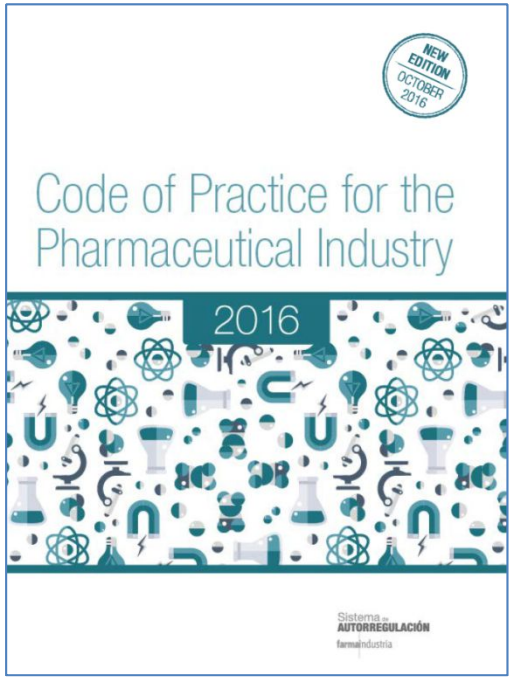
The Eleventh International Pharmaceutical and Medical Device Compliance Congress



Impact of Self-Regulation Schems on Industry Relationships with HCPs, HCOs and Patients Organizations

Lisbon, 16 May 2017

José F. Zamarriego Izquierdo
Director
Code of Practice Surveillance Unit

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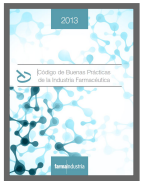
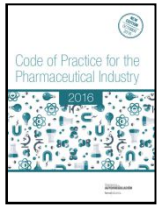
ORIGIN AND EVOLUTION OF THE CODES

1991	Adoption of the EFPIA Code as Spanish Code (Adopted in 1992)
2002	New version of the Code
Version 2004	Guidelines
	Queries (Questions and Answers)
	Surveillance Unit
Version 2005	Adaptation to the EFPIA Code (Nov. 2004)
	Reinforcement and continued development
Version 2008	New version of the Code of Relationships with Healthcare Professionals
	New Code on Relationships with Patient Organisations
Version 2010	Adaptation and development of the HCP Code: Modification of articles 3, 10, 11, 14, 16 y 17
Version 2012	Patients Code: Adaptation to the EFPIA Code (June 2011)
Version 2014	Code of Practice for the Pharmaceutical Industry 2014
	Adapted to the requirements of the EFPIA Disclosure Code
Version 2016	**Code of Practice for the Pharmaceutical Industry 2016**
	Art. 18th amended taking into account SPDPA Report.





AREAS COVERED BY THE CODE

PROMOTION OF PRESCRIPTION-ONLY MEDICINES

INTERACTIONS WITH HEALTHCARE PROFESSIONALS AND HEALTHCARE ORGANISATIONS

RELATIONSHIPS WITH PATIENT ORGANISATIONS

CODE OF PRACTICE FOR THE PHARMACEUTICAL INDUSTRY

3 COMMUNICATION SYSTEMS

- EVENTS (art. 11)
- STUDIES (art. 14.3)
- SERVICES (art. 16)

GENERAL STANDARDS APPLICABLE IN SPAIN TO SCIENTIFIC AND PROFESSIONAL MEETINGS

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CODE OF PRACTICE FOR THE PHARMACEUTICAL INDUSTRY

General standards applicable in Spain to **"Scientific and Professional Meetings"**

	PERMITTED PRACTICES	FORBIDDEN PRACTICES
VENUE & LODGING FACILITIES	➢ 4 * or inferior rating hotel. ➢ Exceptionally, 5* non-ostentatious business hotel (never luxurious) located in an established urban area, provided that the following concur: - Large number of healthcare professionals (at least 200 attendees) expected, - The hotel is also the meeting venue or the venue hotel is fully booked. ➢ When an establishment holds more than one official rating, the company shall take into account the highest one.	➢ 5* hotel, 5* Superior or Luxury hotel, 5* Grand Luxury hotel (when an establishment holds more than one official rating, the company shall take into account the highest one). ➢ Golf Resort hotel, Theme Park Resort hotel, Winery hotel (regardless of star rating). ➢ Venue renowned for its entertainment facilities or extravagance (regardless of star rating).
ACCOMPANYING PERSONS	➢ NONE	➢ Extending hospitality to persons other than healthcare professionals. ➢ Permitting or facilitating presence of accompanying persons, even if they pay for their own expenses.
SOCIAL PROGRAMME	➢ Reasonable and moderate social networking activities that may not damage the pharmaceutical industry´s image, such as lunch or dinner that do not include additional elements (cultural, leisure or entertainment, etc.). ➢ A maximum cost of 60 Euro (including taxes) per guest applies for any form of hospitality associated with meals.	➢ Sponsoring or organising entertainment, cultural or leisure activities. ➢ Social activities interfering with the scientific programme (same schedule). ➢ Social activities whose nature, content, magnitude, etc. prevail over the scientific ones.
SCIENTIFIC PROGRAMME	➢ Designed in accordance with the scientific nature of the meeting.	➢ Highlighting aspects/elements other than those scientific and professional. ➢ Scientific activities below 60% of a working day (Basis for calculation: 8 hours/ day). ➢ Including graphs, pictures, links, etc., without scientific content, that could distort or create confusion regarding the scientific nature and purpose of the meeting.
LOCATION	➢ Ease of travel for the participant, cost, appropriateness and appearance/reputation of the city are taken into account when selecting a location.	➢ Cities of an exclusively touristic nature or predominantly associated with leisure, recreational or sporting activities. For example: mountain locations related to skiing from December to March (included). ➢ Touristic seaside resorts in peak season (second fortnight of June, July, August and first fortnight of September).
TRAVEL SCHEDULE	➢ Hospitality (payment of actual travel, inscription and subsistence expenses), which must be reasonable and not out of proportion, is limited to the days when the scientific meeting is to take place.	➢ Extending the hospitality provided to healthcare professionals beyond what is reasonable before or after the event.
STANDS	➢ Stand designed in a way that transmits and enhances its scientific and professional nature and interest. ➢ Facilitate, when possible, a place within the stand where healthcare professionals can exchange scientific information and opinions. Reasonable & moderate hospitality, limited to coffee or water.	➢ Turning the stand into a "restaurant or bar", contracting catering services, offering food or beverages other than coffee or water, going beyond a moderate/reasonable level of hospitality, installing beverage and food dispensers, fridges, etc. ➢ Level of hospitality provided within the stand being the main/only reason for healthcare professionals to visit it.

