Overview of EU Pharma Compliance Issues and Initiatives:

Farmaindustria

Dr. José F. Zamarriego
Istanbul 2011, May 4th
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THE SPANISH CODE SURVEILLANCE UNIT
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CHALLENGES IN THE PROMOTION OF MEDICINES

The International Pharmaceutical Compliance Congress and Best Practices Forum
EU Directive 2001/83

Spanish Constitution 1978.
Law 34/1988 Publicity.
Royal Decree 1416/1994 Promotion of Medicines for Human Use.
Circulars 6/1997 & 7/1997 from DGFPS.
Law 29/2006 for the Guarantee and Rational Use of Medicines and Medical Devices.
SAS 3470/2009 Order, Post-authorization Studies Guidelines

Catalonian Guide for the Promotion of Medicines, October 2009

EU Directive 2001/83

97.5

“Paragraphs 1 to 4 shall not exclude the voluntary control of advertising of medicinal products by self-regulatory bodies and recourse to such bodies, if proceedings before such bodies are possible in addition to the judicial or administrative proceedings referred to in paragraph 1.”
Competences regarding the “Promotion of Medicines” have been delegated to each Autonomous Regions.

98% of Pharmaceutical Companies are based in Madrid & Catalonia
Self-Regulation: EU Directive 2001/83

Within applicable legal framework (European, national, local)

The aim is to Guarantee:

- Information available and distributed to healthcare professional able to prescribe and dispense medicines, being accurate, balanced, fair, objective and complete.

- That such promotion is done respecting the most stringent ethical principles of professionalism and responsibility.

Establish a framework for the conduct of promotional activities by the industry, offering guidance and facilitating compliance by pharmaceutical companies of applicable rules.
Evaluate and conflicts resolutions by an external and independent association.

Important sanctions

Publication of the agreements and resolutions

External communication, specially to the healthcare professionals
Legality

Absolute respect for the applicable legal framework (national and international)

Responsibility

Guarantee that the information provided to the Healthcare professionals is accurate, fair and immediately
Benefit the Administration, Pharmaceutical Industry and Public Health interests.

Commitment

Continuous improvement process. Continuous reinforcement of its terms and conditions. Objective “Tolerance Zero”

Transparency

Issued between all interested agents: Administration, Healthcare professionals, Scientific Societies. All the resolutions are published.

Prevention

Three Control Bodies: Self-Regulation Jury, Code of Practice Committee and Code of Practice Surveillance Unit. Active monitoring for the Code upheld
SELF-REGULATION SYSTEM

OBJECTIVES

- TO CARRY OUT THE PROMOTION OF MEDICINES AND INTERACTION WITH HEALTHCARE PROFESSIONALS AND PATIENT ORGANIZATIONS UNDER THE STRICTEST ETHICAL PRINCIPLES OF PROFESSIONALISM AND RESPONSIBILITY

- TO POTENTIATE TRUST IN THE PHARMACEUTICAL INDUSTRY
Self-Regulation System

CONTROL BODIES

JURY, DEONTOLOGICAL COMISSION AND SUPERVISION UNIT

SPANISH CODE OF GOOD PRACTICES FOR THE PROMOTION OF MEDICINES AND INTERACTION OF THE PHARMACEUTICAL INDUSTRY WITH HEALTHCARE PROFESSIONALS

SPANISH CODE OF GOOD PRACTICES FOR THE INTERACTION OF THE PHARMACEUTICAL INDUSTRY WITH PATIENT ORGANIZATIONS
External and independent evaluation and resolution of conflicts

Important sanctions to infractors

Yearly publication of processes and resolutions

External diffusion, especially to Healthcare professionals

Technical improvements and adaptation to the normative
Infringements will be classified as minor, serious and very serious based on:

- Magnitude of the infringement, particularly its potential risk for the health of patients.
- Impact on the scientific or medical community of the practice resulting in Code infringement.
- Unfair competition.
- Generalization of the infringement
- Recidivism
- Damage to the image of the pharmaceutical industry.

There may be aggravating circumstances that shall be taken into account:

- Degree of intentionality
- Failure to comply with previous warnings
- Concurrence of several infringements for the same action or promotional activity
- Financial benefit for the pharmaceutical company derived from the infringement.
Based on the aforementioned criteria, the Jury can impose the following monetary sanctions:

- Minor infringements: 6,000 to 120,000 euros
- Serious infringements: 120,001 to 240,000 euros
- Very serious infringements: 240,001 to 360,000 euros

The execution depends on Farmaindustria.

