



PRINCIPLES OF THE SELF-REGULATION SYSTEM

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".

PREVENTION

- Control Bodies: Self-Regulation Jury, Code of Practice Committee and Code of Practice Surveillance Unit.
- Active monitoring of the Code: Communication systems for Events, Studies and Services.

TRANSPARENCY WITH ALL STAKEHOLDERS

- Publication of mediation agreements.
- Publication of all resolutions.
- Publication of all third-party Events evaluation.
- Publication of collaborations and services contracted with Patient Organisations.
- Publication of Transfers of Value to Healthcare Professionals and Healthcare Organisations.



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 REINFORCE TRUST ON THE PHARMACEUTICAL INDUSTRY UNDER THE FUNDAMENTAL PRINCIPLES OF TRANSPARENCY AND PREVENTION

ORIGIN AND EVOLUTION OF THE CODES

1991	Adoption of the EFPIA Code as Spanish Code (Adopted in 1992)	
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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

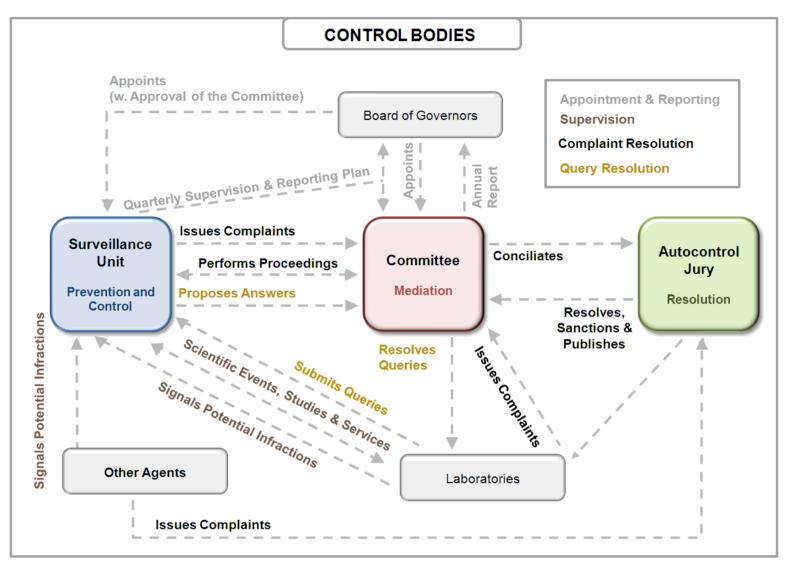


RELATIONSHIPS WITH PATIENT ORGANISATIONS





CONTROL BODIES



HEALTHCARE PROFESSIONALS CODE

3 COMMUNICATION SYSTEMS

- **□ EVENTS** (art. 11)
- **☐** STUDIES (art. 14.3)
- ☐ SERVICES (art. 16)







- **HOSPITALITY**
- Moderate and subordinated to the scientific purpose
- Exclusively to Healthcare Professionals
- **LOCATION** selected transmits an appropriate image
- TRAVEL PLANNING subordinated to the scientific purpose
- SCIENTIFIC CONTENT takes up a minimum of 60% of the working day
- SOCIAL ACTIVITIES no elements of entertainment or leisure are permitted (only welcome cocktail, work lunches and gala dinner)
- Sponsorship of companies will be stated in the articles, papers and documents pertaining thereto.

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: - 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 Regardless of rating: GOLF Hotel WINERY Hotel Hotel affiliated or sited within an AMUSEMENT PARK	NOT PERMITTED	Under no circumstance would use of these hotels be justified.			
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.

❖ ART. 11 – THRESHOLDS IN EUROPE FOR HOSPITALITY TO HCPs

EFPIA CODE ON THE PROMOTION OF PRESCRIPTION—ONLY MEDICINES TO, AND INTERACTIONS WITH, HEALTHCARE PROFESSIONALS

Art. 10.05 establishes that National Associations shall establish a threshold for hospitality.



