二零零六年十二月十九日會議
討論文件

立法會工商事務委員會

建議修訂《專利條例》以落實修訂《與貿易有關的知識產權協議》的議定書

目的

本文件載述當局對《專利條例》的建議修訂，以落實一份待世界貿易組織(“世貿組織”)成員接納的議定書。該議定書修訂世貿組織《與貿易有關的知識產權協議》(“《協議》”)，以利便各成員取得專利藥物的仿製藥，作處理公眾健康問題之用。議定書的文本載於附件1(原文只備英文本)。

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《與貿易有關的知識產權協議》

2. 《協議》載有規管專利保護的條文。專利持有人擁有多項專有權利，包括有權製造、使用、售賣或進口專利產品或透過專利方法直接取得的產品。任何其他人士如擬作出受專利限制的作爲，必須事先獲得專利持有人授權，否則有可能會遭到民事追討。

3. 根據《協議》的第31條，世貿組織的成員可以批出強制性特許，准許第三方在未經專利持有人授權的情況下，使用某一專利物品，但須遵守某些條件。其中一項條件是，此種使用應*主要*爲供應授權有關使用的世貿組織成員本身的內部市場(第31(f)條)。換言之，有關產品的絕大部分數量不應用作出口。另一項條件是，專利持有人應按個別情況獲支付*適當報酬*，而有關報酬須考慮到授權的經濟價值(第31(h)條)。

議定書的歷史背景

4. 二零零一年十一月，在多哈舉行的世貿組織部長級會議通過了《關於與貿易有關的知識產權協議與公共健康的宣言》。這份《多哈宣言》確認了很多發展中和最不發達國家面對嚴重的公眾健康問題，特別是愛滋病、肺結核、瘧疾和其他傳染病導致的問題。該宣言同時亦承認，製藥能力不足或根本沒有能力製藥的世貿組織成員就有效地運用在現行《協議》之下的強制性特許制度上，可能面對困難；具體來說，該等成員不能請求具備製藥能力的其他經濟體系，向其出口仿製專利藥品。爲此，與貿易有關的知識產權理事會便獲指派研究解決這個問題的方法。

5. 二零零三年八月，世貿組織總理事會通過一項決議，在指明的情況下，暫時豁免成員在《協議》第31(f)和 31(h)條下的責任。這項決定實際上容許某世貿組織成員根據強制性特許生產藥品，並出口該些藥品至另一缺乏製藥能力的世貿組織成員，而不受制於第 31(f)條所訂主要爲供應本身內部市場使用的限制。該項決定亦訂明，如出口藥品的世貿組織成員已根據第 31(h)條支付適當報酬，則進口有關藥品的世貿組織成員便無須支付報酬，從而避免雙重報酬的問題。

6. 二零零五十二月六日，世貿組織總理事會最終通過有關的議定書，在符合下文第 7 段的情況下，取代上述的暫時豁免，並永久落實《多哈宣言》提出的安排。

7. 世貿組織成員可在二零零七年十二月一日(或世貿部長級會議決定的較後日期)前接納該份議定書。如議定書獲三分之二的世貿組織成員接納，便告生效。

利用議定書所訂的制度進口藥品

8. 通過《多哈宣言》之後，部分已發展經濟體系認爲，該項用作解決《多哈宣言》所指問題的制度，應只限於最不發達經濟體系及低收入的發展中經濟體系採用。十一個發展中經濟體系[1](包括香港)最終同意，除非在全民處於緊急狀態或在其他極端緊急的情況下，否則不會以進口者身分利用有關制度。

建議的法例修訂

9. 香港積極參與達至制定議定書的世貿組織討論，我們擬在二零零七年十二月一日前，通知世貿組織香港會接納該份議定書。

10. 現行的《專利條例》訂明了強制性特許架構，該架構是以《協議》的第 31 條作爲藍本。爲落實議定書，我們須修訂本地專利法例。

<u>香港作爲進口成員</u>

11. 如上文第 8 段所述，香港只會在處於緊急狀態或在其他極度緊急的情況下，才會使用議定書所訂的架構進口藥品。我們建議，行政長官會同行政會議如認爲爲了公眾利益而有必要或適宜時，可藉在憲報刊登公告，宣布任何期間爲極度緊急期間，以便處理任何公眾健康問題或對公眾健康構成威脅的問題。這個模式與現行《專利條例》第 68 條關於在極度緊急的情況下政府徵用一般專利發明大致相同。