Serious or very serious infringements may also result in:

- Reporting to Healthcare Authorities
- Expulsion from Farmaindustria
ACTIVE MONITORING

SEEKS FOR CONCILIATION

RESOLVES AND PUBLISHES

Code of Practice Surveillance Unit

Code of Practice Committee

Self-Regulation Jury

Resolución de 18 de enero de 2010 de la Sección Quinta del Jurado por la que se desestima la reclamación presentada por Boehringer Ingelheim, S.A. frente a Laboratorios Almirall, S.A.

La reclamación se formula frente a un artículo publicado en la página Web de la revista SCRIP (10/09/09). El texto, firmado por Asher Mullard, lleva por título *Phase III results for Almirall's Eklira prompt plans for 2010 COPD filing 10 September 2009*.

El Jurado, sin entrar ya en el análisis del fondo del asunto planteado, considera acreditado que dicha actividad (artículo periodístico que hace referencia a ciertos medicamentos y líneas de investigación, cuya autoría corresponde exclusivamente al periodista que suscribe el texto, sin que exista una relación contractual entre el laboratorio investigador propietario del medicamento y la empresa responsable de la edición o el autor de dicha información) constituye una de las hipótesis que quedan expresamente
Together with the Code of Practice Committee and the Self-Regulation Jury, the Surveillance Unit is a Control Body.

MISSION: Responsible for active monitoring of compliance with the Code

PRINCIPLES OF OPERATION

Truthfulness
Independence
Confidentiality
Impartiality
Agility
1. Cooperate with the Code of Practice Committee and the Self-Regulation Jury to promote effective application of the rules contained in the Code.

2. Provide advice, guidance and training on the Code.

3. Take any measures as may be required to investigate compliance with the Code, including conduct and investigation procedure.

4. Manage the prior communication of scientific meetings and studies.

5. Send precautionary warnings to pharmaceutical companies.

6. Initiate procedures for the application of sanctions by the Code.

7. Issue technical or ethical opinions on issues relevant to its activities.

8. Issue circulars to the pharmaceutical companies defining the criteria of the Code.

9. Verify by any means it deems appropriate.

10. Notify the competent healthcare authorities about practices.

11. Grant a certificate allowing to accredit the compliance.

12. Any other functions that may fall under its authority.
# Spanish Code Surveillance Unit
## 2004-2010 ACTIVITY DATA

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Verified and Analyzed EVENTS</strong></td>
<td>945</td>
<td>1,747</td>
<td>2,199</td>
<td>2,926</td>
<td>3,388</td>
<td>3,878</td>
<td>5,080</td>
<td>20,163</td>
</tr>
<tr>
<td><strong>EVENTS wihtout incidents</strong></td>
<td>718</td>
<td>1,390</td>
<td>1,909</td>
<td>2,616</td>
<td>3,087</td>
<td>3,345</td>
<td>4,383</td>
<td>17,448</td>
</tr>
<tr>
<td><strong>Analyzed STUDIES</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>687</td>
<td>724</td>
<td>1,411</td>
</tr>
<tr>
<td><strong>STUDIES without incidents</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>397 (i)</td>
<td>546</td>
<td>943</td>
</tr>
<tr>
<td><strong>PREVENTIVE ACTIONS</strong></td>
<td>814</td>
<td>1,801</td>
<td>1,376</td>
<td>2,092</td>
<td>2,440</td>
<td>2,670</td>
<td>3,482</td>
<td>14,675</td>
</tr>
<tr>
<td><strong>CLAIMS</strong></td>
<td>18</td>
<td>11</td>
<td>9</td>
<td>18</td>
<td>8</td>
<td>12</td>
<td>4</td>
<td>80*</td>
</tr>
</tbody>
</table>

* 12 Resolutions of the Self-Regulation Jury in favour of USD
* 59 Resolved in the presence of the Code of Practice Committee by agreement with correction and infringement recognition
* 1 Agreement before Code of Practice Committee meeting
* 5 Filed by petition of USD
* 1 Non considered by the Self-Regulation Jury

