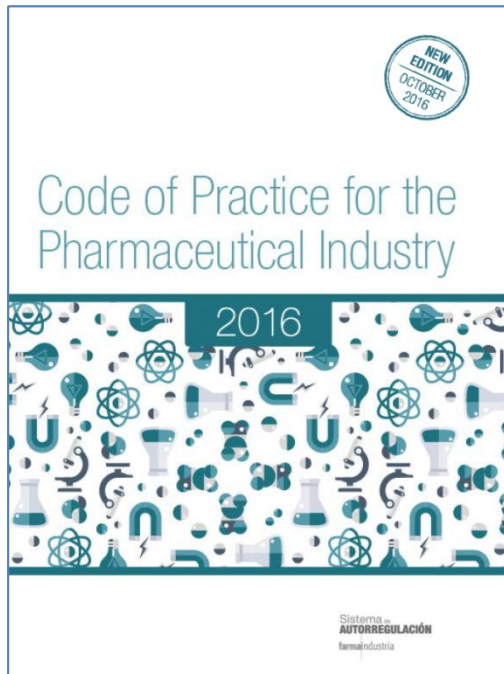


The Eleventh International Pharmaceutical and Medical Device Compliance Congress



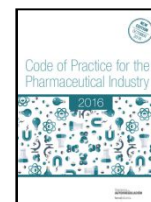
Impact of Self-Regulation Schemes on Industry Relationships with HCPs, HCOs and Patients Organizations

Lisbon, 16 May 2017

José F. Zamarriego Izquierdo
Director
Code of Practice Surveillance Unit

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



CODE OF PRACTICE FOR THE PHARMACEUTICAL INDUSTRY General standards applicable in Spain to "Scientific and Professional Meetings"

	PERMITTED PRACTICES	FORBIDDEN PRACTICES
<u>VENUE & LODGING FACILITIES</u>	<ul style="list-style-type: none"> ➤ 4 * or inferior rating hotel. ➤ Exceptionally, 5* non-ostentatious business hotel (never luxurious) located in an established urban area, provided that the following concur: <ul style="list-style-type: none"> - 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. 	<ul style="list-style-type: none"> ➤ 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).
<u>ACCOMPANYING PERSONS</u>	<ul style="list-style-type: none"> ➤ NONE 	<ul style="list-style-type: none"> ➤ Extending hospitality to persons other than healthcare professionals. ➤ Permitting or facilitating presence of accompanying persons, even if they pay for their own expenses.
<u>SOCIAL PROGRAMME</u>	<ul style="list-style-type: none"> ➤ 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. 	<ul style="list-style-type: none"> ➤ 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.
<u>SCIENTIFIC PROGRAMME</u>	<ul style="list-style-type: none"> ➤ Designed in accordance with the scientific nature of the meeting. 	<ul style="list-style-type: none"> ➤ 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.
<u>LOCATION</u>	<ul style="list-style-type: none"> ➤ Ease of travel for the participant, cost, appropriateness and appearance/reputation of the city are taken into account when selecting a location. 	<ul style="list-style-type: none"> ➤ 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).
<u>TRAVEL SCHEDULE</u>	<ul style="list-style-type: none"> ➤ 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. 	<ul style="list-style-type: none"> ➤ Extending the hospitality provided to healthcare professionals beyond what is reasonable before or after the event.
<u>STANDS</u>	<ul style="list-style-type: none"> ➤ 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. 	<ul style="list-style-type: none"> ➤ 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

<u>EXHIBITION AREA</u>	<ul style="list-style-type: none"> ➤ Establish reasonable measures to guarantee that people accessing the Exhibition Area are Healthcare Professionals. For example: badges, control access, etc. 	<ul style="list-style-type: none"> ➤ Allowing the entrance of people different from Healthcare Professionals.
<u>RESTING AREAS</u>	<ul style="list-style-type: none"> ➤ 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. 	<ul style="list-style-type: none"> ➤ 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.
<u>PROMOTIONAL GIFTS/ AIDS</u>	<ul style="list-style-type: none"> ➤ 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. 	<ul style="list-style-type: none"> ➤ 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.
<u>INFORMATIONAL OR EDUCATIONAL MATERIALS, AND ITEMS OF MEDICAL UTILITY</u>	<ul style="list-style-type: none"> ➤ 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. 	<ul style="list-style-type: none"> ➤ 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.