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[1] 已向世貿組織聲明只會在全民處於緊急狀態或在其他極端緊急的情況下，才會以進口者身分利用有關制度的經濟體系包括中國香港、以色列、韓國、科威特、中國澳門、墨西哥、卡塔爾、新加坡、中國台北、土耳其及阿拉伯聯合酋長國。

12. 在該等極度緊急的情況下，如衞生署署長(“署長”)信納香港沒有能力或沒有足夠能力製造某種藥品以處理公眾健康問題，則香港可利用議定書所訂的制度進口該藥品。儘管香港已就該藥品批予任何專利，署長有權批出強制性特許予任何人，讓該人可作出包括進口、使用及分發該藥品等作爲，而無須取得專利持有人的同意。署長須在切實可行的範圍內，盡快通知專利持有人有關強制性特許的批予。

13. 爲符合議定書的規定，強制性特許須受下列條件限制：

(a) 特許所涵蓋的藥品數量，只限於在上文第 11 段所宣布的緊急情況下處理香港的公眾健康問題所需的數量；

(b) 有關藥品必須全數用於香港，不得輸出往其他地方；以及

(c) 必須以特定的標籤或標記，清楚識別藥品是根據議定書所訂制度生產的。

此外，因應當初基於香港公眾健康需要而作出極度緊急宣布的情況，署長可視乎需要，在強制性特許中加入他認爲適當的其他規定。不遵守特許條件可導致特許被終止。

14. 議定書特別訂明，如出口成員已支付適當的報酬，則進口成員無須支付報酬。因此，除非出口成員沒有向專利持有人支付適當的報酬，否則無須向香港專利持有人支付報酬。

15. 我們建議，在署長批出強制性特許以供進口藥品後，任何一方如因爲署長的決定而感到受屈，可向原

訟法庭提出上訴。法庭可藉頒布命令，更改或取消特許，或按其認爲適當的條款作出其認爲適當的命令。

香港作爲出口成員

16. 香港亦可在指明情況下，利用議定書所訂的制度出口專利藥品的仿製藥。如有世貿組織成員表示擬利用議定書引入某藥品，任何認爲本身有能力製造該藥品的本地製造商，只要獲政府發出強制性特許，便可利用議定書所訂的制度製造該藥品，然後把產品輸出往有關的進口成員。

17. 我們建議賦權署長發出有關強制性特許。如進口的世貿組織成員並無宣布全民處於緊急狀態或其他極度緊急的情況，則欲申請強制性特許出口藥品的申請人應在提交有關特許申請前，作出合理的努力，按合理的商業條款及條件，爭取獲得專利持有人的授權。如申請人未能在 28 天內獲得授權，署長才會考慮批予強制性特許。署長收到有關申請後，如能在一段合理時間內，以合理的努力聯絡到有關的專利持有人，亦會給予專利持有人機會，就申請提出意見。然而，如進口的世貿組織成員正處於全民緊急狀態或其他極度緊急的情況，則前述規定便不適用。

18. 署長批出強制性特許時，可附加其認爲適合的條款及條件，包括但不限於下列各項：

(a) 只限生產進口成員所需應付公眾健康問題的數量，而且所生產的藥品必須全數輸出往該進口成員；

(b) 就此而生產的藥品須加上特定的標籤或標記，使易於識別；以及

(c) 藥品付運前，特許持有人須在指定的網站上刊載

(i) 向進口成員供應的有關藥品數量；以及

(ii) 藥品標籤／標記的特徵。

不遵守任何條款及條件可導致特許被終止。

19. 議定書訂明，出口成員有責任向專利持有人支付適當報酬，而訂定報酬金額時則須考慮使用(獲批強制性特許的)有關藥品對進口成員的經濟價值。在考慮特許持有人須支付的報酬金額時，我們參考了其他已通知世貿組織接納議定書，或已經／正在立法或制定措施以落實議定書的司法管轄區的做法。據我們了解，中國內地會按每宗個案的情況釐訂所支付的報酬；歐盟、加拿大及瑞士則已訂明或正考慮訂明適用於大部分情況的最高報酬額的百分比或報酬計算公式(報酬額一般不超過進口成員就產品所付金額的 4%)。有關這些司法管轄區釐訂
2 報酬金額的機制，詳載於附件 2。