(i) As a result of the analysis done on January 2010
<table>
<thead>
<tr>
<th>Laboratories Involved</th>
<th>147</th>
</tr>
</thead>
<tbody>
<tr>
<td>% Prescription Market</td>
<td>147</td>
</tr>
<tr>
<td>2004 apr. - dec.</td>
<td>94%</td>
</tr>
<tr>
<td>2005 jan. - dec.</td>
<td>93%</td>
</tr>
<tr>
<td>2006 jan. - dec.</td>
<td>88%</td>
</tr>
<tr>
<td>2007 jan. - dec.</td>
<td>88,4%</td>
</tr>
<tr>
<td>2008 jan. - dec.</td>
<td>88,1%</td>
</tr>
<tr>
<td>2009 jan. - dec.</td>
<td>88,7%</td>
</tr>
<tr>
<td>2010 jan. - dec.</td>
<td>82,3%</td>
</tr>
<tr>
<td>Accumulated apr. ‘04 - dec. ‘10</td>
<td>88,7%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Notifications</th>
<th>21</th>
<th>20</th>
<th>7</th>
<th>5</th>
<th>10 HCP</th>
<th>13 HCP</th>
<th>8 HCP</th>
<th>87</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1 PO</td>
<td>1 PO</td>
<td>10 PO</td>
<td></td>
</tr>
<tr>
<td>Scientific Societies</td>
<td>342</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Congress Secretaries Organizers</td>
<td>123</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* HCP: Relating to Healthcare Professionals Code
* PO: Relating to Patient Organizations Code
NOTE: There could be more than one possible violated norm in one complaint.
1991 Adoption of the Spanish Code on the basis of EFPIA Code (Adapted in 1992)

2002 Approved a much more stringent and precise new version of the Code

2004 New version with additional measures to reinforce this self-regulation system
- Implementation Guides
- Queries (Questions & Answers)
- Surveillance Unit

2005
- Adaptation to EFPIA Code (Nov 2004)
- Reinforcement and continuous improvement

2008
- New version for the Interaction with Healthcare Professionals
- New Code for the Interaction with Patients Organizations

2010
- Adaptation and improvement of the Code for the Interaction with Healthcare Professionals
- Modification of Art. 3, 10, 11, 14, 16 and 17

- APPLICABLE TO FARMAINDUSTRIA MEMBERS AND TO PHARMACEUTICAL COMPANIES ADHERED TO THE CODE
- COVERING ALL PROMOTIONAL ACTIONS ADDRESSED AT SPANISH HEALTHCARE PROFESSIONALS WHEREVER THEY MAY TAKE PLACE
INTRODUCTION, PURPOSE AND SCOPE OF THE CODE

ARTICLES

1. MARKETING AUTHORIZATION
2. INFORMATION TO BE MADE AVAILABLE
3. INFORMATION AND ITS RATIONALE
4. ACCEPTABILITY OF MATERIAL
5. TRANSPARENCY OF PROMOTION
6. USE OF REFERENCE QUOTATIONS
7. DISTRIBUTION OF PROMOTIONAL MATERIAL
8. PROMOTION VIA INTERNET
9. SCIENTIFIC SERVICE AND REVIEW OF PROMOTIONAL MATERIAL
10. INCENTIVES
11. HOSPITALITY AND MEETINGS
## ARTICLES

12 PHARMACEUTICAL COMPANY STAFF
13 SAMPLES
14 STUDIES
15 DONATIONS AND GRANTS
16 SERVICES RENDERED BY ENTITIES INTEGRATED BY HEALTHCARE PROFESSIONALS
17 SERVICES RENDERED BY HEALTHCARE PROFESSIONALS
18 RULES OF APPLICATION OF THE CODE
19 REQUEST FOR QUERIES
20 CONTROL OF CODE COMPLIANCE
21 INFRINGEMENTS AND SANCTIONS
22 IMPLEMENTATION GUIDES AND COLLABORATION AGREEMENTS
23 DISCLOSURE AND COMPILATION OF DECISIONS
24 ENTRY INTO FORCE OF THE CODE
3 COMMUNICATION SYSTEMS

1. EVENTS

2. STUDIES

3. SERVICES
<table>
<thead>
<tr>
<th>Título del evento*</th>
<th>DOCUMENTO DE CONSENTIMIENTO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Naturaleza de la participación del laboratorio*</td>
<td>Organizador</td>
</tr>
<tr>
<td>Lugar de celebración*</td>
<td>HOSPITAL DE LEÓN</td>
</tr>
<tr>
<td>País*</td>
<td>ESPAÑA</td>
</tr>
<tr>
<td>Provincia*</td>
<td>ÁVILA</td>
</tr>
<tr>
<td>Fecha de comienzo*</td>
<td>20/05/2010</td>
</tr>
<tr>
<td>Fecha de finalización*</td>
<td>20/05/2010</td>
</tr>
<tr>
<td>Notas</td>
<td></td>
</tr>
<tr>
<td>Categoría*</td>
<td></td>
</tr>
<tr>
<td>Nº de participaciones ofrecidas**</td>
<td>0</td>
</tr>
<tr>
<td>Se adjunta programa científico</td>
<td></td>
</tr>
<tr>
<td>Nº de horas del programa</td>
<td>1/10</td>
</tr>
<tr>
<td>Se adjunta programa social</td>
<td></td>
</tr>
<tr>
<td>Se adjunta carta de invitación al evento</td>
<td></td>
</tr>
<tr>
<td>Especialidad farmacéutica promocionada</td>
<td>ZALDIAR</td>
</tr>
<tr>
<td>Observaciones</td>
<td></td>
</tr>
</tbody>
</table>

