

December 22, 2008

## The 7th Biennial ISAKOS Congress

### Exhibiting Products not Approved in Japan

Exhibitors who intend to exhibit a medical device or product that is not yet approved by the Pharmaceutical Affairs Law of Japan are requested to follow the procedures set forth below and submit the necessary applications.

1. Exhibitors who intend to exhibit a medical device or product that is not yet approved by the Pharmaceutical Affairs Law of Japan shall submit "Application for Exhibition" and "Reason for Exhibition Application" to Dr. Kazunori Yasuda, ISAKOS Program Committee Chairman. Please refer to Attachment 2, Form 1: "Application for Exhibition" and Attachment 3 a/b: "Reason for Exhibition Application." (Please note that the "Company Representative" should be the name of the president or principle representative of the company.)

2. The Congress organizers will evaluate the submitted applications and, if deemed to conform to the purpose of the congress, will send the "Request for Exhibition" to the respective exhibitors, requesting them to exhibit their products, under the following conditions. Please see Attachment 4, Form 2: "Request for Exhibition."

#### *Conditions for Exhibition*

- (1) It shall be clearly indicated that it is an unapproved product and that it cannot be sold or conferred.
- (2) Information on production method, efficacy, and performance shall be solely based on facts including data from experiments conducted precisely and objectively.
- (3) Distribution of related materials, documents, etc. shall not be allowed.
- (4) Proper measures to discard or ship back the product(s) shall be taken instead of selling or conferring when the exhibition is finished.

3. In case a product will be imported from abroad for the Exhibition, the exhibitor is required to submit the above "Request for Exhibition" along with other required documents to the appropriate regional Pharmaceutical Compliance officer at the Kinki Bureau of the Ministry of Health, Labour and Welfare, MHLW, (covering customs matters for import at the ports of Nagoya, Osaka, Kobe, Moji and Nagasaki) or the Kanto-Shinetsu Bureau of the MHLW (covering customs matters for import at the ports of Hakodate, Tokyo and Yokohama) and obtain a "Certificate of Pharmaceutical Compliance."

4. The required procedures for number 3. above to obtain a "Certificate of Pharmaceutical Compliance" should be handled by the Exhibitor. In case the Exhibitor does not have a branch office in Japan, Congress Corporation can offer assistance to the Exhibitor and serve as their representative, for conducting the required procedures. The final documents to be submitted to the Ministry shall be in Japanese, however, all necessary correspondence will be handled in English.

5. Contact for inquiries and application submission:

The 7th Biennial ISAKOS Congress Exhibition Secretariat  
c/o Congress Corporation  
Kohsai-kaikan Building, 5-1 Kojimachi  
Chiyoda-ku, Tokyo 102-8481 Japan  
E-mail: isakos09-exhibit@congre.co.jp FAX: 81-3-5216-3115

#### **Attachments:**

- Attach. 1: Points to be Noted Regarding Exhibition of Products not Approved by the Pharmaceutical Affairs Law
- Attach. 2: Form 1: Application for Exhibition
- Attach. 3 a: Reason for Exhibition (sample for reference)
- Attach. 3 b: Reason for Exhibition (blank form to be filled in)
- Attach. 4: Form 2 (Sample for Reference): Request for Exhibition

Attachment 1:

December 22, 2008

To Exhibitors:

**Points to be Noted Regarding Exhibition of Products not Approved  
by the Pharmaceutical Affairs Law**

The Pharmaceutical Affairs Law of Japan prohibits any advertisement related to unapproved products. Although it is the rule that unapproved products cannot be exhibited since exhibition also corresponds to advertisement, it is permitted to exhibit products specially under certain conditions only when specified procedures are followed based on the industry's voluntary management standard "Exhibition of Products not Approved by the Pharmaceutical Affairs Law (Guidelines)," when the purpose is to improve or advance medical and academic research or to promote development.