Article 11. SCIENTIFIC AND PROFESSIONAL MEETINGS,

Adapted to the new wording of article 10 of the EFPIA HCP Code

In the context of an activity of a scientific / professional nature, a maximum cost of 60 Euro (including taxes) applies to any form of hospitality associated with meals.

For scientific nd professional meetings taking place outside of Spain, the maximum threshold established by the National Association of the country where the Event occurs will apply. Therefore, the general rule of applying the most stric or restrictive rule will not be applicable.



ART. 11 – THRESHOLDS IN EUROPE FOR HOSPITALITY TO HCPs

This information is for purely informative purposes. It is the company's responsibility to verify the current applicable thresholds set by national associations for meals & drinks in compliance with the EFPIA CODE ON THE PROMOTION OF PRESCRIPTION-ONLY MEDICINES TO, AND INTERACTIONS WITH, HEALTHCARE PROFESSIONALS (section 10.05).

AUSTRIA	75 € meal					
	40 € lunch					
BELGIUM						
	80 € dinner					
BULGARIA	100 Levs meal					
CROATIA	500 HRK meal					
CYPRUS	70 € meal					
	1.500 CZK lunch					
CZECH REPUBLIC						
	3.000 CZK day					
	DKK 400 lunch					
DENMARK	DKK 700 dinner					
	DKK 1.200 day					
ESTONIA	80 € meal					
	45 € lunch					
FINLAND	100 € dinner					
FRANCE	60 € meal					
GERMANY	60 € meal					

GREECE	70 € day
HUNGRY	5075 HUF day
IRELAND	80 € meal
ITALY	60 € meal
	60 € meal
LATVIA	100 € day
LITHUANIA	50 € meal
MALTA	60 € meal
NORWAY	822 NOK meal
POLAND	200 PLN meal
PORTUGAL	60 € meal
	150 RON meal
ROMANIA	300 RON day

RUSSIA	Only by buffet
SERBIA	50 € meal
SLOVAKIA	75 € lunch 75€ dinner 100 € day
SLOVENIA	60 € meal
SPAIN	60 € meal
SWEDEN	250 SEK lunch 700 SEK dinner
SWITZERLAND	150 CHF meal
THE	75€ meal
NETHERLANDS	225€ year
TURKEY	60 € meal
UK	£75 meal
	300 UAH meal
UKRAINE	570 UAH day

ART. 33 PROCEDURE FOR COMMUNICATING EVENTS AND SCIENTIFIC MEETINGS

The communication of activities within the scope of article 11.8 of the Code must be notified by the pharmaceutical company, through the person(s) responsible for communicating scientific and professional meetings.

Prior notification shall be compulsory when the following circumstances cocur:

- that they are organised directly or indirectly or sponsored exclusively or in the majority – by the reporting company;
- they include at least one overnight stay; and
- they involve the participation of at least 20 Healthcare Professionals practicing in Spain.

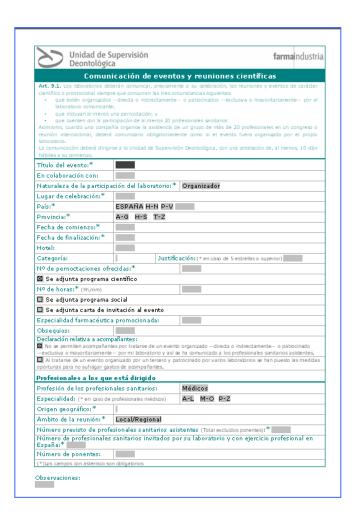
Prior notification shall be compulsory when the company organises attendance of a group over 20 Healthcare Professionals practicing in Spain to a meeting organised by a third party. If such meeting is available in the third-party event database of Farmaindustria's website, prior notification will not be compulsory.

Voluntary prior notifications may be provided.

