

Medicines Promotion

The Catalan Experience

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Generalitat de Catalunya
Departament de Salut

Spain: socio-demographic characteristics

17 Autonomous Communities

Area: **504,750 km²**

Population (2011)¹: **47,213,000**

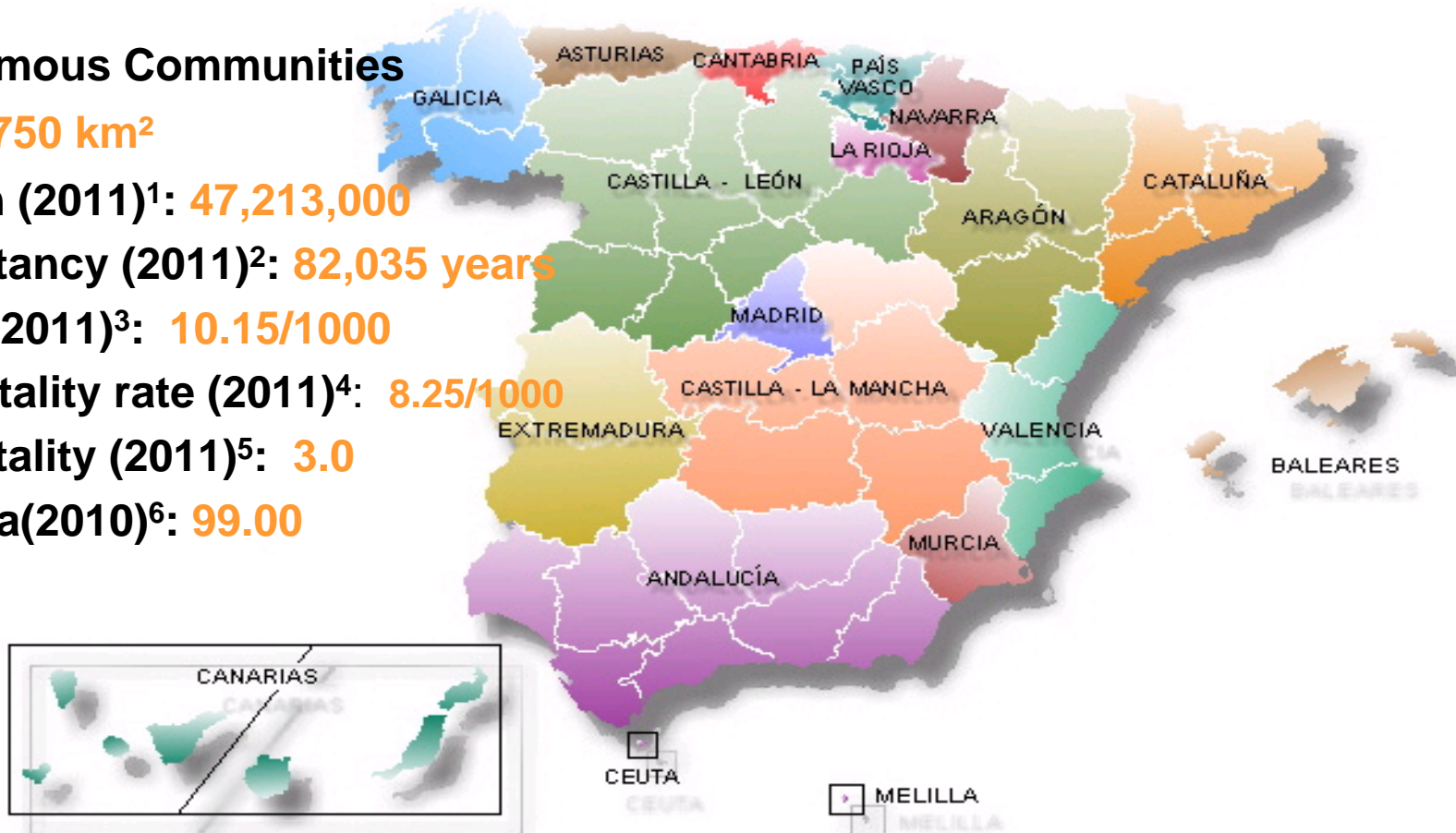
Life expectancy (2011)²: **82,035 years**