**Declaración relativa a los acompañantes:
1. No se permiten acompañantes por lo tanto de un evento organizado por un laboratorio se realizarán servicios de acompañamiento especialmente en el caso de profesionales médicos.
2. El número de acompañantes no se limitará y se mantendrán los mismos acuerdos con los profesionales asociados al evento.

**Profesionales a los que está dirigido:
- Profesión de los profesionales sanitarios: MÉDICOS
- Especialidad: MÉDICOS
- Origen geográfico: Castilla y León
- Ámbito de la reunión: Local/Regional
- Número previsto de profesionales sanitarios asistentes: 16
- Número de profesionales sanitarios invitados por su laboratorio y con ejercicio profesional en España: 34
- Número de pares: 1

---

**Title of the Meeting**

**Place and dates**

**Scientific program (hours)**

**Social Program**

**Professionals to whom it is addressed:**

**Speciality**

**Place of residence**

**Number of participants**

**Number of HCP invited**

**Number of speakers**

---

**Pharmaceutical compliance congress and best practices forum**
GENERAL STANDARDS APPLICABLE IN SPAIN TO “EVENTS AND HOSPITALITY”

https://www.farmaindustria.es/index_secundaria_codigo.htm
HEALTHCARE PROFESSIONALS CODE

Self-Regulation System

EVENTS CS

Hospitality and Events

DOCUMENTO INFORMATIVO EN MATERIA DE HOSPITALIDAD Y REUNIONES

Julie 2009

HOSPITALIDAD (Artículo 11 del Códig)

La hospitalidad debe seguir a toda hora de eventos (congresos, conferencias, presentaciones, reuniones, eventos, reuniones, etc.) que se realicen para fines de marketing y promoción de productos o servicios. No está permitido incluir en los invitaciones a estos eventos la promoción de productos o servicios.

EROGAR DE ENTREGAS

Como regla general, deben entregarse tarjetas que incluyan una imagen, nombre del asistente, y el horario y lugar del evento. No está permitido incluir en las invitaciones a estos eventos la promoción de productos o servicios.

MEDIDAS DE SEGURIDAD

Los receptores no deben ser empleados de hospitales u otras instituciones que participen en la actividad. Se debe asegurar que todos los receptores estén debidamente informados de las medidas de seguridad a seguir.

Comentarios:

- La hospitalidad no debe incluir el nombre de los profesionales de la salud.
- Se recomienda que las invitaciones no incluyan la promoción de productos o servicios.

Algunos puntos a considerar:

1. La hospitalidad debe ser una herramienta conjunta para fomentar relaciones de confianza y cooperación entre profesionales y pacientes.
2. Las actividades de hospitalidad deben estar descentralizadas y centrarse en el desarrollo de la relación con el paciente y el profesional de la salud.

Fuentes:

- Unidad de Supervisión de Farmacéuticos y Medicamentos.
- Farmaindustria.
- Farmamart.

Para más información, dirigirse a la siguiente dirección de correo electrónico:

unidde.%40farmaindustria.org
Observations aimed EXCLUSIVELY at the PHARMACEUTICAL COMPANIES: rules to take into account by pharmaceutical companies interested in participating/collaborating in the event.

The congress information is obtained from public sources.

There is an electronic mail for any doubt, commentary or clarification.

The Code, the Rules of Procedure, the Implementation Guide and the Q&A are available at Farmaindustria website.
Third Party Events Data Base

**COLOUR CODE**

Allows the visualization of the guidelines that must comply PHARMACEUTICAL COMPANIES when interested in participate/ collaborate in the event.

- **AUTHORIZED PARTICIPATION**
- **POSSIBLE PARTICIPATION WITH COMMENTS**
- **EXCLUSIVELY SPEAKERS POSSIBLE PARTICIPATION** Dec. 08
- **NON PERMITTED PARTICIPATION**
- **PENDING ON SCPSU DECISION**
Observations reflect SCPSU’s opinion EXCLUSIVELY on the secondary and accessory aspects/elements related to the organization and its compliance with the provisions of the Code in hospitality and meetings.

