Exhibition of Products Not Approved Under the Act on the Pharmaceuticals, Medical devices, etc.

For the Attention of All Exhibitors

Japan Medical Imaging and
Radiological Systems Industries Association

Exhibition Committee

Exhibition of Products Not Approved Under the Act on Securing Quality, Efficiency and Safety of Pharmaceuticals, medical devices, re-generative and cellular therapy products, gene therapy products, and cosmetics (the Act on the Pharmaceuticals, Medical devices, etc.)

In accordance with the guidance of the Ministry of Health, Labor and Welfare, products not approved under the Act on Pharmaceuticals, Medical devices, etc. may be exhibited only if they are recognized as contributing to the promotion of science, in strict compliance with the conditions below.

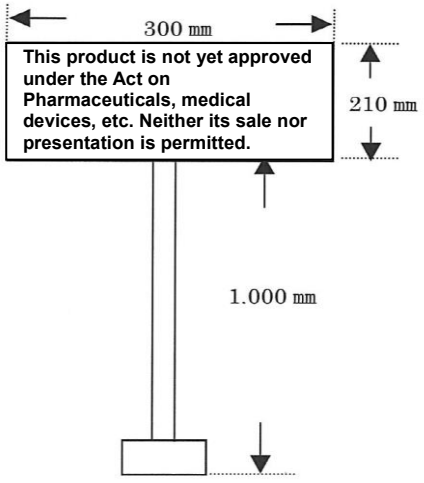
The Exhibition Committee would like to emphasize that exhibition will be refused in the event of any breach of these conditions.

1 The putative exhibitor must submit an Application for Exhibition to the chairperson of the conference. The company will be regarded as having made such a request only if the chairperson of the conference recognizes the product as contributing to the promotion of science.

2 In concrete terms, the exhibitor is requested to complete two forms, one copy of PAL Form 11: Application for Exhibition and one copy of PAL Form 12: Request for Exhibition (two copies in the case of imported items*), and submit these to the exhibition organizer by the deadline indicated in the Exhibition Guidelines. (* One copy is needed for customs clearance.)
Requests will be forwarded to the conference chairperson in a single batch, and the Request for Exhibition returned to each company as soon as it is approved. During the exhibition period, please disclose the forms upon request.
Please prepare the Application for Exhibition and Request for Exhibition in A4 size as attached forms. Also, a sample of a separate documentation for the Request for Exhibition is shown following PAL Form 11: Application for Exhibition for use as a reference. Name of applying company for exhibition shall be the Representative for the applying company.

3 Strict compliance with the following conditions is requested during exhibition.

(a) A notice must be displayed near the exhibit stating that it is a product not approved under the Act on Pharmaceuticals, Medical devices, etc. and that neither its sale nor presentation is permitted. Please buy a notice board that is unified and prepared by us. In total, four types are available. For reasons of consistency, all four types are to be purchased from the Exhibition Committee.



(i) The notice should in principle be the same size as that shown on the right (300 mm x 210 mm), but this does not include the cost of stand for notices for use with machinery.

(ii) medium size (210 mm x 150 mm, self-standing type) for use with panel or mid-size devices.

(iii) desktop size (150 mm x 105 mm, self-standing type) for use with extremely small devices,

(iv) set of three seals (66mm x 15 mm) to be pasted on a PC or a tablet is available.

An application form is Form 13.
One notice is required for each product not approved under the Act on Pharmaceuticals, Medical devices, etc.

(b) Claims concerning method of manufacture, effect and efficacy, and performance must be precise and based on data from objectively performed testing or other similar source. They should avoid advertising-type material, and be restricted to scientific expressions. The same applies to exhibitions consisting solely of clinical photographs. (Please also be careful when producing descriptive panels.)
The following examples are acceptable.
(i) Research data to be presented at the conference involved.
(ii) Data evaluated in applications for approval under overseas pharmaceutical legislation.
(iii) Scientific data provided by the National Institute of Health Sciences, the Tokyo Metropolitan Industrial Technology Center, or the Japan Quality Assurance Organization. (This includes data provided by universities.)
(iv) Research data published as a paper in specialist scientific journals that possess paper review mechanisms.
In this case, the name of the journal concerned must be clearly stated in order to make clear the source of the data.

(c) Related documentation and other materials may not be distributed.
However, it is acceptable to hand out reprints of research papers and similar material from scientific papers that have already been evaluated to doctors and others on request.