GENERAL STANDARDS APPLICABLE IN SPAIN TO SCIENTIFIC AND PROFESSIONAL MEETINGS

EXHIBITION AREA	➢ Establish reasonable measures to guarantee that people accessing the Exhibition Area are Healthcare Professionals. For example: badges, control access, etc.	➢ Allowing the entrance of people different from Healthcare Professionals.
RESTING AREAS	➢ Facilitate the exchange of scientific information and opinions among healthcare professionals. ➢ Offer a moderate and reasonable level of hospitality, taking into account aspects like: (I) the environment/scene and nature of the event "Scientific & Professional meeting", (II) image of the pharmaceutical industry. ➢ Corporate/institutional sponsorship of this area only.	➢ Accessible to persons different from healthcare professionals (accompanying persons). ➢ Offering out of proportion or excessive (I) services (for example: massages), (II) food and beverages (for example: alcoholic drinks, etc.). ➢ Directly or indirectly promoting prescription-only medicines.
PROMOTIONAL GIFTS/ AIDS	➢ NONE related to prescription-only medicines. ➢ In meetings where promotion mainly pertains to medicines other than prescription-only, gifts related to the practice of medicine or pharmacy with a market value of 10€ or less which are not related to prescription-only medicines. ➢ Corporate pens and pads under 10€ in company organised meetings.	➢ Supplying, offering or promising a gift or pecuniary advantage (in cash or benefit in kind) to a healthcare professional. ➢ In meetings where promotion mainly pertains to prescription-only medicines, offering or providing stationery or items for the practice of medicine or pharmacy, inserting pens or pads in the congress bag that include corporate/institutional advertising or product advertising.
INFORMATIONAL OR EDUCATIONAL MATERIALS, AND ITEMS OF MEDICAL UTILITY	➢ Informational or educational materials with a market value of 60€ or less that are directly relevant to the practice of medicine or pharmacy; and directly beneficial to the care of patients. ➢ Items of medical utility aimed directly at the education of healthcare professionals and patient care if they have a market value of 60€ or less and do not offset routine business practices of the recipient.	➢ Informational or educational materials and items of medical utility with a market value over 60€. ➢ The transmission of informational or education materials and items of medical utility that constitute an inducement to recommend, prescribe, purchase, supply, sell or administer a Medicinal Product.

Companies are encouraged to contact their Spanish subsidiary representatives to clarify any aspect related to these provisions and/or their potential participation/collaboration in a scientific or professional meeting in Spain.

This document is provided exclusively for informative purposes. In all cases the provisions included in the Spanish version of the Code of Practice for the Pharmaceutical Industry shall prevail.

FARMAINDUSTRIA. Code of Practice Surveillance Unit (usd@codigo.farmaindustria.es). January 2015.

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❖ ART. 11 – SCIENTIFIC AND PROFESSIONAL MEETINGS
Circular USD/02/14

