EFPIA Codes
Transparency International

Author: Julie Bonhomme  *  Date: June 2016  *

Presentation
EFPIA Mandate

“The aim of the European Federation of Pharmaceutical Industries & Associations is to promote pharmaceutical discovery and development in Europe and to bring to the market medicinal products in order to improve human health worldwide.”

EFPIA, which has no profit-making purpose, pursues a mainly scientific aim, ensuring and promoting the technological and economic development of the pharmaceutical industry in Europe.

EFPIA’s represents the pharmaceutical industry operating in Europe. Its direct membership includes 33 national associations and 41 leading companies. Two specialised groups within EFPIA represent vaccine manufacturers – Vaccines Europe - VE, with 12 member companies and European/emerging bio-pharmaceutical companies – EBE with 55 member companies.

“Partners in Research” is constituted of non-pharma companies that collaborate in the IMI public-private membership. This constituent entity, created in June 2014, counts 13 members.
Legitimate collaboration

“The R&D-based pharmaceutical industry is committed to working in partnership with all stakeholders to improve healthcare across Europe. The creation of new or improved medicines relies upon the collaboration between healthcare professionals and the pharmaceutical industry.

Industry is conscious of the importance of providing accurate, fair and objective information about its medicines to allow rational decisions to be made about their use.

In the same spirit, industry is committed to working towards greater transparency, accountability and ethical behaviour within an industry framework of self-regulation, which has been successful in protecting clinical independence but the expectations are increasing and we need to keep up with these.

Therefore, EFPIA will continue to develop additional guidance around areas where industry’s credibility is engaged.”
Working together for patients

Collaboration between industry and health professionals benefits patients. It is a relationship that has delivered numerous innovative medicines and changed the way many diseases impact on our lives.

Industry and health professionals collaborate in a range of activities from clinical research to sharing best clinical practice and exchanging information on how new medicines fit into the patient pathway:

- Advisory Boards
- Medical Education
- Consultancy
- Media activity
- Speaking at or Chairing meetings
Key ethical principles – *Work in progress*

- **We keep patients at the heart of what we do**
  - Provide access to high quality medicines and appropriate care

- **We act with integrity**
  - We are accountable for our decision, action and interaction

- **We act with respect**
  - Sensitivity to social diversity – Support an independent decision making – Mutual acknowledgement of stakeholders’ ethical standards

- **We are transparent about our actions**
  - We believe in what we do
Legal & Self-regulatory background

Legal background
- National law & regulations

Self regulation background
- Code of Conduct for the Promotion of Medicines (1992)
  - Guidelines for Internet websites (2001 - incorporated to the HCP Code in 2007)
- Joint Declaration between CPME and EFPIA (2005)
- Pre-assessment Platform e4ethics (2012)
- Principles for Responsible Clinical Trial Data Sharing – joint PhRMA-EFPIA Principles (2013)
The subsidiarity principle applied to self-regulation

**EFPIA Codes set general standards**
National standards may be stricter
Code compliance is a membership obligations

**Member Associations**
Member Associations are required to transpose the EFPIA Code in line with national laws & regulations, and ensure enforcement in the countries

**EFPIA corporate members**
EFPIA corporate members are submitted to applicable codes in the 33 EFPIA countries where they operate, whether they have joined EFPIA’s member associations or not.
EFPIA HCP Code

EFPIA Code on the Promotion of Prescription-only Medicines to, and Interactions with, Healthcare Professionals

- Marketing authorisation
- Information to be made available – reference documents
- Promotion and its substantiation
- Use of quotations in promotion
- Transparency of promotion
- No advice on personal medical matters

- Informational & educational materials, and items of medical utility
- Events & hospitality
- Donations & Grants that support healthcare of research
- Fees for Service
- Sponsorship of HCPs
- The use of consultants
- Non-interventional studies for marketed medicines
- Medical Samples

- Prohibition of gifts
EFPIA PO Code

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

- Non-promotion of prescription-only medicines
- Written agreements
- Use of logos and proprietary materials
- Editorial control
- Transparency
- Contracted services
- Single company funding
- Events and hospitality
EFPIA Disclosure Code

What?
Payments for activities such as advisory boards, speaking and chairing meetings and consultancy

What is not covered?
Payments made for clinical trials and hospitality

Where?
The EFPIA Code covers the 28 member states of the EU plus: Norway, Russia, Serbia, Switzerland, Turkey, Ukraine

When?
Companies will disclose payments before 30 June 2016 for payments made in 2015

Why?
Disclosure of payments is about securing the basis for collaboration in the future, securing the integrity of the decision and encouraging a consistent disclosure approach

Where?
Company websites or where available, central platforms for disclosure
Disclosure Obligation

- **General Obligation**: each Member Company shall document and disclose Transfers of Value (ToV) it makes, directly or indirectly, to or for the benefit of a Recipient.