20. 現時未有世貿組織成員使用過該制度，亦只有少數司法管轄區設有機制以實施該制度。因此，我們認爲適宜在法例中，就釐訂應支付予專利持有人的報酬金額保留彈性。我們不建議在《專利條例》訂明一條計算公式，而是根據個別個案釐訂報酬金額，惟金額不應超過進口成員支付予香港製造商總額的 4%。政府會繼續留意國際上的發展，並在需要批出強制性特許時，因應個案的情況考慮應付的報酬金額。

21. 我們又建議，在署長批出強制性特許或拒絕有關申請後，任何人如因署長的決定或就報酬金額而感到受屈，可向原訟法庭提出上訴。法庭可藉頒布命令，更改或取消特許，或按其認爲適當的條款作出其認爲適當的命令。

諮詢

22. 我們已就修訂建議諮詢有關人士，包括主要的醫療、法律及知識產權從業員協會、代表藥劑業的各大商會、本地大學，以及關注公眾健康問題對發展中國家的影響的相關非政府組織。

3 23. 接獲的意見及我們的初步回應撮述於附件 3。

下一步的工作

24. 我們現正草擬所需的法例修訂，並計劃在二零零七年的上半年向立法會提交有關的修訂條例草案。

意見徵詢

25. 請議員就上文第 9 至 21 段所載的建議提出意見。我們擬備法例修訂建議時，會考慮議員的意見。

工商及科技局
工商科
二零零六年十二月

WORLD TRADE ORGANIZATION

WT/L/641
8 December 2005

(05-5842)

AMENDMENT OF THE TRIPS AGREEMENT

Decision of 6 December 2005

The General Council;

Having regard to paragraph 1 of Article X of the Marrakesh Agreement Establishing the World Trade Organization ("the WTO Agreement");

Conducting the functions of the Ministerial Conference in the interval between meetings pursuant to paragraph 2 of Article IV of the WTO Agreement;

Noting the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) and, in particular, the instruction of the Ministerial Conference to the Council for TRIPS contained in paragraph 6 of the Declaration to find an expeditious solution to the problem of the difficulties that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face in making effective use of compulsory licensing under the TRIPS Agreement;

Recognizing, where eligible importing Members seek to obtain supplies under the system set out in the proposed amendment of the TRIPS Agreement, the importance of a rapid response to those needs consistent with the provisions of the proposed amendment of the TRIPS Agreement;

Recalling paragraph 11 of the General Council Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health;

Having considered the proposal to amend the TRIPS Agreement submitted by the Council for TRIPS (IP/C/41);

Noting the consensus to submit this proposed amendment to the Members for acceptance;

Decides as follows:

1. The Protocol amending the TRIPS Agreement attached to this Decision is hereby adopted and submitted to the Members for acceptance.

2. The Protocol shall be open for acceptance by Members until 1 December 2007 or such later date as may be decided by the Ministerial Conference.

3. The Protocol shall take effect in accordance with the provisions of paragraph 3 of Article X of the WTO Agreement.

ATTACHMENT

PROTOCOL AMENDING THE TRIPS AGREEMENT

Members of the World Trade Organization;

Having regard to the Decision of the General Council in document WT/L/641, adopted pursuant to paragraph 1 of Article X of the Marrakesh Agreement Establishing the World Trade Organization ("the WTO Agreement");

Hereby agree as follows:

1. The Agreement on Trade-Related Aspects of Intellectual Property Rights (the "TRIPS Agreement") shall, upon the entry into force of the Protocol pursuant to paragraph 4, be amended as set out in the Annex to this Protocol, by inserting Article 31*bis* after Article 31 and by inserting the Annex to the TRIPS Agreement after Article 73.