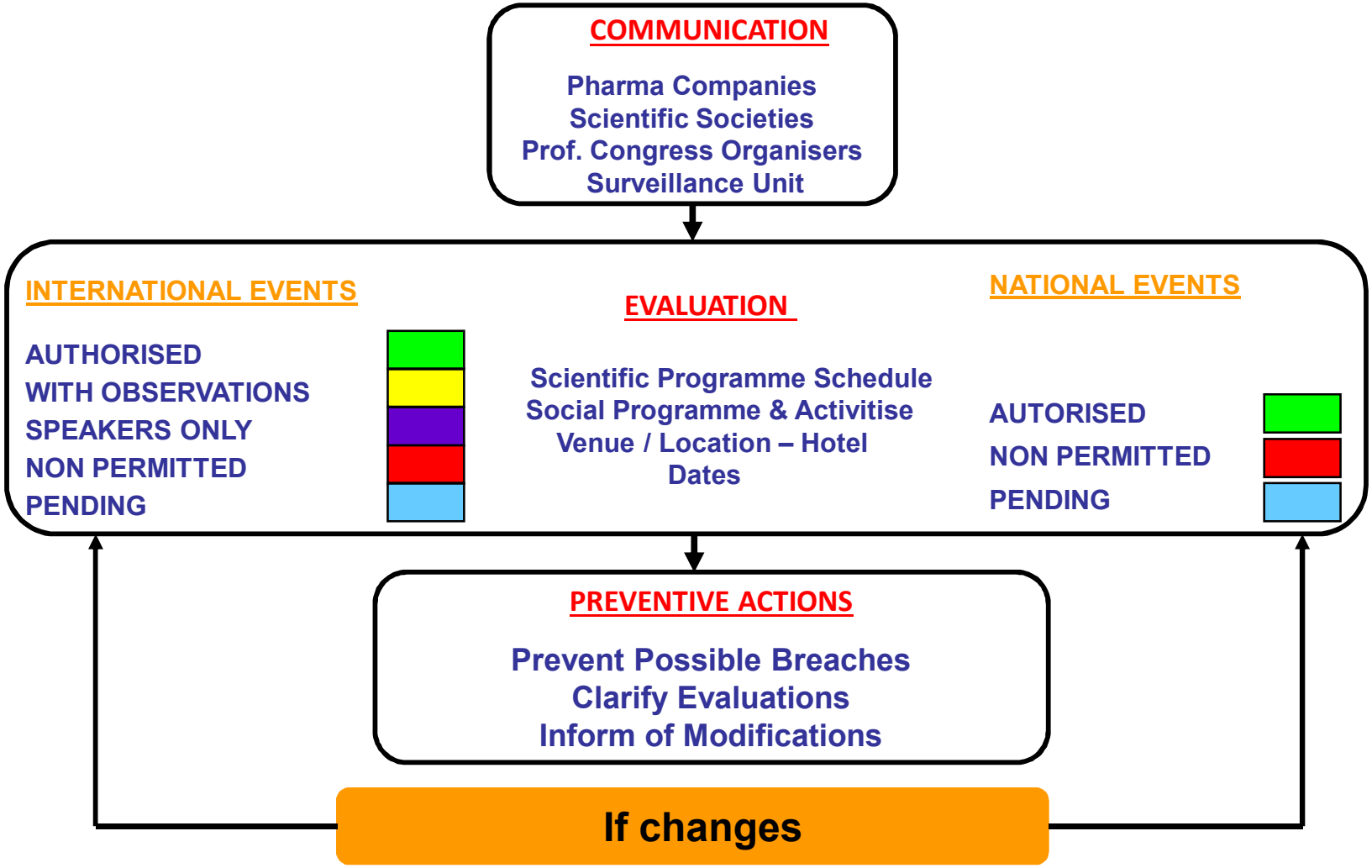
Criteria Applicable to Pharmaceutical Companies on Hotel Use

ART. 11 SCIENTIFIC AND PROFESSIONAL MEETINGS
The venue chosen to hold scientific and professional meetings, organised and/or sponsored by the Pharmaceutical Industry, shall be selected taking into account ease of travel for participants, its cost, appropriateness and appearance.

VENUE	GENERAL RULE	SUPPLEMENTARY REMARKS
4* Hotel or lower rating	**AUTHORISED**	Considered the appropriate standard to hold scientific and professional meetings.
5* Hotel	**NOT PERMITTED**	Use may be exceptionally permitted, provided that all of the following conditions apply: - Venue or venue hotel is fully booked - Non-ostentatious business hotel in an established urban area - Participation of at least 200 Healthcare Professionals
5* Superior, 5* Luxury, 5* Great Luxury Hotel	**NOT PERMITTED**	Under no circumstance would use of these hotels be justified.
Regardless of rating: **GOLF** Hotel **WINERY** Hotel Hotel affiliated or sited within an **AMUSEMENT PARK**		
Hotel **OUTSIDE OF SPAIN**	**SAME RULES APPLY**	Exceptionally, additional criteria may be taken into account, such as the safety of attendees, appearance and the country-specific rating criteria.