ART. 33 PROCEDURE FOR COMMUNICATING EVENTS AND SCIENTIFIC MEETINGS

- Deadline for prior notification to the Surveillance Unit: 10 working days before its beginning.
- Electronic Procedure
 - o E-mail
 - Self-Regulation Website
- Information to be Provided: Company, nature of the participation, name of the meeting, HCPs to whom it is directed, Nr. Of HCPs invited, venue and dates, scientific programme, social programme and parallel activities, other entities involved in the organisation and sponsorship.

The Surveillance Unit will have five working days from receit of the report to make any pronouncements on international Events that, according to the stipulations of article 11.10(b) of the Code, require previous authorization.



NAME, ORGANISER, COLABORADORES,...

VENUE, LOCATION, DATES, ...

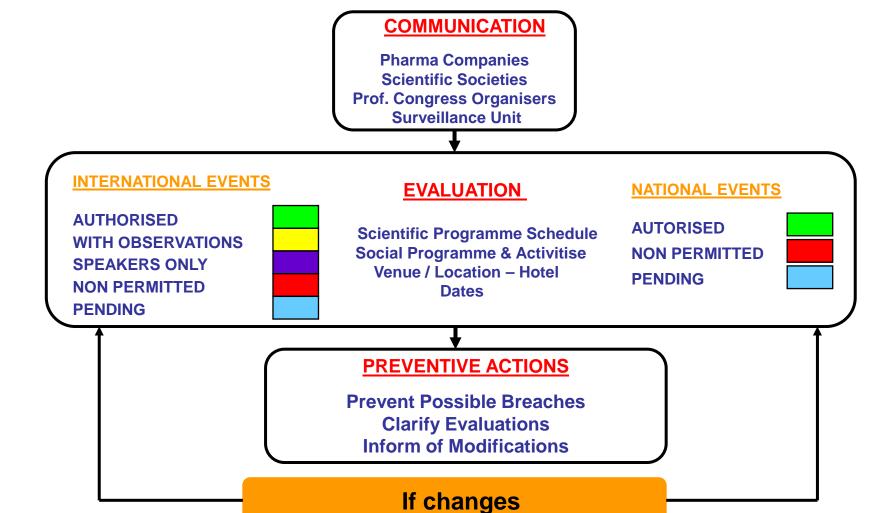
HOTEL, RATING, Nr OF OVERNIGHT STAYS...

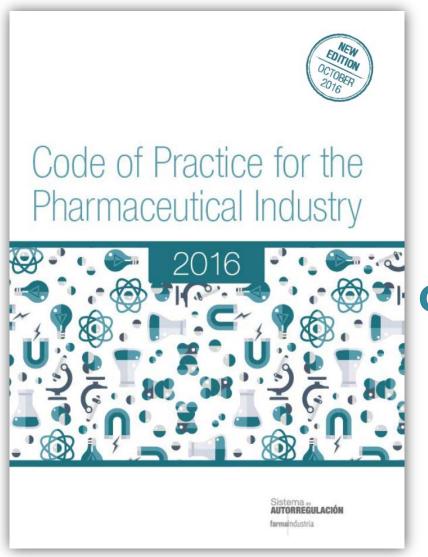
ATTACHMENTS: SCIENTIFIC PROGRAMME, SOCIAL PROGRAMME, WELCOME LETTER, NO ACCOMPANYING PERSONS DECLARATION,...

Nr AND ORIGIN OF THE PARTICIPATING HCPs, SPECIALITY, SCOPE OF THE MEETING,...



