and recommendations of both international and local health authorities as appropriate before deciding whether a period of extreme urgency should be declared.
4.3	Clarity should be provided in the Proposal about how and when normal economic activities would be restored after a "state of urgency" has been resolved. Care should be taken to ensure no long-lasting damage occurs to Hong Kong's commercial principles, including protection of intellectual property rights. Details should be provided in the Proposal concerning how long generic drugs, which infringe a valid patent, can be stocked and sold during and after a "state of urgency", and who will be exempted from liability for infringing patents and for how long. The Government is advised to centralize the	(i) We agree with HKAPI that after the extreme urgency, care should be taken to ensure that the proposals in the Patents (Amendment) Bill 2007 ("the Bill") will not undermine the protection of intellectual property rights in Hong Kong. To achieve this objective, we have devised some measures to protect the interest of the proprietors of the patent of the pharmaceutical product concerned in Hong Kong. An import compulsory licence (licence) granted under the proposed s.72C would terminate upon expiry of its term or under section 72G of the Bill or if the period of extreme urgency leading to the declaration under the proposed s.72B(1) is over, whichever is the earlier. If any person does any act amounting to an act of infringement in relation to any remaining quantity of the patented pharmaceutical product imported (as defined under the Bill) after the expiry of the licence, he may incur civil liability. We suggest that

	purchase, usage, stocking and distribution of affected drugs during a period of "extreme urgency," so that these drugs can be effectively distributed to patients most in need and prevent any possible irrational stocking of drugs due to speculation or panic by the public.	prior consent of the patent proprietor needs to be sought before the remaining quantity could be kept in stock for future use or sale. After the extreme urgency, the licence holders would be required to arrange recall of the products along the supply chain at their own expense. End-users (e.g. patients) who keep the products for personal consumption would be exempted from liability for infringement under the existing s.75(a) of the Patents Ordinance (Cap 514). (ii) That said, for the protection of public health, it may also be worth stockpiling the remaining quantity of patented pharmaceutical product in case Hong Kong faces a similar emergency in the future. To that effect, the Government would liaise with the patent proprietor concerned regarding the disposal of the remaining stock if it intends to keep the stock for future use. During the period of negotiation with the patent proprietor, stocking and any act involved in the recall should not be regarded as patent infringing. We may need to add a provision in the Bill to place it beyond doubt that any such act when the negotiation between the Director of Health and the patent proprietor is taking place would not be patent infringing. Committee Stage Amendments (CSAs) may be proposed to that effect. If the patent proprietor refuses to give consent to the keeping of the remaining stock for future use, the remaining quantity would need to be destroyed. The above measures would protect the interest of the patent proprietor on one hand, and serve the Government's purpose of public health protection on the other. (iii) As the import compulsory licensing system is intended to address a wide range of emergency situations, the mode of procurement and distribution of the required patented pharmaceutical product may vary, depending on the circumstances of the case. A possible

		scenario is that the Government would centralize the purchase, usage, stocking and distribution of the product to the end-users. In this case, the Government would use public money to procure the patented pharmaceutical product. The licence holders and other traders along the supply chain would act as agents of the Government in sourcing and distributing the product. As the Government plays a significant part in the purchase and distribution of the product, speculative or panic stocking could be avoided. Government's coordination would also ensure an effective distribution of the products to end users in need. (iv) Depending on the circumstances, there might also be a need to seek private sector initiative to procure and source the required patented pharmaceutical product. Arrangements would also be in place to safeguard the interest of the licensees and other traders down the supply chain, who in good faith have assisted the Government in importing and distributing the pharmaceutical products during the extreme urgency. We foresee that under this scenario, the licence holders and other traders down the supply chain would be concerned that they could run the risk of patent infringement if they continue to sell the remaining stock after the expiry of the licence. We are now examining if specific provisions should be introduced into the Bill to enable the Government to accept the remaining stock surrendered by the licence holders in return for payment at cost by the Government. If necessary, CSAs may be proposed to that effect. Alternatively, a licence holder may choose to keep the stock and negotiate royalty payment with the patent owner on his own. Depending on the circumstances of the case, the Government may reach a mutual understanding with the prospective licence holder concerning the arrangement prior to the issue of the licence.

		(v) In sum, the measures in (i) – (iv) would be able to protect the interests of the patent proprietors, the end-users of the pharmaceutical product, the licensees and other traders down the supply chain who help import and distribute the pharmaceutical product.
4.4	Bio-equivalence and Bio-availability* data should be required for all generic products affected by a "Compulsory License," so that this process does not give rise to inferior quality generic products being used, which may lead to harmful effects for patients. **Bioequivalence ensures that generic medicines are therapeutically equivalent to the original branded product, while Bio-availability shows how quickly and effectively the active ingredients act on the body. A lot of regulatory bodies in the world put 75% of bio-equivalence/bio-availability compare to the original branded drug a criterion for generics registration.*	We note HKAPI's view on bio-equivalence and bio-availability data requirement to ensure that the generic pharmaceutical products imported would not be of inferior quality. To protect public health, all medicines must be registered with the Pharmacy and Poisons Board (PPB) before they can be sold in Hong Kong. Registration applications are assessed on the basis of their safety, efficacy and quality. At present, bio-equivalence and bio-availability data are not required. We would like to emphasize that the proposals in the Bill would not conflict with the existing mechanism for registration of pharmaceutical products in Hong Kong. Generic medicines imported under the proposed mechanism in the Bill would still have to satisfy the PPB's strict requirement in terms of safety, efficacy and quality in order to obtain registration. Hence, we do not see a need to apply extra onerous requirement on such generic medicines which are imported to address an extreme urgency.