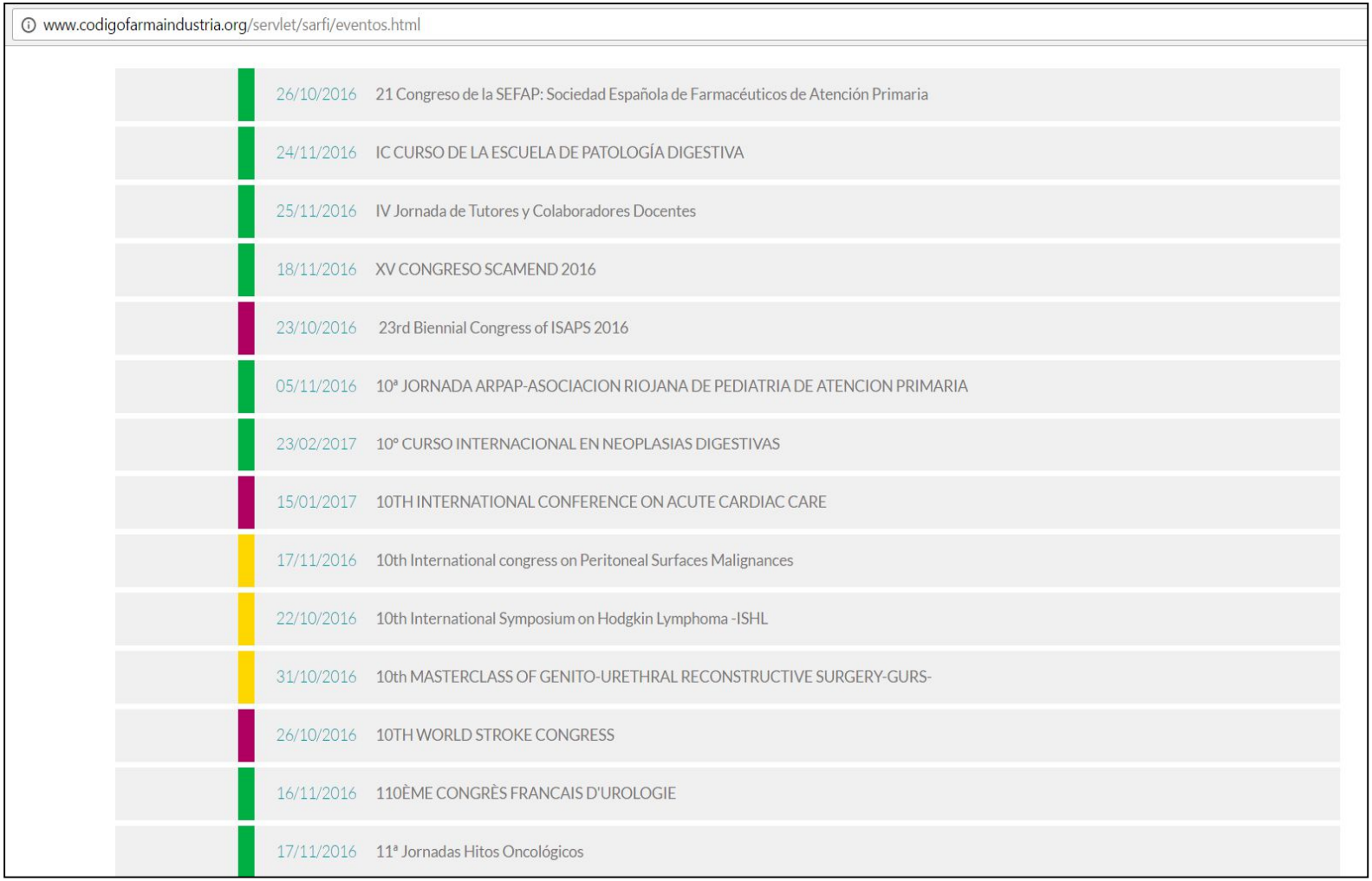
When an establishment holds more than one official rating, the company shall take into account the highest one.