2. Reservations may not be entered in respect of any of the provisions of this Protocol without the consent of the other Members.

3. This Protocol shall be open for acceptance by Members until 1 December 2007 or such later date as may be decided by the Ministerial Conference.

4. This Protocol shall enter into force in accordance with paragraph 3 of Article X of the WTO Agreement.

5. This Protocol shall be deposited with the Director-General of the World Trade Organization who shall promptly furnish to each Member a certified copy thereof and a notification of each acceptance thereof pursuant to paragraph 3.

6. This Protocol shall be registered in accordance with the provisions of Article 102 of the Charter of the United Nations.

Done at Geneva this sixth day of December two thousand and five, in a single copy in the English, French and Spanish languages, each text being authentic.

ANNEX TO THE PROTOCOL AMENDING THE TRIPS AGREEMENT

Article 31bis

1. The obligations of an exporting Member under Article 31(f) shall not apply with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out in paragraph 2 of the Annex to this Agreement.

2. Where a compulsory licence is granted by an exporting Member under the system set out in this Article and the Annex to this Agreement, adequate remuneration pursuant to Article 31(h) shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member. Where a compulsory licence is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31(h) shall not apply in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.

3. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products: where a developing or least-developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least-developed countries, the obligation of that Member under Article 31(f) shall not apply to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or least-developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question.

4. Members shall not challenge any measures taken in conformity with the provisions of this Article and the Annex to this Agreement under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994.

5. This Article and the Annex to this Agreement are without prejudice to the rights, obligations and flexibilities that Members have under the provisions of this Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2), and to their interpretation. They are also without prejudice to the extent to which pharmaceutical products produced under a compulsory licence can be exported under the provisions of Article 31(f).

ANNEX TO THE TRIPS AGREEMENT

1. For the purposes of Article 31*bis* and this Annex:

(a) "pharmaceutical product" means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2). It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included[1];

(b) "eligible importing Member" means any least-developed country Member, and any other Member that has made a notification[2] to the Council for TRIPS of its intention to use the system set out in Article 31*bis* and this Annex ("system") as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. It is noted that some Members will not use the system as importing Members[3] and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency;

(c) "exporting Member" means a Member using the system to produce pharmaceutical products for, and export them to, an eligible importing Member.

2. The terms referred to in paragraph 1 of Article 31*bis* are that:

(a) the eligible importing Member(s)[4] has made a notification[2] to the Council for TRIPS, that:

(i) specifies the names and expected quantities of the product(s) needed[5];

(ii) confirms that the eligible importing Member in question, other than a least-developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Appendix to this Annex; and

(iii) confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Articles 31 and 31*bis* of this Agreement and the provisions of this Annex[6];

(b) the compulsory licence issued by the exporting Member under the system shall contain the following conditions:

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[1] This subparagraph is without prejudice to subparagraph 1(b).

[2] It is understood that this notification does not need to be approved by a WTO body in order to use the system.

[3] Australia, Canada, the European Communities with, for the purposes of Article 31*bis* and this Annex, its member States, Iceland, Japan, New Zealand, Norway, Switzerland, and the United States.

[4] Joint notifications providing the information required under this subparagraph may be made by the regional organizations referred to in paragraph 3 of Article 31*bis* on behalf of eligible importing Members using the system that are parties to them, with the agreement of those parties.

[5] The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to the system.

[6] This subparagraph is without prejudice to Article 66.1 of this Agreement.

(i) only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS;

(ii) products produced under the licence shall be clearly identified as being produced under the system through specific labelling or marking. Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price; and

(iii) before shipment begins, the licensee shall post on a website[7] the following information:

- the quantities being supplied to each destination as referred to in indent (i) above; and

- the distinguishing features of the product(s) referred to in indent (ii) above;

(c) the exporting Member shall notify[8] the Council for TRIPS of the grant of the licence, including the conditions attached to it.[9] The information provided shall include the name and address of the licensee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the licence. The notification shall also indicate the address of the website referred to in subparagraph (b)(iii) above.