It cannot be interpreted, under any circumstance that the observations given by the SCPSU to the events refer to the quality or content of the scientific programme, or to the quality of the speakers.

<table>
<thead>
<tr>
<th>OBSERVATIONS</th>
<th>CODE</th>
<th>Q&amp;A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accompanying persons</td>
<td>Art 11.3</td>
<td>2, 13 y 40</td>
</tr>
<tr>
<td>Entertainment activities (golf tournament, tennis, cruise, others)</td>
<td>Art 11.2</td>
<td>1, 5, 9, 12, 13, 33, 44 y 49</td>
</tr>
<tr>
<td>Social events</td>
<td>Art 11.2</td>
<td>1, 5, 8, 9, 12, 13, 28, 31, 33 y 44</td>
</tr>
<tr>
<td>Scientific programme unavailable</td>
<td>Art 11</td>
<td></td>
</tr>
<tr>
<td>Hospitality offered should be adjusted to the duration of the scientific content of the meeting</td>
<td>Art 11.1</td>
<td>2 y 31</td>
</tr>
<tr>
<td>Place</td>
<td>Art 11</td>
<td>1, 4, 20, 21, 22, 37 y 49</td>
</tr>
<tr>
<td>Do not install stands, do not use lounges or installations to carry out any type of activity (symposium, conference, seminars, lunches, etc.), neither accommodate healthcare professionals in: hotels 5* (attending less than 200 healthcare professionals)/ 5* superior/ 5* luxury/ 5* grand luxury/ sports resorts/ theme park/ wine hotels</td>
<td>Art 11.1</td>
<td>19, 20, 37 y 48</td>
</tr>
<tr>
<td>Pending</td>
<td>Art 11</td>
<td></td>
</tr>
<tr>
<td>Pending on scientific program</td>
<td>Art 11</td>
<td></td>
</tr>
<tr>
<td>Overnight extra stay</td>
<td>Art 11.1</td>
<td>2 y 31</td>
</tr>
<tr>
<td>Ludic and entertainment aspects prevail against scientific</td>
<td>Art 11.2</td>
<td>1, 12, 13, 28, 31, 44 y 49</td>
</tr>
<tr>
<td>Please support EXCLUSIVELY the assistance of healthcare professionals exercising in Spain who will attend the meeting as SPEAKERS</td>
<td>Art 11</td>
<td></td>
</tr>
<tr>
<td>Please watch over the attendance of healthcare professionals to planned scientific sessions</td>
<td>Art 11.2</td>
<td>44</td>
</tr>
<tr>
<td>VENUE: hotels 5* (attending less than 200 healthcare professionals)/ 5* superior/ 5* luxury/ 5* grand luxury/ sports resorts/ theme park/ wine hotels</td>
<td>Art 11.1</td>
<td>19, 20, 37 y 48</td>
</tr>
<tr>
<td>As it is an event in which predictably people different from healthcare professionals will take part, please adopt the necessary measures to avoid carrying out any promotional activity related to prescription only medicines directed to public in general</td>
<td>Art 7.1</td>
<td></td>
</tr>
<tr>
<td>As it is an event aimed at healthcare professionals not authorized to prescribe or dispense prescription only medicines, please take into account the Circular USPD/PS/10/09</td>
<td>Art 7.1</td>
<td></td>
</tr>
<tr>
<td>It is forbidden to pay the event registration fee as it includes elements against the Code</td>
<td>Art 11</td>
<td>1, 2, 5, 8, 9, 12, 13, 28, 31, 33, 40, 44, 49</td>
</tr>
</tbody>
</table>
Third Party Events Data Base

**OBSERVATIONS INDEX**

- Accompanying persons
- Entertainment activities (golf tournament, tennis, cruise, others)
- Social events
- Scientific programme unavailable
- Hospitality offered should be adjusted to the duration of the scientific content of the meeting
- Place
- Do not install stands, do not use lounges or installations to carry out any type of activity (symposium, conference, seminars, lunches, etc.), neither accommodate healthcare professionals in: hotels 5* (attending less than 200 healthcare professionals)/ 5 * superior/ 5* luxury/ 5* grand luxury/ sports resorts/ theme park/ wine hotels
- Pending on scientific program
- Overnight extra stay
Recreational and entertainment aspects prevail against scientific

Please support EXCLUSIVELY the assistance of healthcare professionals exercising in Spain who will attend the meeting as SPEAKERS

Please watch over the attendance of healthcare professionals to planned scientific sessions

VENUE: hotels 5* (attending less than 200 healthcare professionals)/ 5 * superior/ 5* luxury/ 5* grand luxury/ sports resorts/ theme park/ wine hotels

As it is an event in which predictably people different from healthcare professionals will take part, please adopt the necessary measures to avoid carrying out any promotional activity related to prescription only medicines directed to public in general

As it is an event aimed at healthcare professionals not authorized to prescribe or dispense prescription only medicines, please take into account the Circular USD-PS/10/09

It is forbidden to pay the event registration fee as it includes elements against the Code
## SCPSU CIRCULAR USD/02/07 - General table of uses of hotels

### Uses of Hotels Criterion applicable to Pharmaceutical Companies

<table>
<thead>
<tr>
<th>National and International Events</th>
<th>Events Organized by Pharmaceutical Companies or Mainly Sponsored</th>
<th>Events Organized by Third Parties</th>
</tr>
</thead>
<tbody>
<tr>
<td>4* Hotels or Inferior Class</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>5* Hotels</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td>- YES given the following circumstances:</td>
<td>- Business hotel not ostentatious in built-up area</td>
<td></td>
</tr>
<tr>
<td>- Participation of at least 200 healthcare professionals</td>
<td>- Participation of at least 200 healthcare professionals</td>
<td></td>
</tr>
<tr>
<td>- Venue of the event</td>
<td>- Venue of the event or rooms unavailable in venue hotel</td>
<td></td>
</tr>
<tr>
<td>- Previous SCPSU’s authorization</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5* Superior/5* Luxury Hotels</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td>5* Grand Luxury Hotels</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td>Sports Resorts (Golf, Tennis, etc.), Theme Park, Wine Hotels Irrespective of its Official Class</td>
<td>NO</td>
<td>NO</td>
</tr>
</tbody>
</table>

**NO**: Means that stands cannot be installed, neither its lounges or its installations can be use to carry any type of activity: (symposium, conference, seminars, lunches, etc.), or accommodation of healthcare professionals.

**INTERNATIONAL EVENTS**: Additionally criterion as the following will be applied (i) security of the attendants, (ii) appearance and ranking at local level (in absence of equivalent classification).
EVENTS HELD OUTSIDE SPAIN: RESOURCE OR RELEVANT EXPERTISE

- Visit of a management center or administration offices of the laboratory.
- Availability of meeting rooms.

- Visit or a production plant or I+D center.
- Visit of a medical or prestigious investigation center, speakers belonging to them.

USD/05/08: laboratories organizing or sponsorizing in their majority these kind of events (Art. 11.10 (b)), must obtain previous authorization from the Surveillance Unit.
SCPSU CIRCULAR USD/04/08

Subject: “National events organized by third parties being the venue chosen one of the following hotels: 5* grand luxury, 5* Superior, 5* Luxury, sports resort (golf), including theme parks, wine hotels, etc.”

The typology and characteristics of hotels capable of being used for scientific events or activities are a matter extensively regulated in the Code (specifically in article 11 related to hospitality and meetings), in its Implementation Guide and in Q&A document. Additionally, the SCPSU´s Circular USD/02/07 summarizes the criterion of uses of hotels by pharmaceutical companies.

In national events organized by third parties, sometimes it is selected as venue a type of hotel for which the SCPSU, applying the criterion specified in the Circular above mentioned, has requested pharmaceutical companies to avoid installing stands or using its lounges or installations to carry out any type of activity (symposium, conferences, seminars, lunches, etc.), or accommodating healthcare professionals invited to the meeting, etc.

In honour of preserving the pharmaceutical industry image, and being loyal to the coherence principle, indicate you that national events organized by third parties, in which the selected venue for its celebration is a hotel of this characteristics and typology, will be classified by the SCPSU as NON PERMITTED ("red colour"), where the pharmaceutical companies must refrain from collaborating/ taking part directly or indirectly in such events.

We are at your disposal for any clarification on this matter.

Madrid, 15th of September of 2008

The Director of the Spanish Code of Practice Surveillance Unit
Third Party Events Data Base

Yes, I’ve read the General information
Events sorted out by:

- Name
- Date
- Country
- Classification
- 15 Last Days

include those events registered or modified in some sense (change in dates of celebration, from study to definitive evaluation, modifications in evaluations, etc.) by the Spanish Code of Practice Surveillance Unit in the last 15 days.

www.farmaindustria.es
Third Party Events Data Base

CONGRESSES EVALUATION PROCESS

EVENT COMMUNICATION
By
- Laboratories
- Scientific Societies
- Congresses Organizers
- USD

CHECKING EVALUATION
• Scientific program (schedule)
• Social program and activities
• Venue - Hotel
• Dates