❖ ART. 11 – SCIENTIFIC AND PROFESSIONAL MEETINGS

Circular USD/02/14

Criteria Applicable to Pharmaceutical Companies on Hotel Use

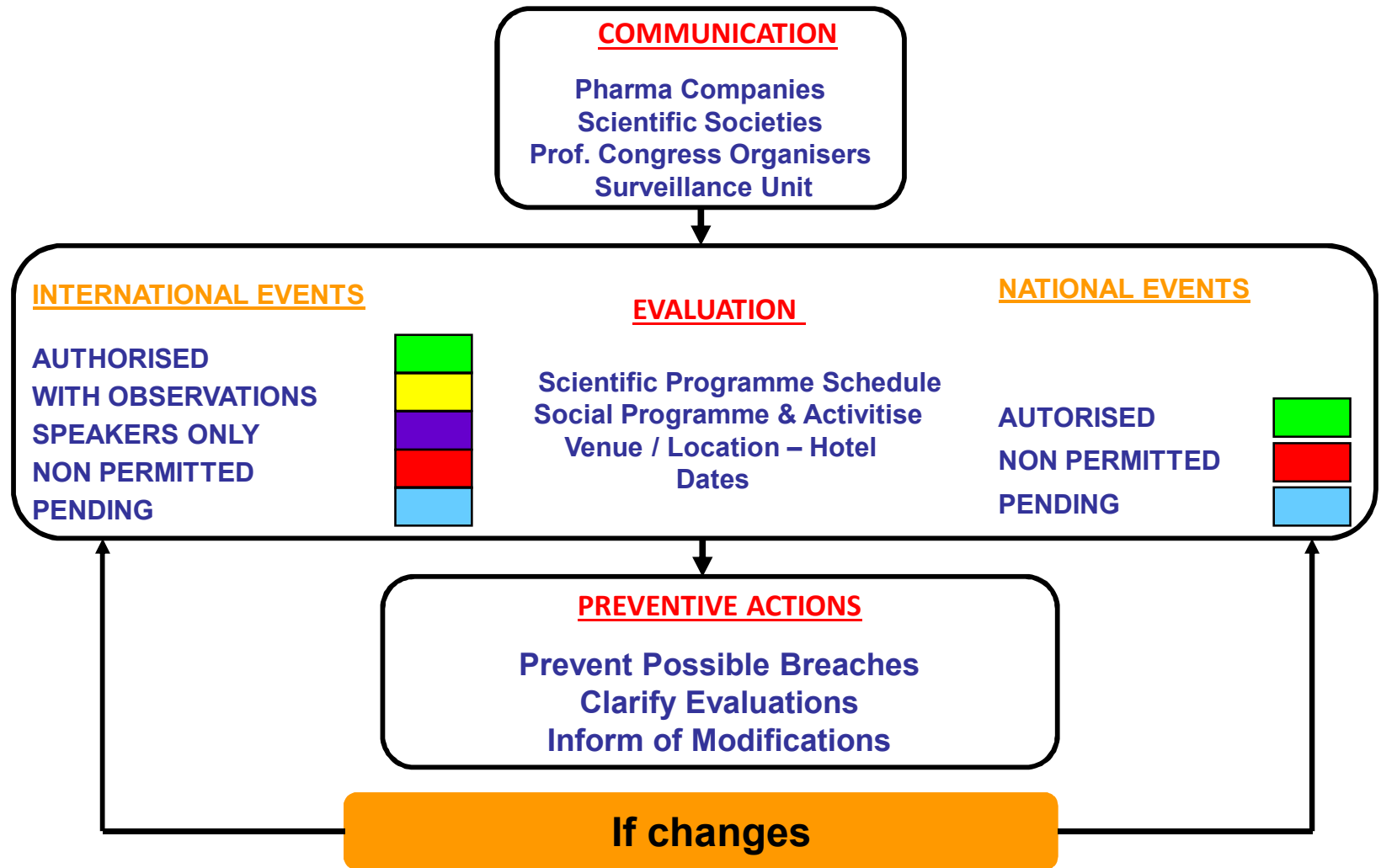
ART. 11 SCIENTIFIC AND PROFESSIONAL MEETINGS

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 <u>all</u> of the following conditions apply: <ul style="list-style-type: none"> - 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>