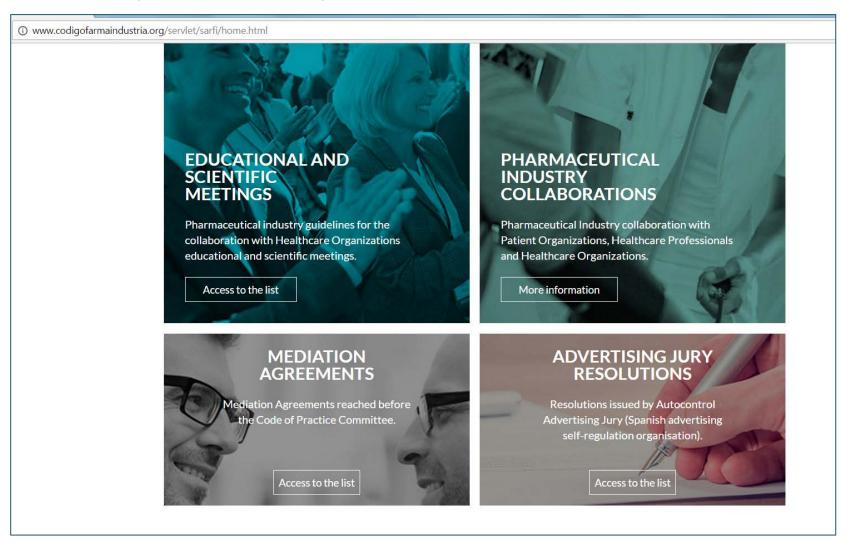
EVALUATION PROCESS

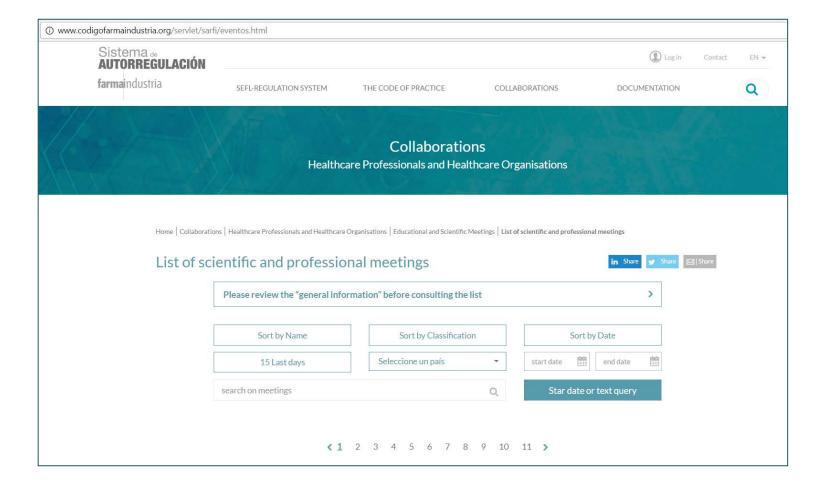




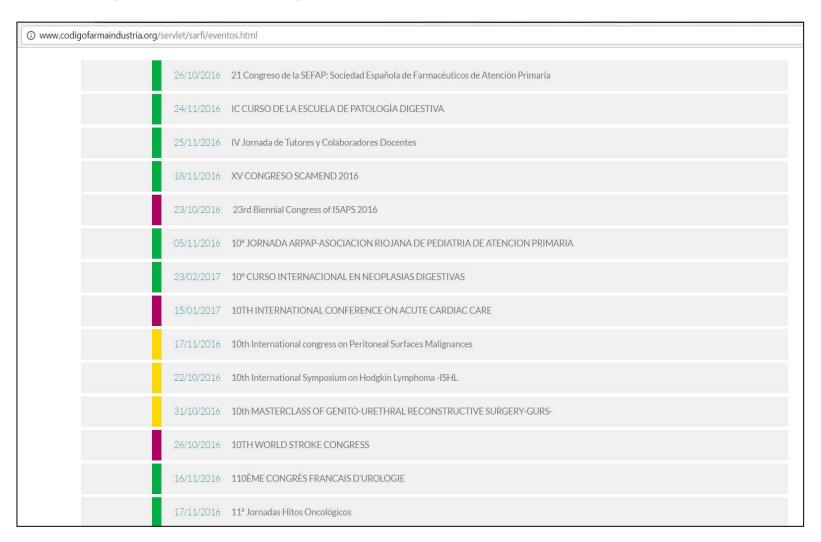
Third-Party Events Database of the Spanish Association of the Pharmaceutical Industry













