

**DEPARTMENT OF HEALTH
PHARMACEUTICAL SERVICE
PHARMACEUTICALS IMPORT/EXPORT CONTROL SECTION**

**Guidance Notes on
Application for an Export Compulsory Licence of Pharmaceutical Products
Under the Patents Ordinance**

Export compulsory licences of patented pharmaceutical products

1. Under the Pharmacy and Poisons Ordinance, a person manufacturing a pharmaceutical product is required to hold an appropriate licence for manufacturer.
2. If you are a licensed pharmaceutical manufacturer, and if you intend to manufacture and export a pharmaceutical product which is patented in Hong Kong, you can apply to the Director of Health under the Patents Ordinance for the grant of an export compulsory licence to do so.

Things to do before you make the application

3. If the country/territory to which you intend to manufacture and export the pharmaceutical product has not notified the TRIPS Council that it is faced with a national emergency or other circumstances of extreme urgency, you should:
 - (a) at least 28 days before you make the application, make reasonable efforts to obtain, from the proprietor of the patent concerned granted in Hong Kong (“**the proprietor**”), on reasonable commercial terms and conditions, authorization to manufacture and export the product of such amount as requested by the importing country/territory; and
 - (b) at least 14 days before you make an application, notify “the proprietor” of your intention to apply, providing him the following information –
 - (i) your name and address, and if you have authorized any agent or representative for the purpose of the application, the name and address of the agent or representative;
 - (ii) the name and amount of the pharmaceutical product to be manufactured and exported under a compulsory licence you will apply for;
 - (iii) the name of the importing country/territory;
 - (iv) the duration of the export compulsory licence you will apply for;
 - (v) the Hong Kong patent number(s) of the pharmaceutical product;
 - (vi) the proposed labelling, marking, packaging, colouring or shaping of the pharmaceutical product;
 - (vii) information (if any) you have obtained from the importing country/territory concerning the amount of the pharmaceutical product to be manufactured and exported to it by any exporting country/territory other than Hong Kong under any compulsory licence granted elsewhere.
 - (c) when you notify “the proprietor” of the matters under (b) above, you should also attach to the notification copies of the documents referred to in paragraph 7(a), 7(b) and 7(e) below.

4. If the country/territory to which you intend to manufacture and export the patented pharmaceutical product has notified the TRIPS Council that it is faced with a national emergency or other circumstances of extreme urgency:

- (a) at any time before you make the application, you should notify “the proprietor” of your intention to make it, providing him the information contained in the 7 items listed in paragraph 3(b) above; **or**
- (b) as soon as practicable after you have made the application, you should notify “the proprietor” of your application, providing him the information contained in the 7 items listed in paragraph 3(b) above, and the address of a website on which you are required to post the amount of the pharmaceutical product to be exported, and the labelling, marking, packaging, colouring or shaping of the pharmaceutical product; and
- (c) when you notify “the proprietor” under (a) or (b) above, you should also attach to your notification copies of the documents referred to in paragraph 7(a), 7(b) and 7(e) below; and
- (d) as soon as practicable, you should also submit a copy of your notification to the Director of Health.

5. In either case, before you submit the application, you should also take reasonable steps to obtain from the country/territory concerned information on the amount of the pharmaceutical product to be manufactured and exported to it by any exporting country/territory other than Hong Kong under any compulsory licence granted elsewhere.

Where to apply?

6. You can submit your application, along with the required documents, to:

Pharmaceuticals Import/Export Control Section
 Pharmaceutical Service,
 3/F, Public Health Laboratory Centre,
 382 Nam Cheong Street,
 Shek Kip Mei, Kowloon,
 Hong Kong. (Enquiries: 2319 8460)

How to apply?

7. You should hand in the completed application form (please see the **Appendix** to these Guidance Notes) to the Pharmaceuticals Import/Export Control Section at the above address along with:

- (a) a copy of the written request issued to you by the relevant authority of the importing country/territory, or by the representative, non-governmental organization or international health organization authorized by the relevant authority, stating therein the name and amount of the pharmaceutical product requested;

- (b) a copy of the notification made by the relevant authority of the importing country/territory to the TRIPS Council stating the following particulars:
 - i) the name and amount of the pharmaceutical product;
 - ii) (if the importing country/territory is not a least-developed country recognized by the United Nations) that the importing country/territory has no or insufficient capacity to manufacture the pharmaceutical product; and
 - iii) (if the pharmaceutical product is also patented in the importing country/territory) that the relevant authority of the importing country/territory has granted or intends to grant a compulsory licence to import the product in accordance with the relevant instrument or legislation;
- (c) where applicable, a copy of the notice of the intended application given to “the proprietor” of the patent concerned under paragraph 3(b) or 4(a) above;
- (d) where applicable, a declaration made by you under the Oaths and Declarations Ordinance declaring that you have made reasonable efforts in accordance with paragraph 3(a) above to obtain authorization from “the proprietor” of the patent concerned on reasonable commercial terms and conditions but the efforts have not been successful within 28 days after they had been made; and
- (e) (if the pharmaceutical product is also patented in the importing country/territory) documentary evidence of any compulsory licence granted by the relevant authority of the importing country/territory.

If your application for the export compulsory licence is approved

8. If your application is approved, the Director of Health will grant the relevant export compulsory licence, subject to such terms and conditions imposed on the licence. The following are the standard terms and conditions (there may be other additional terms and conditions):

- (a) the acts authorized to be done (e.g. to manufacture and to export the pharmaceutical product);
- (b) the name and amount of the pharmaceutical product;
- (c) the name of the importing country/territory;
- (d) the duration of the licence;
- (e) that the licence is non-assignable except with that part of the enterprise or goodwill which enjoys the use of the patent under the licence;
- (f) that the pharmaceutical product should be clearly identified as being made under the licence through specific labelling or marking;
- (g) that the pharmaceutical product should be distinguished from the “originator” product (i.e. the same product manufactured by, or under authorization of, the proprietor of the patent concerned) through special packaging, colouring or shaping;
- (h) that before you export the product, you should post on a website maintained by you or on your behalf, or on the World Trade

Organization website, the amount of the product you will export and the labelling, marking, packaging, colouring or shaping of the product as per (f) and (g) above;

- (i) that you should pay, to “the proprietor” of the patent concerned, an amount of remuneration as determined by the Director of Health;
- (j) that where there is more than one patent, you should apportion on an equal share basis among all the patent proprietors the total amount of remuneration as determined by the Director of Health under (i) above;
- (k) that subject to (l) below, the product should be exported only to the country/territory specified in the licence; and
- (l) that if the pharmaceutical product is also patented in the importing country/territory, you should export the product only after the relevant authority of the country/territory has granted an import compulsory licence for the pharmaceutical product.

Application for an export licence under the Import and Export Ordinance

9. Before you export the pharmaceutical product, you are reminded to apply for an export licence under the Import and Export Ordinance as for the export of other pharmaceutical products you manufacture. In the present case, an application for an export licence will only be approved if you have complied with the terms and conditions of the export compulsory licence granted to you, particularly items (f) and (g) of paragraph 8 above. Therefore, you should submit a sample of the pharmaceutical product for inspection when you apply for the export licence.

Termination of the export compulsory licence granted to you

10. The Director of Health may terminate the export compulsory licence granted to you by informing you in writing if he is satisfied that:

- (a) any terms or conditions of the licence has been contravened; or
- (b) any information, document or documentary evidence specified in or accompanying your application is false, incorrect or incomplete in any material particular.