3. In order to ensure that the products imported under the system are used for the public health purposes underlying their importation, eligible importing Members shall take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system. In the event that an eligible importing Member that is a developing country Member or a least-developed country Member experiences difficulty in implementing this provision, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in order to facilitate its implementation.

4. Members shall ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the system and diverted to their markets inconsistently with its provisions, using the means already required to be available under this Agreement. If any Member considers that such measures are proving insufficient for this purpose, the matter may be reviewed in the Council for TRIPS at the request of that Member.

5. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products, it is recognized that the development of systems providing for the grant of regional patents to be applicable in the Members described in paragraph 3 of Article 31*bis* should be promoted. To this end, developed country

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[7] The licensee may use for this purpose its own website or, with the assistance of the WTO Secretariat, the page on the WTO website dedicated to the system.

[8] It is understood that this notification does not need to be approved by a WTO body in order to use the system.

[9] The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to the system.

Members undertake to provide technical cooperation in accordance with Article 67 of this Agreement, including in conjunction with other relevant intergovernmental organizations.

6. Members recognize the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem faced by Members with insufficient or no manufacturing capacities in the pharmaceutical sector. To this end, eligible importing Members and exporting Members are encouraged to use the system in a way which would promote this objective. Members undertake to cooperate in paying special attention to the transfer of technology and capacity building in the pharmaceutical sector in the work to be undertaken pursuant to Article 66.2 of this Agreement, paragraph 7 of the Declaration on the TRIPS Agreement and Public Health and any other relevant work of the Council for TRIPS.

7. The Council for TRIPS shall review annually the functioning of the system with a view to ensuring its effective operation and shall annually report on its operation to the General Council.

APPENDIX TO THE ANNEX TO THE TRIPS AGREEMENT

Assessment of Manufacturing Capacities in the Pharmaceutical Sector

Least-developed country Members are deemed to have insufficient or no manufacturing capacities in the pharmaceutical sector.

For other eligible importing Members insufficient or no manufacturing capacities for the product(s) in question may be established in either of the following ways:

(i) the Member in question has established that it has no manufacturing capacity in the pharmaceutical sector;

or

(ii) where the Member has some manufacturing capacity in this sector, it has examined this capacity and found that, excluding any capacity owned or controlled by the patent owner, it is currently insufficient for the purposes of meeting its needs. When it is established that such capacity has become sufficient to meet the Member's needs, the system shall no longer apply.

其他世貿組織成員作為出口一方時的特許使用費安排

（截至二零零六年十二月五日的情況）

世貿組織成員	特許使用費的安排
歐盟[1]	✦ 相關的歐洲議會規例沒有訂明如何計算有關報酬的方法，但表明在全民處於緊急狀態或在其他極度緊急的情況下，或在公共非商業性使用的情況下，有關報酬最高為進口世貿組織成員就有關藥品所付總額的 4%。 ✦ 至於其他情況，則須考慮使用有關藥品對進口成員的經濟價值，以及與發出強制性特許有關的人道及非商業情況，從而釐訂報酬金額。
加拿大	✦ 須支付的報酬金額按照訂明公式計算，考慮因素包括批予特許的人道及非商業依據。 ✦ 該公式根據進口成員在聯合國人力發展指標[2]的排名計算。進口成員在聯合國人力發展指標的排名越低，須支付的特許使用費便越少。 ✦ 計算公式如下： $\frac{1 + (\text{聯合國人力發展指標涵蓋的地方數目} - \text{有關成員在聯合國人力發展指標的排名})}{\text{聯合國人力發展指標涵蓋的地方數目}} \times 0.04 = \text{特許使用費比率}$ ✦ 這公式計算出的特許使用費比率不會超過 4%。加拿大政府認為，這百分比符合人道和非商業考慮的原則，而這些正是加拿大引用二零零三年八月的《多哈宣言》下衍生的醫療機制所持的基本原則。