- The listing of scientific and professional meetings organised by a third party (scientific and medical societies, professional organisations, etc.) provides guidance to be taken into account by Farmaindustria member companies and the laboratories affiliated to the Codes of Good Practice.
- ➤ It is pharmaceutical companies that freely decide to participate in an event, always taking the Code into consideration when acting as sponsors.
- The observations express the views of the Surveillance Unit exclusively regarding those secondary and accessory elements/aspects related to its organisation (for example: venue, dates, prevalence of scientific activities, etc.) and their compliance with the provisions of the Code for hospitality and meetings.
- The observations provided by the Surveillance Unit in relation to events cannot, under any circumstance, be interpreted as a judgement on the quality or content of the scientific programme, or on the quality of the speakers.
- The listing consists of all those scientific events organised by a third-party for which the laboratories have requested their classification by the Surveillance Unit. Only those pending on celebration are listed.

EVENT DATABASE: OBSERVATIONS

OBSERVATIONS	CODE	QUERIES
Accompanying Persons	Article 11.3	46, 51, 72
Entertainment events (golf tournament, tennis, cruise, other)	Article 11.1	13, 45, 48, 51,
	Article 11.2	68, 74, 77
Social events	Article 11.1	13, 45, 48, 50,
	Article 11.2	51, 63, 66, 68, 74
Scientific programme unavailable with less than one month before its beginning for national events or two months before its beginning for international events	Article 11	
Hospitality offered must be adjusted to the duration of the scientific content of the meeting	Article 11.2	46, 66
Location	Article 11	16, 45, 47, 49,
		52, 55, 56, 57, 71, 77
Do not install stands, do not use lounges or installations to carry out any type of activity (symposia, conferences, seminars, lunches, etc.), nor accommodate healthcare professionals	Article 11.1 Article 11.2	54, 55, 71, 76
n: 5* hotels (under 200 healthcare professionals attending), 5* superior, 5* luxury, 5* grand	Article 11.2	
uxury, sports resorts, theme parks, wine hotels.		
Non promotion due to the nature of the program content	Article 7	
Pending	Article 11	
Pending on scientific programme	Article 11	
Extra overnight stay	Article 11.2	46, 66
Leisure and entertainment aspects prevail against scientific	Article 11.2	45, 51, 63, 66,
		74, 77
Please support exclusively the participation of healthcare professionals, exercising in Spain, attending the meeting as speakers	Article 11.2	
Please ensure the attendance of healthcare professionals to planned scientific sessions	Article 11.2	74
Venue: 5* hotels (under 200 healthcare professionals attending), 5* superior, 5* luxury, 5*	Article 11.1	54, 55, 71, 76
grand luxury, sports resorts, theme parks, wine hotels	Article 11.2	
As it is a meeting in which predictably people other than healthcare professionals will	Article 7.1	
participate, please adopt the necessary measures to avoid carrying out any promotional activity related to prescription-only medicines directed to the general public		
Do not exceed the established limit of 60 euro (tax incl.) per person in any form of hospitality associated with meals in Spain	Article 11.1	50
Do not exceed the monetary threshold set by the relevant Member Association (holding the event) in its national Code, in any form of hospitality associated with meals (food and beverages)	Article 11.1	50



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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
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).
NONE	 Extending hospitality to persons other than healthcare professionals. Permitting or facilitating presence of accompanying persons, even if they pay for their own expenses.
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.
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.
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).
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.
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
	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. 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. Designed in accordance with the scientific nature of the meeting. Ease of travel for the participant, cost, appropriateness and appearance/reputation of the city are taken into account when selecting a location. 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. 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