Birth rate (2011)³: **10.15/1000**

Gross Mortality rate (2011)⁴: **8.25/1000**

Infant mortality (2011)⁵: **3.0**

GDP/Capita(2010)⁶: **99.00**



(1) Municipal Register 01/01/2009 INE /INS National Institute of Statistics

(2-6) Eurostat (UE 27=100)



Health System Decentralization

Central Government

- **Basic legislation and coordination**
- Financing
- Minimum package funded through NHS
- **Pharmaceutical policy**
- International health policy
- Educational requirement



Autonomous Government

- **Subsidiary legislation**
- Public health
- System's organizational structure
- Accreditation and planning
- Purchasing and service provision
- **Execution of pharmaceutical products legislation**



Generalitat de Catalunya
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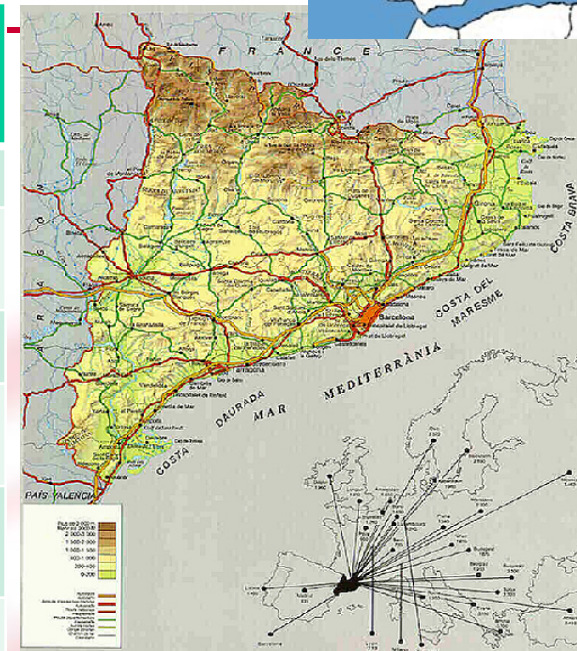
Devolution process to AA CC



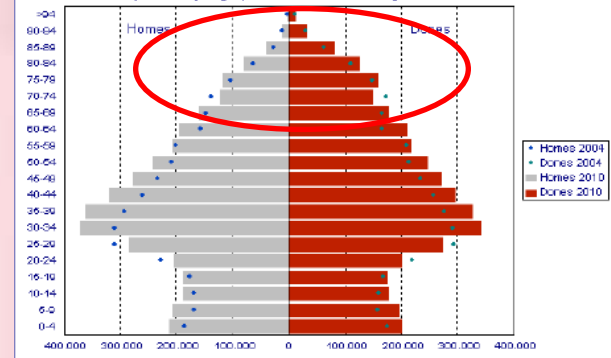
Catalonia: short profile



Geographic location: North-east corner of the Iberian Peninsula	Official languages: Catalan, Spanish and Aranese
Capital: Barcelona	Climate: Mediterranean
Surface area: 32,107 km ²	Natural spaces: 17 natural parks
Population: 7,565,603 inhabitants (2012)	
Population density: 231.5 hab/km ² (2011)	2/3 live in metropolitan area
GDP: 197,919 millions of euros (2010)	18% of Spanish GDP
Immigration rate: 15.7% (2011)	
Expectancy of life: 82,3 years (2010)	Men: 79,2 Women: 85,2
Population ≥ 65 years: 16,5%	
Healthcare system: universal coverage	Medicines reimbursement: Copayment (recent)



Distribució de la població per grup d'edat i sexe. Catalunya 2004 i 2010



Pharma: some figures



- Pharmaceutical industry
 - 260 laboratories. 91 manufacturers (50% of Spain)
 - 75% SMEs; 77,2% local capital
 - 21.200 workers: 55% Spanish pharma sector; 0,7% workforce in Catalonia
 - 58,2% Spanish production; 3,5% european production(N, D, S)
- Fine chemicals industry
 - 61 API manufacturers
 - 2/3 Spanish production; 80% for export
- Medical device industry
 - 360 manufacturers and importers; 50% Spain
 - Aprox.15.000 workers
 - Overall turnover 4.000 M€; 15% export
- Cosmetics Industry
 - 550 manufacturers and importers; 60% Spain
 - Aprox 13.000workers
 - Overall turnover >3.000 M€



Drug Promotion Control



Purpose

- Ensuring health protection right
- Promoting rational use of medicines
- Ensuring rigorous information: objective, not exaggerated, well founded and adjusted to the SCP
- Ensuring information is not misleading or unfair
- Ensuring consistency through EU market

Legal framework ⁽¹⁾

- General Health Act (1986)
- General Advertising Act (1988)
- 29/2006 Act (July 26th), of guarantees and rational use of medicines and health products

Legal framework (2)

- Royal Decree **1416/1994** Regulates medicines promotion, amended by 109/2010 Royal Decree
- Directorate General for Pharmacy and Health Products Notices (6/95, 7/99)
- Interterritorial Council of the Spanish National Health Service Agreement (1996)
- Royal Decree 1345/2007, which regulates the authorization procedure, registration and conditions of supply of medicinal products for human use manufactured industrially
- AEMPS Instruction (2007)

Guía para la
PUBLICIDAD de
medicamentos
de uso HUMANO



Generalitat de Catalunya
Departament de Salut

Guidelines
Since 1995
3rd edition 2009

Departament de Salut

Departament

Serveis i tràmits

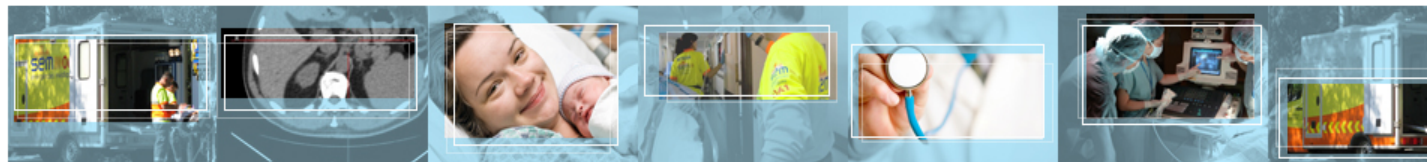
Àmbits d'actuació

Per perfils

- ▶ Ciutadania
- ▶ Professionals
- ▶ Entitats prestadores de serveis
- ▶ **Empreses i establiments**
- ▶ Ens locals
- ▶ Centres educatius

Línies d'actuació

- ▶ Salut i qualitat
- ▶ Model assistencial
- ▶ Recerca
- ▶ Escenaris de sostenibilitat i progrés
- ▶ Tecnologies de la informació i la comunicació



[Inici](#) > [Àmbits d'actuació](#) > [Per perfils](#) > [Empreses i establiments](#) > [Empreses farmacèutiques](#) > [Medicaments](#) > Promoció i publicitat

Promoció i publicitat

- ▶ **Guia per a la publicitat de medicaments d'ús humà** [PDF,308,13 KB.]
Aquest document és una eina que facilita l'aplicació de la legislació sobre publicitat de medicaments d'ús humà a Catalunya, i contribueix a obtenir una publicitat de qualitat, de conformitat amb els interessos de salut pública que concorren en aquesta matèria.
- ▶ **Comunicació de publicitat de medicaments d'ús humà**
- ▶ **Preguntes i respostes sobre publicitat de medicaments d'ús humà** [PDF,48,46 KB.]
- ▶ **Model d'Informe del Servei Científic** [PDF,15,86 KB.]

Magada 0 Tweet 0 +1 0

Data d'actualització: 07.02.2013



FAQs



Butlletin

New

Drug Promotion Control



What do we control?

- Systematic review
 - Submissions
 - Advertising in publications
 - websites
- Processing reported cases of breach and files
- Material collected from sentinel PC centers and hospitals

Control Criteria (1)



All materials are reviewed verifying:

- Material suitability (SPC, valid support, ...)
- Approved and marketed drug
- Indications authorized
- Main promotional claims
- Date of elaboration
- Incentive relevant to professional practice
- Value of Incentives (negligible)

Control Criteria (2)



20% materials submitted (sampling)

- Objective information, no exaggerations
- References, quotes and charts are faithful reproductions; adaptations not allowed
- Absolute terms of efficacy, safety, quality avoided
- comparative advertising made correctly



Control Criteria (3)

Specialized press

- Advertisements
- Minimum required information

MAH websites

- Institutional promotion
- Links & banners
- Information about medicines
- Information to the public
- Warnings for non professionals

Drug Promotion Control



Current activity (2012)

- 4,500 submissions corresponding to
 - 3,000 different advertising materials
 - 1,200 sponsoring activities
 - Valid support (including websites)
- 50 orders of withdrawal or amendment of advertising material
- 3 penalty proceedings
- 6-8 daily consultations

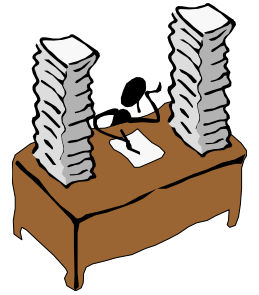
Breaches

 Formal issues

 Content aspects



Formal issues (1)



- Diffusion without prior notification
- Lack of administrative data
- Lack of documentation
- Submission unclear
- Valid support: confounding conception
- Skipping date of preparation or revision

Formal issues (2)

- Reminder advertising content
- Lack of the Scientific Service Report
- Lack of minimum content
- Incentive not relevant to professional practice
- Publishers / valid supports



Content aspects (1)

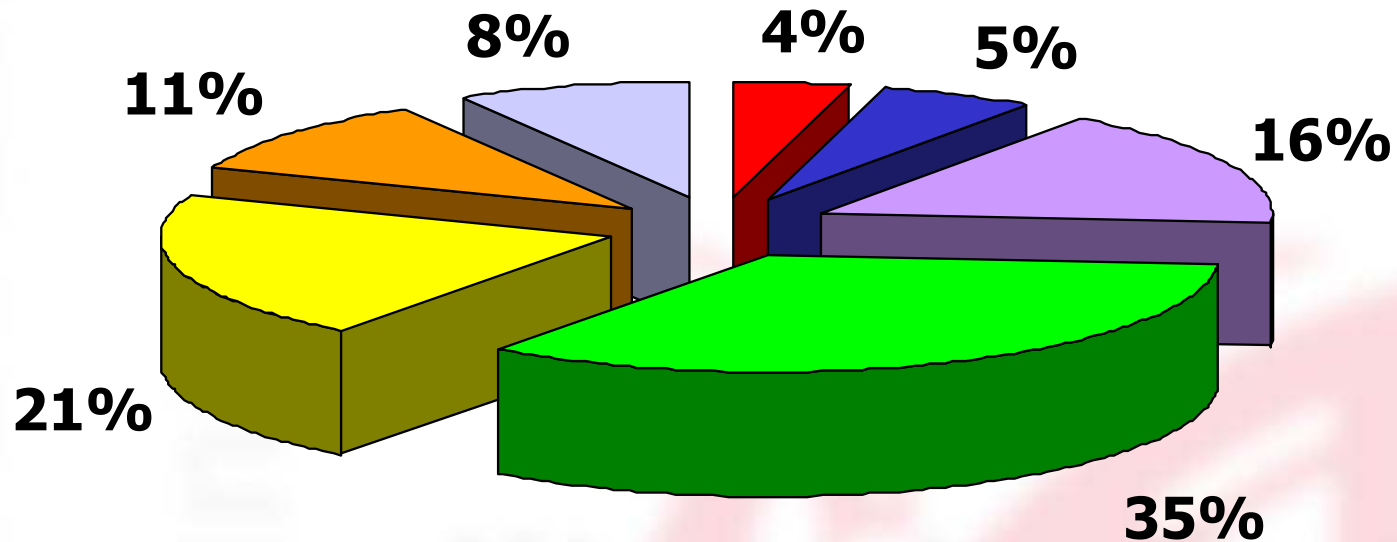
- Published studies, not being quoted exactly nor faithfully
- Exaggerated statements/claims
- Lack of quotations from medical and scientific literature
- Statements/claims not adjusted to SPC



Content aspects (2)

- Promoting not approved indications
- Skipping relevant information
- Comparative advertising out of fair competition
- Contents of the Product Website

Breaches incidence



- **Penalty proceedings**
- **Valid Supports**
- **Information not adjusted to SPC**
- **Advertising unsubmitted**
- **Unadequate Incentives**
- **Prescription drugs advertising to the public**
- **Incorrect literature references**



Spanish Code of Good Practices
for the Promotion of
Medicines and Interaction
with Healthcare Professionals

farmaindustria



UNIDAD DE
SUPERVISIÓN
DEONTOLÓGICA



Spanish Code of Good Practices for the Promotion of Medicines and Interaction with Healthcare Professionals

Purpose

- Guarantee that promotion of medicines for human use as well as interactions with the healthcare professionals are carried out in the respect of the strictest ethical principles of professionalism and responsibility
- Information to healthcare professionals complete, up-to-date and accurate
- Contribute to strengthening confidence in the pharmaceutical industry

Farmaindustria Code

- Scope
 - Farmaindustria members
 - Adhered to the Code companies
 - IFPMA members



Ethics codes

- **Common Basic Ethical Rules**

- legality
- decency
- honesty
- veracity
- good taste
- identification

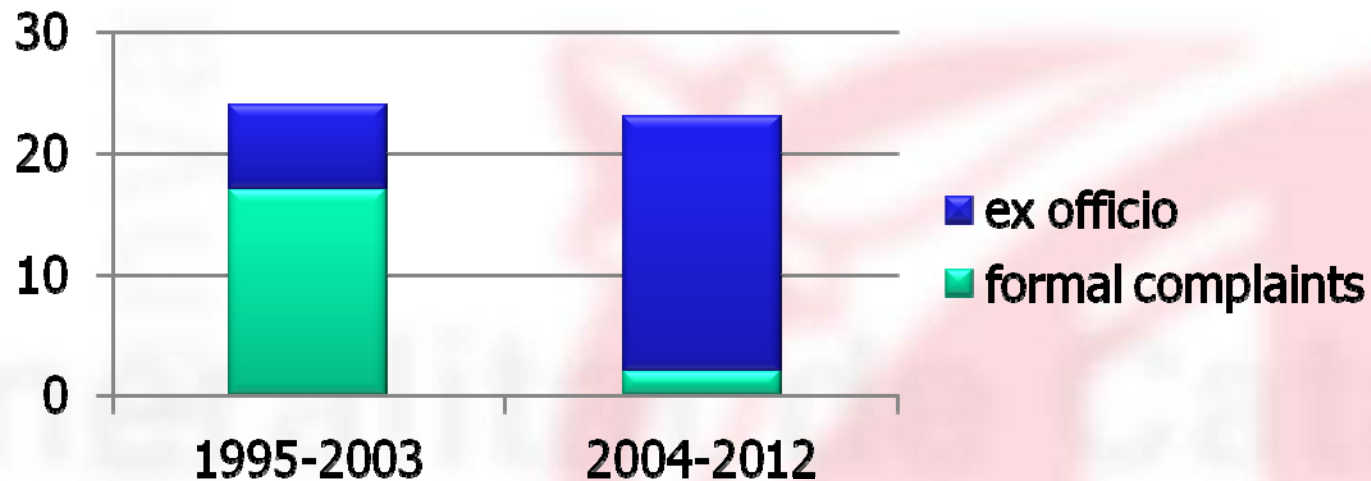


Beyond the law

Implementation of the Code



- Penalty proceedings: Reduction in the number of formal complaints against competitors




- Reinforcing messages about the validity of certain promotional activities

30/11


RELATED INFORMATION

Presentaciones de las Jornadas "Profundización en el sistema de autorregulación: Código 2010"

 3 Dec 10







 21 Oct 09

AGREEMENTS


USD. vs. ANGELINI FCA., S.A.

 14 Dec 12

GILEAD, S.A. vs. JANSSEN CILAG, S.A


 4 Dec 12

USD vs BIAL


 19 Dec 11

RESOLUTIONS


FERRING S.A.U. vs. BIAL INDUSTRIAL FARMACEÚTICA SPAIN, S.A. ("Misofar®")

 7 Apr 11

FERRING S.A.U. vs. Shire Pharmaceuticals Ibérica, S.L. "Mezavant®"

 8 Mar 12

MERCK SHARP & DOHME DE ESPAÑA, S.A. vs. ASTELLAS PHARMA, S.A - Actividad promocional Mycamine®.

 24 May 12

Revisión de la Declaración sobre las relaciones entre los médicos...
12/10/09

The most recent

LABORATORIOS SALVAT, S.A.
04/22/13

NOVARTIS FARMACEUTICA S.A.
04/17/13

SANOFI - AVENTIS, S.A.
04/15/13

BRISTOL-MYERS SQUIBB, S.A.
04/11/13

MERZ PHARMA ESPAÑA, S.A.
04/05/13

ROCHE FARMA, S.A.
04/04/13

Complementary systems



What do they cover



- Advertising and promotion
 - To the public
 - To professionals
 - Medical representatives
 - Free samples
 - sponsorships of scientific or professional meetings/congresses
- Studies and clinical trials

Furthermore...

- All forms of interaction between the Pharmaceutical companies and
- Healthcare professionals
 - Including collaborations, Consulting,...
- Patient organizations

Complementary systems



- Scope
 - Universal
- Mandatory
- Slower reaction time
- Longer time to solve procedures
- Difficult updating
(1994)

- Scope
 - Limited
- Voluntary
- Faster reaction time
- Shorter time to solve procedures
- Easier updating
(2002-04-05-07-08)

Advertising and promotion

Permanence

- Principles
 - Ethics
 - Control
- Legal framework
 - Stable



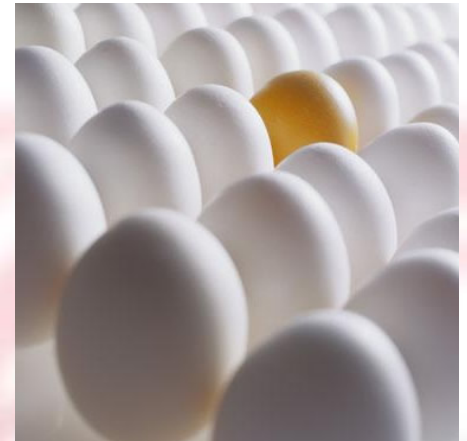
Adaptation

- Creativity:
 - Continuous evolution
 - New ways to do
- Criteria
 - Adaptive to trends
 - Consistent



Evolution trend examples

- Strategies for reaching the patient
 - DTC unbranded
 - Call centers
 - Product websites
 - Social media
- Information *vs* promotion
 - Premarketing
 - New forms of relationship and sponsoring
 - Publicity, generating opinion



Conclusion

- Complementary systems
- Nonexclusive systems
- Need for ongoing evolution



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