www.codigofarmaindustria.org/servlet/sarfi/eventos.html

26/10/2016	21 Congreso de la SEFAP: Sociedad Española de Farmacéuticos de Atención Primaria
24/11/2016	IC CURSO DE LA ESCUELA DE PATOLOGÍA DIGESTIVA
25/11/2016	IV Jornada de Tutores y Colaboradores Docentes
18/11/2016	XV CONGRESO SCAMEND 2016
23/10/2016	23rd Biennial Congress of ISAPS 2016
05/11/2016	10ª JORNADA ARPAP-ASOCIACION RIOJANA DE PEDIATRIA DE ATENCION PRIMARIA
23/02/2017	10º CURSO INTERNACIONAL EN NEOPLASIAS DIGESTIVAS
15/01/2017	10TH INTERNATIONAL CONFERENCE ON ACUTE CARDIAC CARE
17/11/2016	10th International congress on Peritoneal Surfaces Malignances
22/10/2016	10th International Symposium on Hodgkin Lymphoma -ISHL
31/10/2016	10th MASTERCLASS OF GENITO-URETHRAL RECONSTRUCTIVE SURGERY-GURS-
26/10/2016	10TH WORLD STROKE CONGRESS
16/11/2016	110ÈME CONGRÈS FRANCAIS D'UROLOGIE
17/11/2016	11ª Jornadas Hitos Oncológicos

www.codigofarmaindustria.org/servlet/sarfi/evento.html?pageve=0A119639B3E7AD60C12580410054E613

Home | Collaborations | Healthcare Professionals and Healthcare Organisations | Educational and Scientific Meetings | List of scientific and professional meetings

Authorised participation

- XV CONGRESO SCAMEND 2016

Organiser	SCAMEND: SOCIEDAD CASTELLANO MANCHEGA DE ENDOCRINOLOGÍA, NUTRICIÓN Y DIABETES
Venue	Hotel Be Live City Center Talavera
City	TOLEDO
Country	ESPAÑA
Starting date	18/11/2016
Ending date	19/11/2016
Web	http://scamendweb.blogspot.com.es/2016/09/xv-congreso-scamend-2016-programa.html

Surveillance Unit observations

Pharmaceutical companies are responsible for identifying the Healthcare Organisation organising or managing the educational activity or scientific-professional meeting. Pharmaceutical companies shall not sponsor nor collaborate, directly or indirectly, in educational activities and scientific-professional meetings organised individually by Healthcare Professionals.

General information >

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

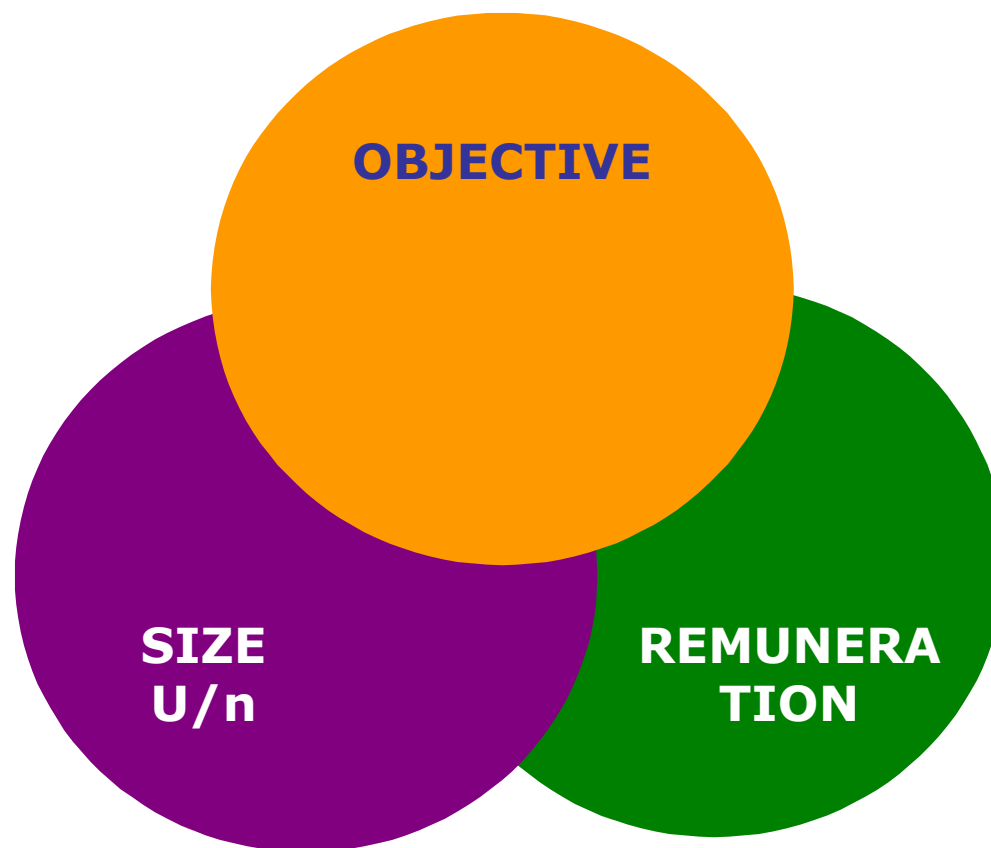
Estimado Presidente,

La Asociación Nacional Empresarial de la Industria Farmacéutica establecida en España, ofrecer una información honesta, precisa y objetiva de los medicamentos, acordó registrarse al Código Español de Buenas Prácticas de Promoción de Medicamentos y de Interrelación de Profesionales de la Industria Farmacéutica (“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