Review by the court

11. If you are aggrieved by any term or condition of the export compulsory licence, you may, within 28 days after the date the Director of Health advertised in the Hong Kong Intellectual Property Journal of the grant of the licence and its terms and conditions (or such further period as may be allowed by the court), apply to the court for a review. The above-mentioned Journal is accessible on the following website: http://www.ipd.gov.hk/eng/ip_journal.htm

12. If you are aggrieved by the termination of a licence granted by the Director of Health, you may, within 28 days after the date of the termination (or such further period as may be allowed by the court), apply to the court for a review.

Submitting an application

13. When your application is ready, you can submit it to the address shown in paragraph 6 above. When your application is approved, you will be asked to collect the export compulsory licence from the same address. The opening hours of the office are:

Monday to Friday

9:00 am – 1:00 pm

2:00 pm – 5:30 pm (Tuesday to Friday) or

2:00 pm – 5:45 pm (Monday)

Registration fees

14. No fees are required to be paid for the application or grant of a compulsory export licence.

These notes are only a general guide and must not be treated as a complete or authoritative statement of the law on any particular case. Copies of the Patents Ordinance, the Pharmacy and Poisons Ordinance and its subsidiary legislation can be purchased by calling the Publications Sales Section of Information Services Department at Tel: 2537 1910, or by email at puborder@isd.gov.hk. Contents of the relevant legislation may also be found at the Department of Justice's website <http://www.justice.gov.hk/index.htm>.

**Application for an Export Compulsory Licence
under the Patents Ordinance**

We _____ of _____
(Name of business)

(Address of business)

hereby apply for an export compulsory licence under section 72L of the Patents Ordinance in respect of the manufacture and the export of the following pharmaceutical product:

- (1) Name of the pharmaceutical product: _____
- (2) Amount of the pharmaceutical product: _____
- (3) Name of the importing country/territory: _____
- (4) Duration of the licence applied for : _____
- (5) The Hong Kong patent number(s) in relation to the pharmaceutical product:

- (6) The proposed labelling, marking, packaging, colouring or shaping of the product (please use separate sheet of paper, with diagrams or photographs if appropriate).
- (7) The address of a website on which we shall, before we export the product, post information related to (1), (2), (3) and (6) above:

- (8) Information (if any) we have obtained from the importing country/territory concerning the amount of the pharmaceutical product to be manufactured and exported to it by any exporting country/territory other than Hong Kong under any compulsory licence granted elsewhere (please use separate sheet of paper).

In support of the application, we submit herewith documents referred to in paragraph 7 of the “Guidance Notes on Application for an Export Compulsory Licence of Pharmaceutical Products Under the Patents Ordinance” issued by the Department of Health.

Signature _____

Full name of signatory _____

Signed on behalf of _____
(Name of business)

DH PSIL/14/1

19 February 2008

To: Holders of Licence for Manufacturer

Dear Sirs,

**Application for an Export Compulsory Licence of Pharmaceutical Products
under the Patents Ordinance**

The Patents (Amendment) Ordinance 2007, which comes into effect on 22.2.2008, permits generic versions of patented pharmaceutical products to be manufactured and exported in certain circumstances without infringing the rights of the proprietor of the patent concerned.

The purpose of the amendment is to implement an international agreement made under the World Trade Organisation related to the manufacture and export of such pharmaceutical products by persons other than the proprietor of the patent concerned, or a person authorized by the proprietor, particularly in respect of exports to a least-developed country/territory recognized by the United Nations, or to a country/territory when it has declared a state of national emergency or other circumstances of extreme urgency.

As a licensed manufacturer, you may wish to make use of the provisions of this Ordinance to apply for an export compulsory licence under the Ordinance to manufacture and export patented pharmaceutical products in the circumstances permitted under the Ordinance.

To assist you to do so, the attached Guidance Notes have been prepared for your perusal. Please let me know if you should have any enquiries on this subject.

Yours faithfully,

(W.Y.CHOW)
for Director of Health

c.c. The Hong Kong Pharmaceutical Manufacturers Association Ltd.

We are committed to providing quality client-oriented service