GENERAL STANDARDS APPLICABLE IN SPAIN TO SCIENTIFIC AND PROFESSIONAL MEETINGS

	TABLE II.	
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 Healthcare Professionals.	nt from
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 he professionals (accompanying persons). Offering out of proportion or excessive (i): (for example: massages), (ii) food and be (for example: alcoholic drinks, etc.). Directly or indirectly promoting prescription medicines. 	services everages don-only
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 population advantage (in cash or benefit in kind) healthcare professional. In meetings where promotion mainly pertains to related to the practice of prescription-only medicines, offering or promising a gift or population advantage (in cash or benefit in kind) healthcare professional. In meetings where promotion mainly pertains to redictine prescription-only medicines, offering or promising a gift or population professional. 	tains to roviding dicine or congress
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 i medical utility with a market value over 60€. The transmission of informational or educational materials and i medical utility with a market value over 60€. The transmission of informational or educational materials and i medical utility with a market value over 60€. The transmission of informational or educational materials and i medical utility with a market value over 60€. The transmission of informational or educational materials and i medical utility with a market value over 60€. The transmission of informational or educational materials and i medical utility with a market value over 60€. The transmission of informational or educational materials and its medical utility with a market value over 60€. The transmission of informational or educational materials and its medical utility with a market value over 60€. 	ducation onstitute urchase,

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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ACTIVITY OF THE CODE OF PRACTICE (COP) SURVEILLANCE UNIT

ACTIVITY OF THE CODE OF PRACTICE (COP) SURVEILLANCE UNIT																
		200 4 AprDec	2005 JanDec	2006 JanDec	2007 JanDec	2008 JanDec	2009 (a JanDec	2 010 JanDec	2011 (b) JanDec	2 012 JanDec	2013 JanDec	2014 JanDec	2015 JanDec	2016 JanDec	2017 JanDec	TOTAL
SCIENTIFIC AND	ANALYSED	945	1.747	2.199	2.926	3.388	3.878	5.080	5.335	5.003	4.954	5.566	5.337	5.382	5.377	57.117
PROFESSIONAL	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	5.110	5.064	51.276
MEETING	% 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%	94,95%	94,18%	87,81%
STUDIES	ANALYSED No Incidents						687 397	724 546	626 565	512 416	400 332	449 368	300 251	317 280	293 271	4.308 3.426
(a)	% Adapted	-					57,79%	75,41%	90,26%	81,25%	83,00%	81,96%	83,67%	88,33%	92,49%	80,21%
SERVICES	ANALYSED								357	330	306	350	368	363	364	2.438
SERVICES	No Incidents	-							282	272	230	292	301	274	321	1.972
(1-7)	% Adapted								78,99%	82,42%	75,16%	83,43%	81,79%	75,48%	88,19%	79,55%
PREVENTIVE AC	CTIONS	814	1.801	1.376	2.092	2.440	2.670	3.482	3.131	2.488	2.112	2.180	2.138	1.483	1.674	29.881
USD COMPLA	INTS	18	11	9	18	8	12	4	3	1	9	7	7	2	3	112

^{* 7} cases resolved in Court

^{* 6} Final rulings from the Self-Regulation Panel in favour of the USD

^{* 85} Resolved by mediation before the Deontology Committee with the infringement acknowledged and corrective measures accepted

^{* 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, 7º planta
 E - 28006 Madrid

🏝 Tel.: +34 91 745 20 50

昌 Fax.: +34 91 745 04 08

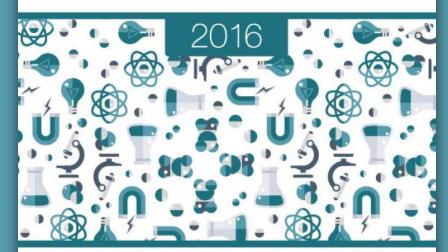
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Code of Practice for the Pharmaceutical Industry



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