The screenshot shows a web browser window with the URL www.codigofarmaindustria.org/servlet/sarfi/colaboracionesop.html. The page header includes the logo 'Sistema de AUTORREGULACIÓN farmaindustria' and navigation links: 'SEFL-REGULATION SYSTEM', 'THE CODE OF PRACTICE', 'COLLABORATIONS', and 'DOCUMENTATION'. There are also links for 'Log in', 'Contact', and 'EN'. A search icon is visible in the top right corner.

Collaborations

Home | Collaborations | Disclosure | Collaborations with Patient Organisations

Collaborations with Patient Organisations

[in Share](#) [Twitter Share](#) [Email Share](#)

The laboratories subject to the Code of Practice for the Pharmaceutical Industry publicly inform since 2009 of their collaborations with patient organisations. Additionally, since 2013, this information includes collaboration and service agreements. The name of the patient organisation, scope and nature of the collaboration, amount and services contracted are indicated.

Collaboration between pharmaceutical companies and patient organisations is recorded in writing, describing at least: activities to be carried out, level and sources of funding, purpose of said funding, relevant indirect support (ex.: free availability of their public relations agencies) and any other type of non-financial collaboration that may be relevant. Pharmaceutical companies shall establish a process to approve this type of collaborations prior to their taking place.

This information must be published during the first quarter of each year including the activities that were carried out the previous year.

The list published below, exclusively includes those companies that have collaborated with Patient Organizations during the previous year

COLLABORATION

www.codigofarmaindustria.org

www.codigofarmaindustria.org/servlet/sarfi/colaboracionesop.html

This information must be published during the first quarter of each year including the activities that were carried out the previous year.

The list published below, exclusively includes those companies that have collaborated with Patient Organizations during the previous year

A - B	-
ABBVIE FARMACEUTICA, S.L.U. ACTELION PHARMACEUTICALS ESPAÑA S.L. ALK ABELLO, S.A. ALLERGAN, S.A. AMGEN, S.A. ASTELLAS PHARMA, S.A. ASTRAZENECA FARMACEUTICA SPAIN, S.A.	BAXALTA SPAIN, S.L.U. BAXTER, S.L. BAYER HISPANIA, S.L. BIOGEN IDEC IBERIA, S.L. BOEHRINGER INGELHEIM, S.A. BRISTOL-MYERS SQUIBB, S.A.
C - G	+
H - L	+
M - R	+
S - Z	+

Code References

[Code Reference Art.: 18](#)

SELF-REGULATION SYSTEM CODE OF PRACTICE COLLABORATIONS DOCUMENTATION

Transparency with all Stakeholders

<http://www.codigofarmaindustria.org>

www.codigofarmaindustria.org/servlet/sarfi/home.html

EDUCATIONAL AND SCIENTIFIC MEETINGS
Pharmaceutical industry guidelines for the collaboration with Healthcare Organizations educational and scientific meetings.
[Access to the list](#)

PHARMACEUTICAL INDUSTRY COLLABORATIONS
Pharmaceutical Industry collaboration with Patient Organizations, Healthcare Professionals and Healthcare Organizations.
[More information](#)

MEDIATION AGREEMENTS
Mediation Agreements reached before the Code of Practice Committee.
[Access to the list](#)

ADVERTISING JURY RESOLUTIONS
Resolutions issued by Autocontrol Advertising Jury (Spanish advertising self-regulation organisation).
[Access to the list](#)

ACTIVITY OF THE CODE OF PRACTICE (COP) SURVEILLANCE UNIT

		2004	2005	2006	2007	2008	2009 (a)	2010	2011 (b)	2012	2013	2014	2015	2016	TOTAL
		Apr.-Dec	Jan.-Dec	Jan.-Dec	Jan.-Dec	Jan.-Dec	Jan.-Dec	Jan.-Dec	Jan.-Dec	Jan.-Dec	Jan.-Dec	Jan.-Dec	Jan.-Dec	Jan.-Sept	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

 C/ María de Molina 54, 7ª planta
E - 28006 Madrid

 Tel.: +34 91 745 20 50

 Fax.: +34 91 745 04 08

 usd@codigo.farmaindustria.es

 www.codigofarmaindustria.org

 www.farmaindustria.es



Code of Practice for the Pharmaceutical Industry



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