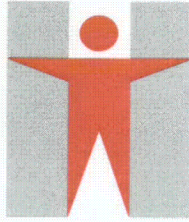


衛生署  
醫療儀器管制辦公室

香港灣仔皇后大道東 213 號  
胡忠大廈 18 樓



DEPARTMENT OF HEALTH  
MEDICAL DEVICE CONTROL OFFICE

18/F., WU CHUNG HOUSE,  
213 QUEEN'S ROAD EAST, WAN CHAI  
HONG KONG

本署檔號 OUR REF.: S/F(4) in DH/MDCO/18-25/2

來函檔號 YOUR REF.:

電話 TEL.: 2961 8788

傳真 FAX No.: 3157 1286

24 July 2006

To whom it may concern

Dear Sir/Madam,

Consultation on  
Proposed Import Control on Polyacrylamide Gel (PAAG)

In view of recent cases involving the abuse of polyacrylamide gel (PAAG) for breast augmentation, the government proposes to impose import control on this substance in order to protect public health. I write to seek your views on this proposal.

The government envisages a public expectation for a speedy measure to protect public health while permitting of the legitimate uses of PAAG. It is being considered to amend the existing Import and Export (General) Regulations (CAP 60A) to include PAAG (polyacrylamide gel) as a product which requires a licence for its importation. Under this proposal, all importers of PAAG are required to apply for an import licence from this department. For import approval to be granted, the importer has to declare that the product is not intended for use inside human body.

A questionnaire has been prepared to give more details on this proposal and solicit your views on this matter. Briefing sessions on the proposal will also be held on 2.8.2006 and 4.8.2006 respectively. Please fill in the questionnaire and send it back to us (preferably by fax: 3157 1286) on or before 10.8.2006. If you have any queries, please feel free to contact us.

Yours faithfully,

( Yorkie Y.K. CHOW )  
for Director of Health

**Questionnaire on  
Proposed Import Control on Polyacrylamide Gel (PAAG)**

Please return to: Medical Device Control Office  
18/F, Wu Chung House, 213 Queen's Road East, Wan Chai, Hong Kong  
(Fax: 3157 1286)

**Note:** All information collected will only be used for statistical analysis, and the results will be presented in a collective manner. No information on a particular individual will be disclosed in all circumstances. Please feel free to make copies of this questionnaire for others whom you think may be interested in the matter.

**Proposal:** To amend the First Schedule in the Import and Export (General) Regulations (CAP 60A) to include PAAG (polyacrylamide gel) as a product which requires a licence for its importation. No import licence is required for polyacrylamide products not in gel form or acrylamide products. All importers of PAAG are required to apply for an import licence from the Department of Health (DH). The application procedures will be similar to those for pharmaceutical products and medicines (related information available at <http://www.psdh.gov.hk/eps/index.jsp>). For import approval to be granted, the importer has to declare that the product is not intended for use inside human body.

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**Part A    Particulars**

Name (of individual or organisation representing): \_\_\_\_\_

Address: \_\_\_\_\_

Tel No.: \_\_\_\_\_ Fax No: \_\_\_\_\_ E-mail: \_\_\_\_\_

Nature of your business:      ☐ importer of PAAG  
   ☐ manufacturer of PAAG  
   ☐ carrier of PAAG  
   ☐ laboratory user of PAAG  
   ☐ others (please specify) \_\_\_\_\_

☐ I prefer not to be contacted for issues related to this matter (please skip the remaining questions and return this page only)

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**Part B    Briefing Session**

Two briefing sessions will be held at 10:00 a.m. at the following venue:

Lecture Hall, Sheung Wan Civic Centre  
5/F, Sheung Wan Municipal Services Building  
345 Queen's Road Central, Sheung Wan

- ☐ I would like to attend the briefing session on 2 August 2006 (Targeted for importers, manufacturers, sellers or carriers of PAAG)\*
- ☐ I would like to attend the briefing session on 4 August 2006 (Targeted for users of PAAG or other stakeholders)\*
- ☐ I would not attend any of the briefing sessions.

\*If you are unable to attend the briefing session targeted for your group, you are welcome to choose the other session.

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**Part C    Opinion**

*Please indicate your view on the following statements by ticking the appropriate box.*

	Agree	Neutral	Disagree	N/A
1 There should be some level of control by the Government to stop the abuse of PAAG to ensure public safety.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2 The sale of PAAG products forms a major part of my income source.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3 The carriage of PAAG forms a major part of my income source.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4 The use of PAAG forms a major part of my business activity	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5 I am familiar with the existing import control of products such as pharmaceuticals, textiles, frozen meat, etc. under the Import and Export Ordinance.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6 The proposed import control will induce operational difficulty to my organisation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7 The proposed import control will induce price increase in PAAG products.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8 The proposed import control will induce price increase in the carriage of PAAG products.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9 I support the proposed import control on PAAG products.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Other comments: