

The Latin American

Pharmaceutical Regulatory and Compliance Congress

and Best Practices Forum



Global Compliance Codes Roundtable

European Codes

José F. Zamarrigo Izquierdo

Spanish Code Surveillance Unit

Farmaindustria (Spain)



The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the pharmaceutical industry operating in Europe.

33 national associations, 35 leading pharmaceutical companies, EBE, EVM.

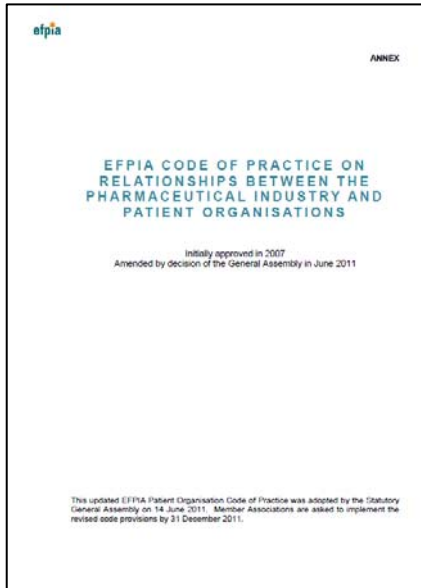
Ethics:



EFPIA Code on the Promotion of prescription-only medicines to, and interactions with, Healthcare Professionals

1. Marketing authorization
2. Information to be made available
3. Promotion and its substantiation
- 4-7. Use of Quotations, Acceptability, Distribution & Transparency of Promotion
9. Events & Hospitality
10. Gifts
11. Donations & Grants
12. Fees for Service
13. Sponsorship of HCPs
14. Consultants
15. Non-Interventional Studies
16. Samples





EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations

1. Non-Promotion of Prescription-Only Medicines
2. Written Agreements
3. Use of Logos & Proprietary Materials
4. Editorial Control
5. Transparency
6. Contracted Services
7. Single Company Funding
8. Events & Hospitality

ANNEX B (guidelines)



GUIDELINES FOR INTERNET WEBSITES AVAILABLE TO HEALTHCARE PROFESSIONALS, PATIENTS AND THE PUBLIC IN THE EU



Evaluation of Events	
New Event	
Event Selection	
EFPIA HCP Code	
National Associations Codes	
<input type="checkbox"/>	AUSTRIA
<input type="checkbox"/>	BELGIUM
<input type="checkbox"/>	BULGARIA
<input type="checkbox"/>	CROATIA
<input type="checkbox"/>	CYPRUS
<input type="checkbox"/>	CZECH REPUBLIC
<input type="checkbox"/>	DENMARK
<input type="checkbox"/>	ESTONIA
<input type="checkbox"/>	FINLAND
<input type="checkbox"/>	FRANCE
<input type="checkbox"/>	GERMANY
<input type="checkbox"/>	GREECE
<input type="checkbox"/>	HUNGARY
<input type="checkbox"/>	IRELAND
<input type="checkbox"/>	ITALY
<input type="checkbox"/>	LATVIA
<input type="checkbox"/>	LITHUANIA
<input type="checkbox"/>	MALTA
<input type="checkbox"/>	THE NETHERLANDS
<input type="checkbox"/>	NORWAY
<input type="checkbox"/>	POLAND
<input type="checkbox"/>	PORTUGAL
<input type="checkbox"/>	ROMANIA
<input type="checkbox"/>	SERBIA
<input type="checkbox"/>	SLOVAKIA
<input type="checkbox"/>	SLOVENIA
<input type="checkbox"/>	SPAIN
<input type="checkbox"/>	SWEDEN
<input type="checkbox"/>	SWITZERLAND
<input type="checkbox"/>	TURKEY
<input type="checkbox"/>	UNITED KINGDOM

e4ethics - Educational Events & Ethical Evaluation Event Listing	
Order by: Name Organiser Speciality Date Country 15 Last Days	
06/03/2013	10th Annual ENETS Conference
19/09/2013 ESG	10th Congress of the European Society of Gynecology
30/09/2012 ILAE	10th European Congress on Epileptology
06/09/2012 EANO	10th meeting of European Association of NeuroOncology
24/10/2012	11th Congress of the European Federation of Internal Medicine (EFIM)
11/11/2012	11th International Congress on Drug Therapy in HIV Infection
06/09/2012 EURETINA	12th EURETINA Congress
26/10/2012	12th SIOG International Congress
14/10/2012	14th Annual Meeting of the International Society of Addiction Medicine (ISAM)
16/10/2013	14th European AIDS Conference
03/10/2012 ESID	15th Biennial Meeting of the European Society for Immunodeficiencies (ESID 2012)
12/09/2012	15th Congress of the European Neuroendocrine Association
06/12/2012 ESSM	15th Congress of the European Society for Sexual Medicine
27/04/2013	15th European Congress of Endocrinology (ECE 2013)
23/09/2012 EFB	15th European Congress on Biotechnology of the European Federation of Biotechnology (ECB 15)
22/11/2012	16th Annual Meeting of the European Society of Surgery (ESS 2012)
08/09/2012 EFNS	16th Congress of the European Federation of Neurological Societies
08/11/2012	17th Controversies in Obstetrics, Gynecology and Infertility (COGI)
13/03/2013 EAHP	18th Congress of the European Association of Hospital Pharmacists
05/10/2013 ESGO	18th International Meeting of the European Society of Gynaecological Oncology (ESGO)
09/09/2012	18th International Pathogenic Neisseria Conference
22/05/2013	1st Global Conference on Contraception, Reproductive and Sexual Health
12/05/2013	20th European Congress on Obesity (ECO 2013)

Transparency initiative

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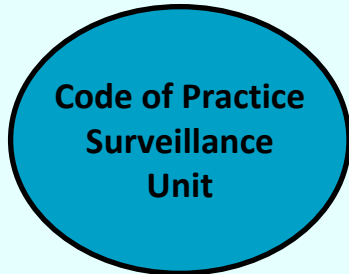
ASSOCIATES

	National	International
Large	7	25
Medium	6	24
Small	71	51
Total	84	100



Spanish Pharma Market: 20 Bill. \$

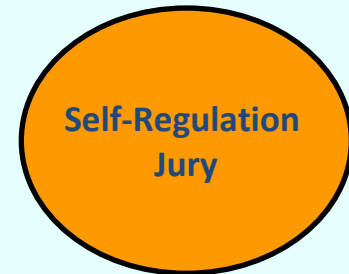
CONTROL BODIES



ACTIVE
MONITORING



SEEKS FOR
CONCILIATION



RESOLVES
AND
PUBLISHES

COMMUNICATION SYSTEMS

EVENTS

Launched 2004
25,498 analysed

STUDIES

Launched 2009
626 analysed

SERVICES

Launched 2011
357 analysed

SANCTIONS

Minor infringements

6,000 to 120,000 euros

Serious infringements

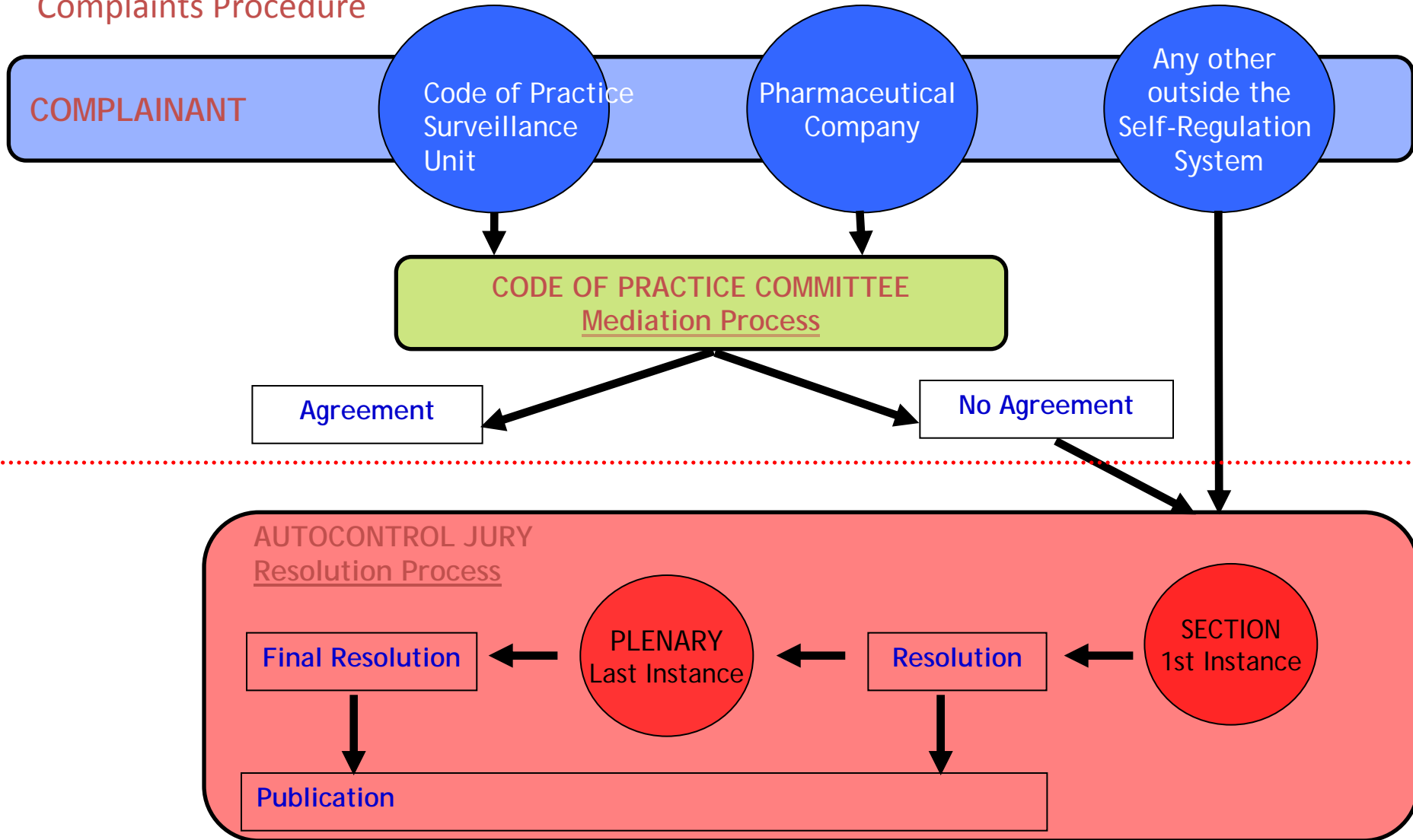
120,001 to 240,000 euros
Reporting to Healthcare
Authorities
Expulsion from
Farmaindustria

Very serious infringements

240,001 to 360,000 euros
Reporting to Healthcare
Authorities
Expulsion from
Farmaindustria

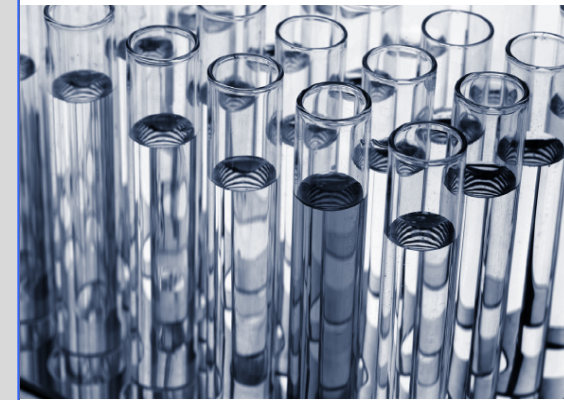
EFPIA: Implementation & Enforcement in Spain

Complaints Procedure





Código Español de Buenas Prácticas
de Promoción de Medicamentos
y de Interrelación de la Industria Farmacéutica
con los Profesionales Sanitarios



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UNIDAD DE SUPERVISIÓN DEONTOLÓGICA

Serrano 116

E - 28006 Madrid

Tel. +34 91 7452050

Fax +34 91 7450408

usd@codigo.farmaindustria.es

www.farmaindustria.es

CÓDIGO ESPAÑOL
DE **BUENAS PRÁCTICAS**
DE INTERRELACIÓN
DE LA **INDUSTRIA**
FARMACÉUTICA CON
LAS ORGANIZACIONES
DE **PACIENTES**