EVENT CLASSIFICATION

PREVENTIVE MESSAGE
to Laboratories in order to
• Prevent possible breaches
• Clarify classifications
• Inform regarding possible classification modified

If any change
EVENT COMMUNICATION
Associations + Companies
- 71 members
- usernames/passwords

PREVIOUS EVENT EVALUATION
SCPSU FARMAINDUSTRIA
- Scientific program (schedule)
- Hospitality provided
- Venue - Location
- Other Activities
- Accompanying persons

EVALUATION VALIDATION
MAR (Steering Committee Assoc.)
- Scientific program (schedule)
- Hospitality provided
- Venue - Location
- Other Activities
- Accompanying persons

EVENT CLASSIFICATION AT EFPIA CONGRESSES WEBSITE
SCPSU FARMAINDUSTRIA

EVENTS CS

Self-Regulation System
HEALTHCARE PROFESSIONALS CODE

PROPOSAL: EUROPEAN CONGRESSES BY EFPIA
CONGRESSES EVALUATION PROCESS

EFPIA ONLINE PLATFORM
(In development)

If any change

INFORMING OF EVALUATION TO HOST COUNTRY ASSOCIATION

In 3 working days the Host Country Association will inform to EFPIA

LETTER INFORMING OF EVALUATION TO CONGRESS ORGANIZATORS

In 10 working days EFPIA will send the final evaluation

The International
Pharmaceutical Compliance Congress
and Best Practices Forum
MAY 2010 - SATISFACTION SURVEY REGARDING THIRD PARTIES EVENTS WEBSITE
In general, How do yo qualify events evaluations done by the USD?

- Highly Restrictive: 1.59%
- Restrictive: 11.11%
- Appropriate: 55.56%
- Tolerant: 20.63%
- Highly Tolerant: 9.52%
- Non Answer: 1.59%
INFORMATION RELATED WITH ARTICLE 14.3

SPANISH CODE OF PRACTICE FOR THE PROMOTION OF MEDICINES AND INTERACTION WITH HEALTHCARE PROFESSIONALS

INFORMATION RELATED WITH ARTICLE 14.3. ALL KIND OF STUDIES CARRIED OUT BY PHARMACEUTICAL COMPANIES EXCEPT CLINICAL TRIALS & NON-INTERVENTIONAL STUDIES.

Pharmaceutical companies also conduct other types of studies distinct from clinical trials and non-interventional studies, but collect data or opinions from healthcare professionals about their clinical practice, a given disease, the health status of their patients, or their understanding or use of certain medicines;

In these cases, it is important to adopt a series of precautions in order to avoid that these studies could imply an inducement to prescription or contain an incentive prohibited by the Code. So, besides complying with the current regulation in every case, any study distinct from clinical trials and non-interventional studies which is carried out, funded or sponsored in its majority by a company, shall:

(i) Be communicated before its beginning, in accordance with what established in the Rules of Procedure for the Control Bodies of the Spanish Code of Practice.

(ii) Be carried out with a scientific purpose. The objectives, methodologies and expected results shall be scientifically consistent.

(iii) Ensure the study does not modify the physicians’ prescriptions habits or the pharmacists’ dispensing habits.

(iv) Issue a written protocol in which its objectives, methodology, expected results and its use are clearly established. In this respect, written agreements shall be signed with the professionals and/or the entities with which the studies will be carried out on one side, and the company sponsoring the study on the other side, specifying the nature of the services to be accomplished, the professionals’ participation and remuneration conditions, etc.

(v) The payment of professional participants shall obey to market criteria and correspond to the usual time, the work carried out and the assumed responsibilities, and shall be adequately formalized. The payment shall be monetary. Exceptionally, and with a previous authorization from the Unit, some payments shall be made in kind.

(vi) Guarantee that they do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

(vii) Be approved prior to its accomplishment, by the Pharmaceutical company scientific service of by the compliance officer planned in Article 12.11 of the Code.
**METHODOLOGY**

**TIME FRAME EXECUTION**

**HEALTHCARE PROFESSIONALS INVOLVED**
- PHYSICIANS / PHARMACISTS / OTHERS
- SPECIALTY IF PHYSICIANS
- NUMBER

**RESULTS PUBLICITY**

**COMMENTS**
RISK ZONE: TO USE STUDIES AS AN INCENTIVE FOR HEALTHCARE PROFESSIONALS
Communication of activities under articles 16 and 17 of the Code must be performed by the laboratory through the figure of project communication delegate.