EVALUATION PROCESS



EVENT DATABASE

http://www.codigofarmaindustria.org



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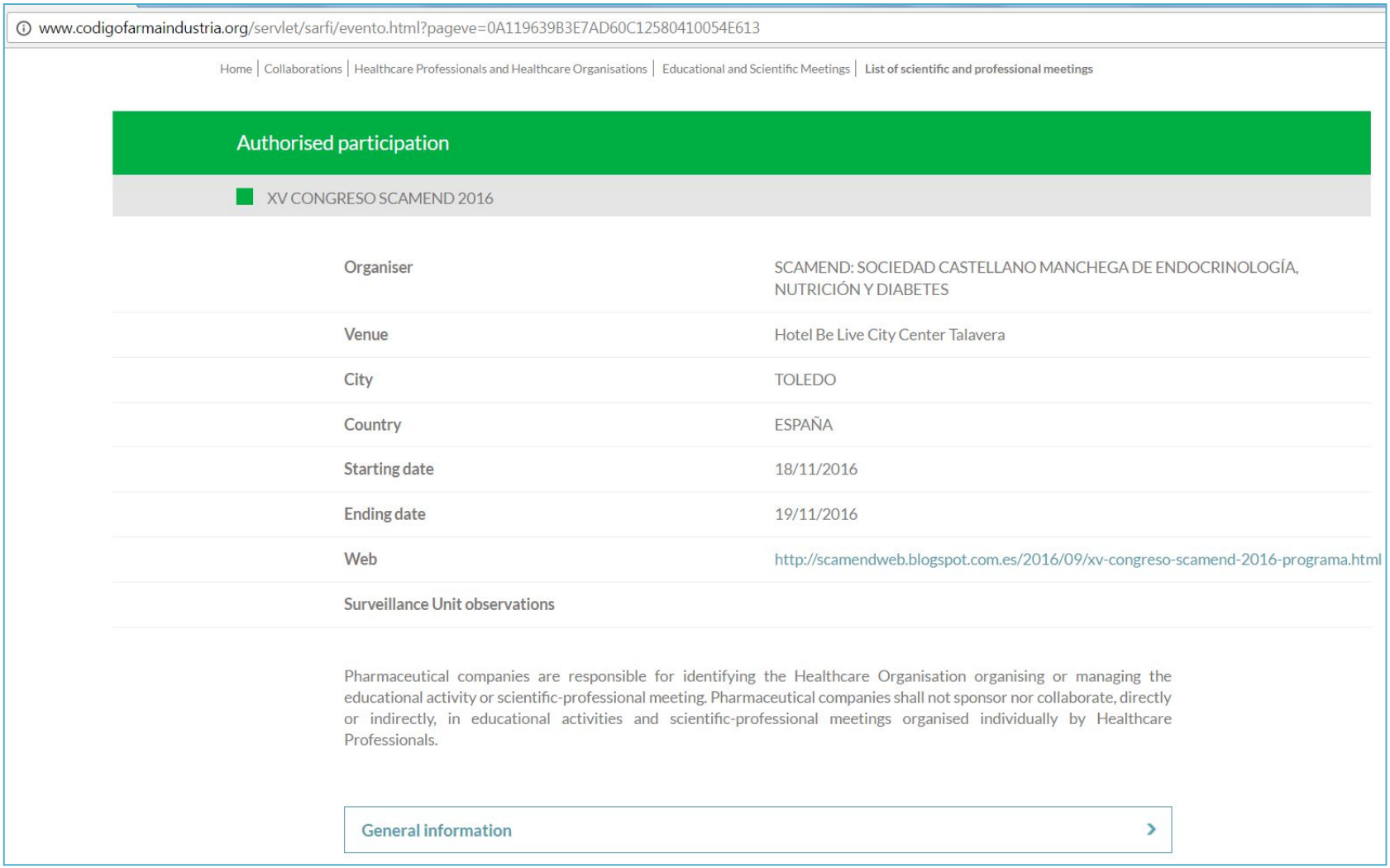


NATIONAL EVENTS – SCSU & Stakeholders

COLLABORATION WITH EVENT ORGANISERS:
Scientific & Medical Societies, PCOs, HCPs, etc.

"With the aim of easing the possible collaboration / participation of those pharmaceutical companies belonging to our self-regulation system, please take into account the information presented in this letter, adapting or modifying, where necessary, the above detailed elements."

De: Eventos - USD
Enviado el: viernes, 15 de marzo de 2013 12:22
Para:
CC:
Asunto:

Importancia: Alta

Att. Comité Organizador

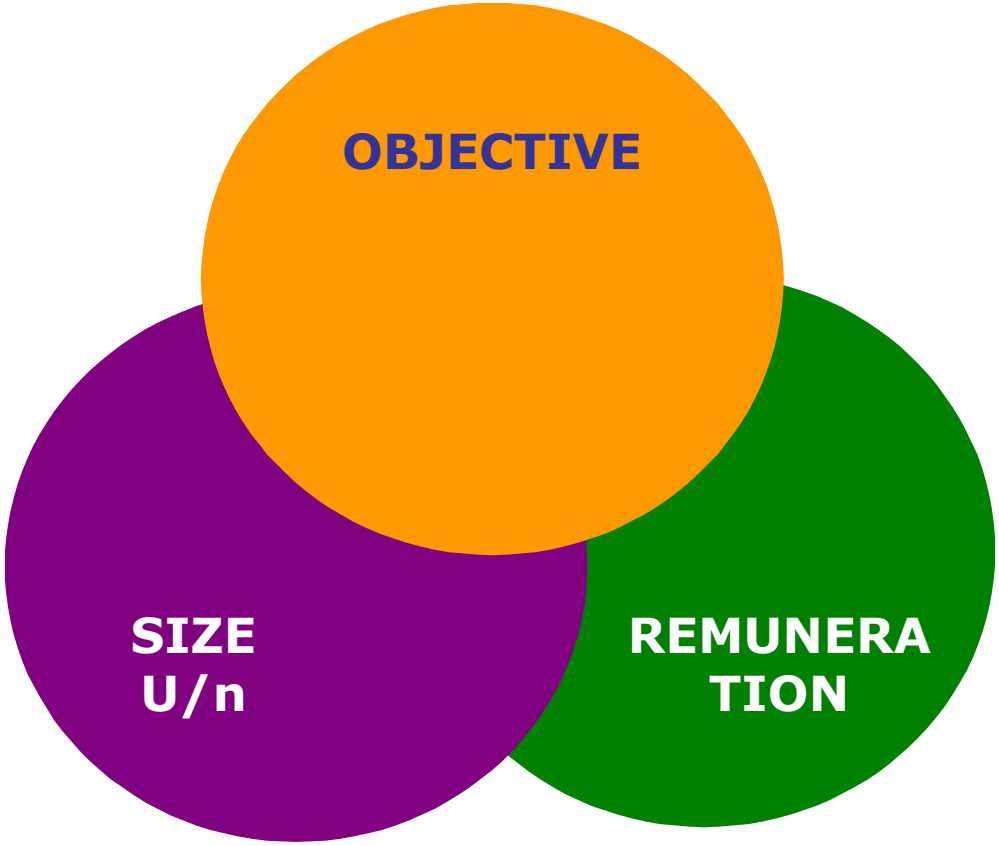
Estimado Presidente,

La Asociación Nacional Empresarial de la Industria Farmacéutica establecida en España, ofrecer una información honesta, precisa y objetiva de los medicamentos, acordó regirse Código Español de Buenas Prácticas de Promoción de Medicamentos y de Interrelación d Código").