[1] 有關法例(歐洲議會規例第 816/2006 號(第 10 條))對所有歐盟成員國具約束力。目前歐盟共有 25 個成員：奧地利、比利時、塞浦路斯、捷克共和國、丹麥、愛沙尼亞、芬蘭、法國、德國、希臘、匈牙利、愛爾蘭、意大利、拉脫維亞、立陶宛、盧森堡、馬耳他、波蘭、葡萄牙、斯洛伐克、斯洛文尼亞、西班牙、瑞典、荷蘭及英國。

[2] 用以評估全球各國人力發展的指標。

世貿組織成員	特許使用費的安排
瑞士	✦ 現正就其專利法提出修訂建議，以實施世貿組織的決定，幫助有需要的世貿組織成員解決公眾健康問題。 ✦ 草擬中的法例訂明，報酬金額應根據特許對進口成員的經濟價值及該成員的發展水平而定。正考慮採用加拿大的計算公式，並將會透過訂立規例，指明計算方法。 ✦ 根據建議的計算公式，符合資格而且目前正在聯合國人力發展指標內排名最低的成員須支付的特許使用費比率為 0.02%，最高者理論上則是 4%。
中國內地	✦ 國家知識產權局頒布的相關命令只規定須向專利權人支付合理的報酬，但沒有載述如何計算出合理報酬，因此可能須按個別個案處理。

附件 3

諮詢團體回覆摘要
（截至 2006 年 12 月 11 日為止）

諮詢團體	觀點/意見	當局的初步回應
香港科研製藥聯會	✦ 同意在香港作為出口成員的情況下，強制性特許的報酬的數額應按個別情況而定，但要求取消最高為百分之四的上限。 ✦ 要求當局向立法會提交條例草案前，該會可查看實際條文。	✦ 基於訂立議定書背後的人道立場精神及其他非商業用途考慮，我們認為設定酬金上限是合理的。
亞洲專利代理人協會香港分會	✦ 在香港作為出口成員的情況下報酬的上限訂得過低。 ✦ 就進口成員並非面臨全民處於緊急狀態或極度緊急的情況，應考慮提高報酬的上限。	✦ 現時，報酬的上限訂為進口成員購買藥品的總金額的百分之四。在訂定有關百分比時，我們已考慮了現時外國的構思（包括歐盟、加拿大及瑞士）。我們可因應未來的國際發展，檢討將報酬上限訂於百份之四是否適當。

諮詢團體	觀點/意見	當局的初步回應
無國界醫生	✦ 支持衞生署署長決定何時利用強制性特許進口仿製專利藥物。儘管這情況只會在行政長官宣佈為極度緊急的時期時才發生。 ✦ 對在專利持有人與有關的仿製藥物製造商須作事前磋商的情況下，訂立 28 日的談判期以避免不當延誤的建議，表示贊同。 ✦ 對在以強制性特許出口的情況下，訂立百分之四的報酬上限以避免濫收的建議，表示贊同。 ✦ 對於未有簡化及快速程序去更改在建議機制下製造及出口的藥物的數量，感到可惜。	✦ 我們會研究是否有需要在條文中加入有關快速程序。
香港中文大學	✦ 強烈支持建議	

諮詢團體	觀點/意見	當局的初步回應
香港律師會	✦ 對建議並無意見	
香港商標師公會	✦ 大致上支持建議，特別是香港可根據議定書在極度緊急的情況下進口藥物。 ✦ 就在香港作為出口成員的情況下將報酬的上限定為百分之四的建議，需要更多時間諮詢其會員。	
香港大學	✦ 大致上支持建議 ✦ 認為議定書不會影響大學的學術活動，亦不會對工業科技轉移帶來負面的影響。 ✦ 認為就衞生署署長發出強制性特許的情況，應制訂適當的規例或規則。	

諮詢團體	觀點/意見	當局的初步回應
港大科橋有限公司 (屬於香港大學進行科技轉移的機構)	✦ 就執行細節提出了一些觀點(例如：當香港作為出口成員時，怎樣向專利持有人支付報酬) ✦ 當獲得法律條文的細節時，會進一步評估建議對本地專利持有人和香港大學的影響。	