(d) The proposed brand name may also be used, provided that this is solely for the purpose of the improvement and development of scientific research.
However, the distribution of prepaid cards or free gifts carrying the brand name is unacceptable unless it is directly connected to the improvement and development of scientific research.

(e) Notes on exhibition
It is prohibited to carry out the same PR activities for non-approved products as for products that are already approved, under Article 68 of the Act on Pharmaceuticals, Medical devices, etc.
Examples of such actions include the following.
(i) Using amplifying devices (speakers) such as microphones or tape recorders to introduce non-approved products.
(ii) Using video or similar recordings other than those of conference presentations or reports to introduce non-approved products.
(iii) Displays using spotlight or similar means to make non-approved products more eye-catching than products that are already approved.
(iv) Material used on panels must be limited to scientific content. (Descriptions of features, etc. are not permitted.)
(v) Actions pursuant to the above.

(f) After the exhibition closes, the product may not be sold or given away, but must be disposed of, sent back, or dealt with in another appropriate way.
However, this shall not apply should specific administrative procedures be undergone to permit use in treatment, change of use for the purpose of an application for approval, or storage pending expected early approval being obtained.

4 Should the exhibitor cancel the exhibition or approval be obtained after an application has been submitted, the exhibitor is requested **to notify the organizers prior to the opening of the exhibition** by submitting the Notification of Withdrawal of Application for Exhibition of Product Not Approved Under the Act on Pharmaceuticals, Medical devices, etc.

Address for submission of Application for Exhibition and Request for Exhibition

Sumitomo Fudosan Iidabashi Bldg. No.2, 2-2-23, Kouraku, Bunkyo-ku, Tokyo 112-0004, Japan
Attn: Exhibition Committee Secretariat, Japan Medical Imaging and Radiological Systems Industries Association
Tel: 81-3-3816-3450. Fax: 81-3-3818-8920

For the Attention of All Exhibitors

Japan Medical Imaging and
Radiological Systems Industries Association
Exhibition Committee

Exhibition of Products Not Approved Under the Act on Pharmaceuticals, Medical devices, etc. (Detailed guidelines)

The Act on Pharmaceuticals, Medical devices, etc. prohibits advertising or publicity for products not approved under the law. As exhibition comes into the category of advertising and publicity, in principle non-approved products may not be exhibited. However, if the objective is to further the improvement of medical or scientific research or to promote its development, products may receive special permission for exhibition, based on the industry's voluntary management standards "Detailed guidelines concerning non-approved medical equipment and similar items" and solely subject to certain criteria.

The main conditions set out by these detailed guidelines are given below.

1 Types of Exhibition: Aimed at specialists in related fields, with the objective of improving and developing scientific research.
2 Organizers: Organizations consisting of scientists in related fields and which hold public conferences and other events with the objective of improving and developing scientific research.
3 Means of Exhibition:
   (a) The product must display a notice stating that it is non-approved and may not be sold or given away (the method of displaying such a notice should be as consistent as possible)
   (b) Claims concerning method of manufacture, effect and efficacy, and performance must be precise and based on data from objectively performed testing or other similar source. (They should avoid advertising-type material, and be restricted to scientific expressions.)
   (c) Related documentation and other materials may not be distributed in principle. However, it is reasonable to hand out reprints of research papers and similar material from scientific papers that have already been evaluated to doctors and others on request.
   (Catalogs are classified as advertising or publicity materials and may not be distributed.)
   (d) The proposed brand name may also be used, provided that this is solely for the purpose of the improvement and development of scientific research.
   (However, the distribution of prepaid cards or free gifts carrying the brand name is prohibited.)
   (e) It is not permitted to carry out the same PR activities for non-approved products as for products that are already approved. (This means not introducing products by using microphones, speakers, or other amplifying devices, audiovisual equipment other than recordings of conference presentations or reports; or display methods that make non-approved products more eye-catching than products already approved.)

Exhibitors should be aware that partial modifications to existing products also result in their classification as non-approved products.

Should a problem arise owing to a breach of these conditions, this may result in grave inconvenience being caused not only to the chair of the conference, who has overall responsibility for the Exhibition, and the JIRA, which is responsible for the Exhibition itself, but also to the exhibitor. **We appreciate your cooperation in complying with the rules and enabling the progress of this Exhibition.**