ELEMENTS PREVENTING MEMBER COMPANIES' COLLABORATION:

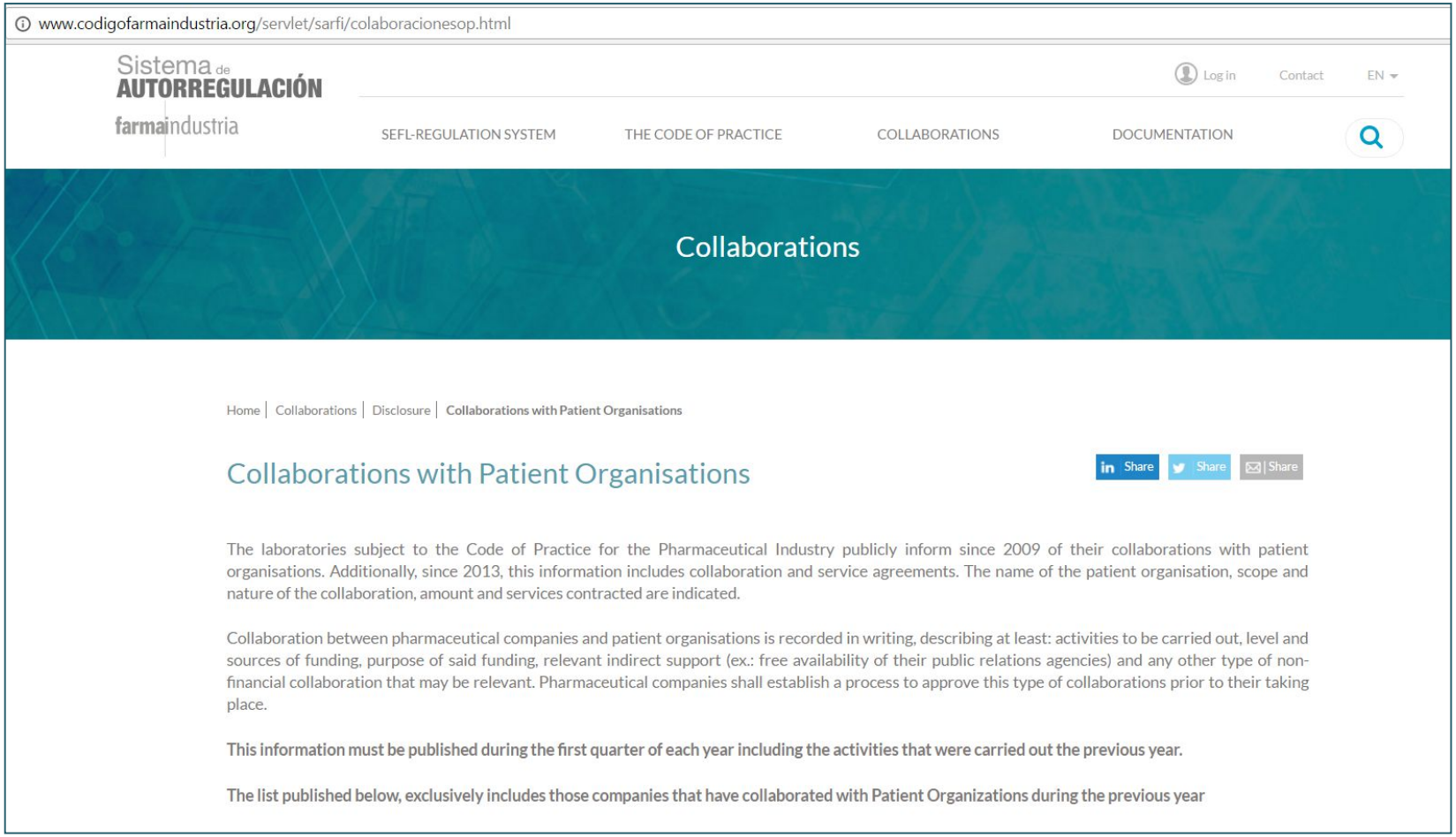
- Entertainment
- Accompanying persons
- 5* Lux Hotel as Venue
- et alt.