The main conditions set forth in the guidelines are listed as follows:

1. Type of exhibition: The exhibition shall be held for specialists in the field for the purpose of scientific research improvement and development.
2. Organizer: It shall be organized by a public scientific society or similar organization composed of scientists in the field with the purpose of improving and developing scientific research.
3. Method of exhibition:
  - (1) There shall be clear indication that the product for exhibition is an unapproved product and that it cannot be sold or conferred. The mode of indication shall be unified throughout the exhibition.
  - (2) Information on production method, efficacy, and performance shall be solely based on facts including data from experiments conducted precisely and objectively (it shall be limited to scientific expressions avoiding any advertising-like expressions).
  - (3) Distribution of related materials and so forth shall not be allowed in principle. However, it is not prohibited to provide copies of scientific reports that have already been reviewed, including supplementary volumes of research reports, in response to requests from doctors (catalogs, etc. are considered to be advertising material and therefore cannot be distributed).
  - (4) It is acceptable to adopt the planned sales name as long as the purpose is to improve and develop academic research. (Distribution of prepaid cards or gifts with sales names is prohibited).
  - (5) Advertisement similar to that for approved products shall not be conducted for unapproved products (e.g. introduction of unapproved products using microphones or loud speakers, introduction by audiovisual devices of matters that have not been presented or reported in academic societies, and exhibition methods that will make the unapproved product stand out from approved products are prohibited).

In case any violation of these rules occurs and is considered a problem, it may cause significant inconvenience to the Society organizing the congress and exhibition as well as other exhibitors and related organizations.

**Please observe the rules and cooperate in the development of this exhibition.**

Exhibition Secretariat  
The 7th Biennial ISAKOS Congress

**Application for Exhibition**

Date: \_\_\_\_\_

Kazunori Yasuda, MD, PhD  
2007-2009 ISAKOS  
Program Committee Chairman

We would like to apply for the exhibition of the following items under observation of the Pharmaceutical Affairs Law of Japan with the attached materials, as it is considered to contribute to academic advancement at the 7<sup>th</sup> Biennial ISAKOS Congress

1. Item to be exhibited

General name: \_\_\_\_\_

Product name: \_\_\_\_\_

If the product is imported, state the product name in the country of export.

Quantity: \_\_\_\_\_

2. Reason for exhibition: (Circle the applicable number.)

1. There will be a scientific presentation on the item in this application at this scientific meeting.
2. It is a newly developed product based on introduction of a new technology.
3. It is an improved product based on introduction of a new technology.
4. It is a newly developed product based on a new principle.
5. It is an improved product based on a new principle.
6. Other

3. Exhibition venue : Osaka International Convention Center, Osaka, Japan

4. Date and time of exhibition: April 5-8, 2009

Exhibiting company's name \_\_\_\_\_

Company Representative \_\_\_\_\_

Signature and Company Seal \_\_\_\_\_

Attachment 3 a. (sample for reference)

### **Reason for Exhibition Application**

1. Outline of the grounds for improved image quality

a) It is capable of collecting a large amount of data in a short time using continuous x-ray and obtaining a more precise image by suppressing the effects of resting and moving.

b) By adopting the radio-frequency inverter method in the generation of high-voltage x-ray, high quality can be addressed in a scanning over a short period using a stable high voltage.

2. Other (Add if there are materials that show the features of the exhibited product.)

End of document

Attachment 3 b.

### **Reason for Exhibition Application**

1. Outline of the grounds for

a)

b)

2. Other (Add if there are materials that show the features of the exhibited product.)

End of document

**(SAMPLE FOR REFERENCE ONLY)**

**Request for Exhibition**

Date

To: Mr./Ms. XXXXX, XXXX Company

Kazunori Yasuda, MD, PhD  
2007-2009 ISAKOS  
Program Committee Chairman

Regarding the following medical device(s)/product(s) that has not been approved by the Pharmaceutical Affairs Law of Japan for which you have applied for exhibition, we have deliberated and decided that it will contribute to the academic advancement of the 7<sup>th</sup> Biennial ISAKOS Congress.

We would like to request that you exhibit the product(s) in our exhibition under the conditions specified below:

1. Item(s) requested to be exhibited

2. Conditions for exhibition

2-1 It shall be clearly indicated that it is an unapproved product and that it cannot be sold or conferred.

2-2 Information on production method, efficacy, and performance shall be solely based on facts including data from experiments conducted precisely and objectively.

2-3 Distribution of related materials and so forth shall not be allowed in principle. However, this does not always apply when providing copies of scientific reports that have already been reviewed, including supplementary volumes of research reports, in response to requests from doctors.

2-4 Proper measures to discard or ship back the product(s) shall be taken instead of selling or conferring when the exhibition is finished.