Communication shall not be mandatory when:

- The sponsoring or financing from the company is not in its majority, or
- The project involves paid participation of less than 20 healthcare professionals. The fragmentation of a study in several smaller units is not permitted.
- The project consists of a trial or study specified in Art. 14.1 or 14.2 of the Code.
- Period of communication to the Surveillance Unit: 10 working days before its beginning.
- Electronic procedure, starting January 1st 2011
- Information to be provided: Laboratory, promoter, title of the project, objective, methodology, planned execution period, number and specialty of healthcare professionals involved, geographical area, planned remuneration, other entities involved.
- Together with the aforementioned, the laboratory must provide the Unit a report containing rationale for need to contract services, criteria used for selecting healthcare professionals, criteria used to calculate compensation for their serviced, planned documentation to verify actual provision of the service, copy of the contract or contracts (when applicable, anonymized) or model contract, if available.
PHARMACEUTICAL INDUSTRY: recognizes having common interests with patient organizations.

OBJECTIVE: To assure interaction between the Industry and patient organizations is carried out according to:

- ETHICS
- TRANSPARENCY
PRINCIPLES

- INDEPENDENCE
- MUTUAL RESPECT
- NO MONITORING
- TRANSPARENCY
- PLURAL FUNDINGS

APPLICATION SCOPE
“ANY KIND OF INTERACTION BETWEEN PHARMACEUTICAL COMPANIES AND PATIENT ORGANIZATIONS”
1. INTRODUCTION, DEFINITION AND OBJECT OF THE CODE, SCOPE OF THE CODE

2. ARTICLES

   1. NON PROMOTION OF MEDICINES
   2. WRITTEN AGREEMENTS
   3. USE OF LOGOS AND PROPRIETARY MATERIALS
   4. EDITORIAL CONTROL
   5. TRANSPARENCY
   6. SINGLE COMPANY FUNDING
   7. EVENTS AND HOSPITALITY
   8. RULES OF APPLICATION OF THE CODE
ARTICLES

9 REQUEST FOR QUERIES
10 CONTROL OF CODE COMPLIANCE
11 INFRINGEMENTS AND SANCTIONS
12 IMPLEMENTATION GUIDES AND COLLABORATION AGREEMENT
13 DISCLOSURE AND COMPILATION OF DECISIONS
14 DATE OF ENTRY INTO FORCE OF THE CODE
COLLABORATION www.farmaindustria.es

TRANSPARENCY ON RELATIONSHIPS WITH PATIENT ORGANISATIONS

Article 5, Spanish Code of Practice on Relationships Between the Pharmaceutical Industry and Patient Organisations.

5.1 Each company must make publicly available a list of patient organisations to which it provides financial support and/or any other type of support – indirect or non-financial support. This should include a short description of the nature and scope of the support. This information may be provided on a national or European level and should be updated at least once a year. This information shall be published before April 30th, 2009 and shall include the activities carried out since January 1st, 2008.

5.2 Companies must ensure that their sponsorship is always clearly acknowledged and apparent from the outset.

- ABROTT CIENTIFICA, S.A.
- ALCON CUSI, S.A.
- ALK ABELO, S.A.
- ALLERGAN, S.A.
- AMGEN, S.A.
- ASTELLAS PHARMA, S.A.
- AZTENALCE FARMACEUTICA, S.A.
- BAXTER, S.L.
- BIOTECNECIBIA, S.L.
- BOEHRINGER INGELHEIM, S.A.
- BRUSCEL-zaqce SQUIBB, S.A.
- CELGENE, S.L.
- CHEST SPAIN, S.A.
- CRUCELL SPAIN, S.A.
- FERRI FARMACEUTICA, S.A.
CONSTANT AND REAL COMMITMENT OF THE LABORATORIES

CONTINUOUS IMPROVEMENT PROCESSES: TRANSPARENCY AND CREDIBILITY

CREATE VALUE FOR THE LABS: INFORMATION AND MAKE DECISIONS PROCESSES

VISIBILITY OF THE EFFORT DONE BY THE LABS TO ADEQUATE THEIR PRACTICES TO THE CODE

BALANCE BETWEEN THE DIFFERENT CONTROL BODIES

COLLABORATION WITH THE RELEVANT HEALTH AUTHORITIES
THE SELF-REGULATION SYSTEM IS A STRENGTH OF THE PHARMACEUTICAL INDUSTRY TO POSITIVELY IMPROVE ITS IMAGE BEFORE THE WHOLE SOCIETY (PUBLIC ADMINISTRATION, HEALTHCARE PROFESSIONALS AND PATIENTS)
SPANISH CODE OF GOOD PRACTICES
SURVEILLANCE UNIT

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