MARKET RESEARCH STUDIES & FEE FOR SERVICES

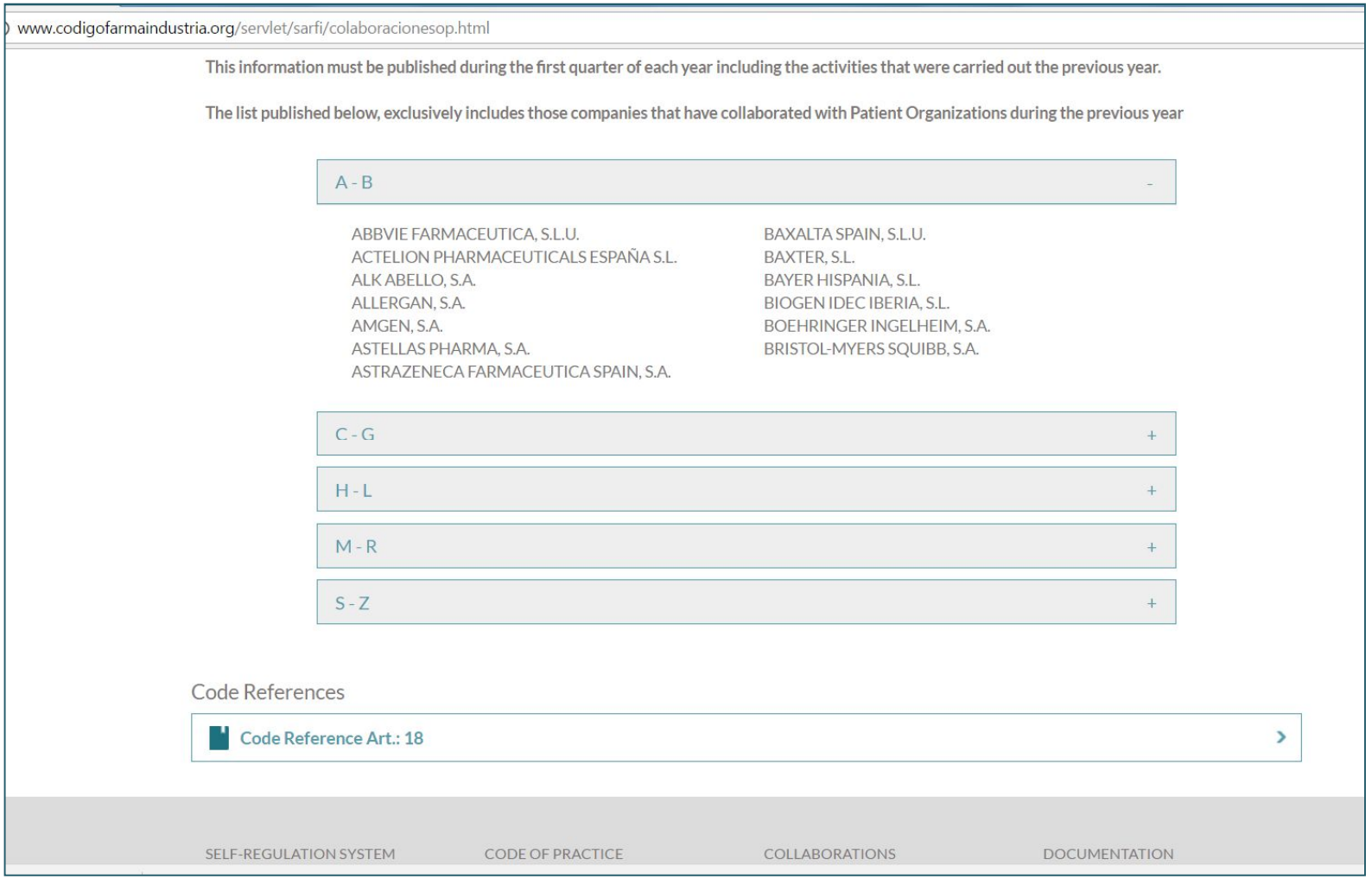


RISK ZONE: TO USE STUDIES AS AN INCENTIVE FOR HEALTHCARE PROFESSIONALS

COLLABORATION
www.codigofarmaindustria.org

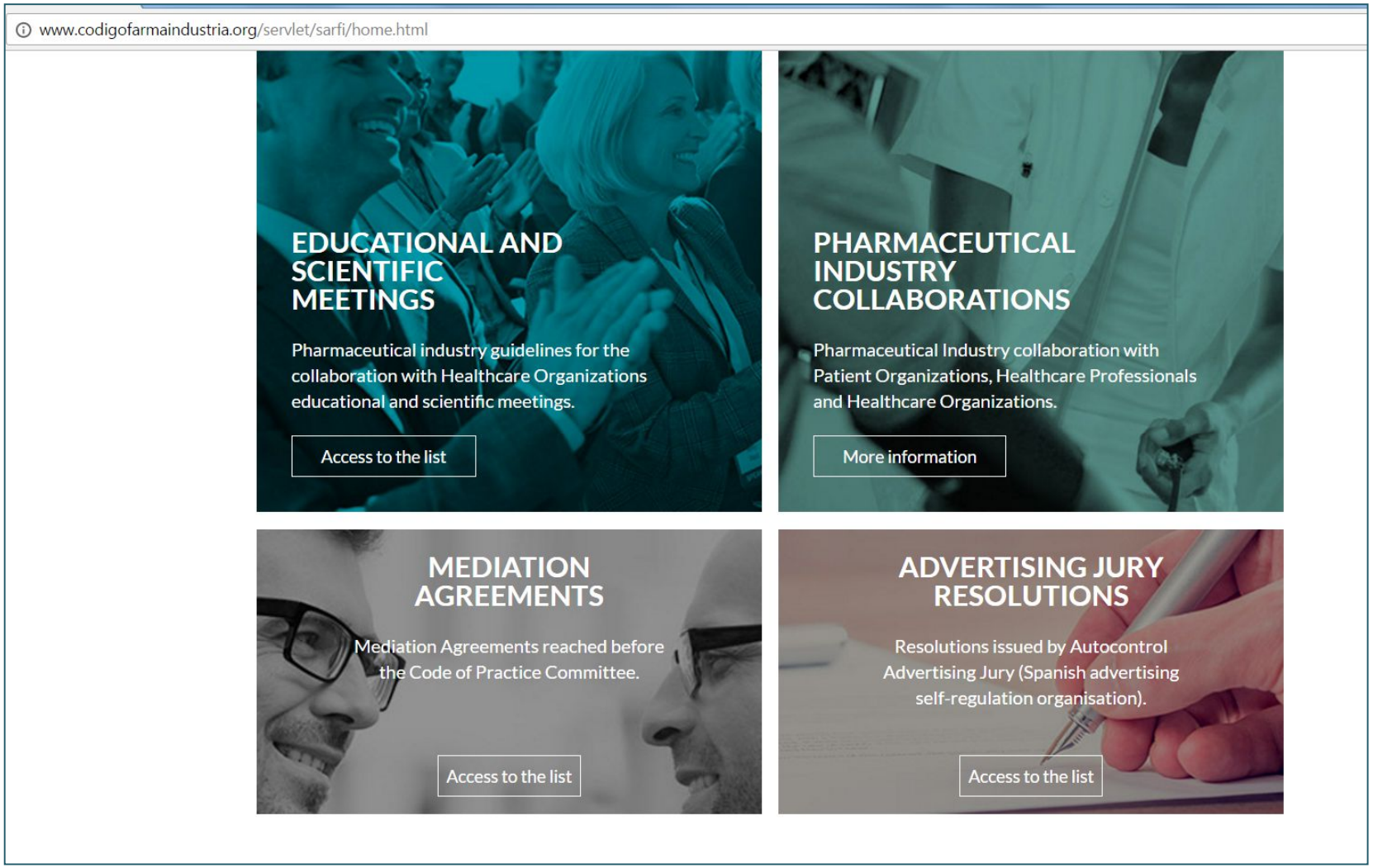


COLLABORATION
www.codigofarmaindustria.org



Transparency with all Stakeholders

http://www.codigofarmaindustria.org



ACTIVITY OF THE CODE OF PRACTICE (COP) SURVEILLANCE UNIT

		2004 Apr.-Dec	2005 Jan.-Dec	2006 Jan.-Dec	2007 Jan.-Dec	2008 Jan.-Dec	2009 (a) Jan.-Dec	2010 Jan.-Dec	2011 (b) Jan.-Dec	2012 Jan.-Dec	2013 Jan.-Dec	2014 Jan.-Dec	2015 Jan.-Dec	2016 Jan.-Sept	TOTAL Apr.04 - Sept.16
SCIENTIFIC AND PROFESSIONAL MEETING	ANALYSED	945	1.747	2.199	2.926	3.388	3.878	5.080	5.335	5.003	4.954	5.566	5.337	4.497	50.855
	No Incidents	718	1.390	1.909	2.616	3.087	3.345	4.383	4.862	4.389	4.412	5.124	4.867	4.271	45.373
	% Adapted	75,98%	79,56%	86,81%	89,41%	91,12%	86,26%	86,28%	91,13%	87,73%	89,06%	92,06%	91,19%	94,97%	87,81%
STUDIES (a)	ANALYSED						687	724	626	512	400	449	300	255	3.953
	No Incidents						397	546	565	416	332	368	251	210	3.085
	% Adapted						57,79%	75,41%	90,26%	81,25%	83,00%	81,96%	83,67%	82,35%	79,46%
SERVICES (b)	ANALYSED								357	330	306	350	368	300	2.011
	No Incidents								282	272	230	292	301	218	1.595
	% Adapted								78,99%	82,42%	75,16%	83,43%	81,79%	72,67%	79,08%
PREVENTIVE ACTIONS		814	1.801	1.376	2.092	2.440	2.670	3.482	3.131	2.488	2.112	2.180	2.138	1.224	27.948
USD COMPLAINTS		18	11	9	18	8	12	4	3	1	9	7	7	2	109

** 5 cases resolved in Court*

** 7 Final rulings from the Self-Regulation Panel in favour of the USD*

** 59 Resolved by mediation before the Deontology Committee with the infringement acknowledged and corrective measures accepted*

** 24 Agreements reached between parties prior to coming before the Deontology Committee*

** 12 Discontinued at the request of the USD*

** 2 Being processed in the Committee*

** 0 Not upheld by the Self-Regulation Panel*

(a) System for Communicating Studies approved under the 2008 Code
(b) System for Communicating Services approved under the 2010 Code Note.

Sistema de AUTORREGULACIÓN

farmaindustria

CODE OF PRACTICE SURVEILLANCE UNIT

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