- **Excluded Disclosures**:
  - ToV solely related to OTC
  - Informational & educational materials and Items of medical utility
  - Meals & Drinks – subject to a threshold (review of HCP Code)
  - Medical Samples – subject to the “4x2” standard
  - ToV relating to purchasing and selling medicinal products

Concomitantly, when preparing the new Code, it has been advised that EFPIA should include stricter rules on hospitality and gifts. The EFPIA HCP Code includes a strict **ban on gifts**, an **hospitality threshold** and the introduction of **informational & educational materials** and **items of medical utility**.
# Disclosure Categories

<table>
<thead>
<tr>
<th>Level of Disclosure</th>
<th>Disclosure Categories</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Aggregate</strong></td>
<td><strong>Research &amp; Development</strong></td>
</tr>
<tr>
<td></td>
<td>ToV to HCPs/HCOs related to the planning and conduct of:</td>
</tr>
<tr>
<td></td>
<td>a. Non-clinical studies <em>(as defined in the OECD Principles of GLP)</em></td>
</tr>
<tr>
<td></td>
<td>b. Clinical trials <em>(as defined in Directive 2001/20/EC)</em></td>
</tr>
<tr>
<td></td>
<td>c. Non-interventional studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, HCPs specifically for the study <em>(cfr Section 15.02 of the EFPIA HCP Code)</em></td>
</tr>
<tr>
<td>Individual HCO Recipient</td>
<td><strong>Donations &amp; Grants to HCOs</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Contribution to costs of events</strong></td>
</tr>
<tr>
<td></td>
<td>➢ Sponsorship agreements with HCOs/third parties appointed by HCOs to manage an event</td>
</tr>
<tr>
<td></td>
<td>➢ Registration fees</td>
</tr>
<tr>
<td></td>
<td>➢ Travel &amp; accommodation</td>
</tr>
<tr>
<td></td>
<td><strong>Fee-for-service &amp; consultancy</strong></td>
</tr>
<tr>
<td></td>
<td>➢ Fees</td>
</tr>
<tr>
<td></td>
<td>➢ Related expenses agreed in the fees for service or consultancy contract</td>
</tr>
<tr>
<td>Individual HCP Recipient</td>
<td><strong>Contribution to costs of events</strong></td>
</tr>
<tr>
<td></td>
<td>➢ Registration fees</td>
</tr>
<tr>
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</tr>
<tr>
<td></td>
<td>➢ Related expenses agreed in the fees for service or consultancy contract</td>
</tr>
</tbody>
</table>

*Each company shall publish a note summarising the methodologies used in preparing their disclosures and identifying transfers of value for each category described above (Methodological Note).*
## Schedule 2 - Template

<table>
<thead>
<tr>
<th>HCPs: City of Principal Practice</th>
<th>Country of Principal Practice</th>
<th>Principal Practice Address</th>
<th>Unique Country Identifier</th>
<th>Contribution to costs of Events (Art. 3.01.1.b &amp; 3.01.2.a)</th>
<th>Fee for service and consultancy (Art. 3.01.1.c &amp; 3.01.2.c)</th>
<th>Related expenses agreed in the fee for service or consultancy contract, including travel &amp; accommodation relevant to the contract</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full Name</td>
<td>(Art. 1.01)</td>
<td>(Schedule 1)</td>
<td>(Art. 3)</td>
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<td></td>
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</tr>
</tbody>
</table>

### Individual Named Disclosure - one line per HCP

(i.e. all transfers of value during a year for an individual HCP will be summed up: itemization should be available for the individual Recipient or public authorities’ consultation only, as appropriate)

<table>
<thead>
<tr>
<th>HCP</th>
<th>Yearly amount</th>
<th>Yearly amount</th>
<th>Yearly amount</th>
<th>Yearly amount</th>
<th>Yearly amount</th>
<th>Yearly amount</th>
<th>Yearly amount</th>
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</thead>
<tbody>
<tr>
<td>Dr A</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dr B</td>
<td>N/A</td>
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<tr>
<td>etc.</td>
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<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
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### Other, Not Included Above

(where information cannot be disclosed on an individual basis for legal reasons)

<table>
<thead>
<tr>
<th>Aggregate amount attributable to transfers of value to such Recipients</th>
<th>Aggregate HCPs</th>
<th>Aggregate HCPs</th>
<th>Aggregate HCPs</th>
<th>Aggregate HCPs</th>
<th>Aggregate HCPs</th>
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</thead>
<tbody>
<tr>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
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</tbody>
</table>

### Individual Named Disclosure - one line per HCO

(i.e. all transfers of value during a year for an individual HCO will be summed up: itemization should be available for the individual Recipient or public authorities’ consultation only, as appropriate)

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<tr>
<th>HCO</th>
<th>Yearly amount</th>
<th>Yearly amount</th>
<th>Yearly amount</th>
<th>Yearly amount</th>
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<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HCO 2</td>
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<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
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<tr>
<td>etc.</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
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</table>

### Other, Not Included Above

(where information cannot be disclosed on an individual basis for legal reasons)

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<tr>
<th>Aggregate amount attributable to transfers of value to such Recipients</th>
<th>Aggregate HCOs</th>
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<th>Aggregate HCOs</th>
<th>Aggregate HCOs</th>
<th>Aggregate HCOs</th>
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</thead>
<tbody>
<tr>
<td>Number of Recipients in aggregate disclosure</td>
<td>Aggregated HCPs</td>
<td>Aggregated HCPs</td>
<td>Aggregated HCPs</td>
<td>Aggregated HCPs</td>
<td>Aggregated HCPs</td>
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<tr>
<td>Number of Recipients in aggregate disclosure</td>
<td>Aggregated HCOs</td>
<td>Aggregated HCOs</td>
<td>Aggregated HCOs</td>
<td>Aggregated HCOs</td>
<td>Aggregated HCOs</td>
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<tr>
<td>% of the number of Recipients included in the aggregate disclosure in the total number of Recipients disclosed</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
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</table>

### Aggregate Disclosure

Transfers of Value re Research & Development as defined - Article 3.04 and Schedule 1

<table>
<thead>
<tr>
<th>Aggregate HCPs</th>
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<tr>
<td>% of the number of Recipients included in the aggregate disclosure in the total number of Recipients disclosed</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

### Date of publication: ………………..
Disclosure examples: company

Public disclosure of transfers of value from Janssen to Healthcare Professionals and Healthcare Organisations

The data of transfers of value to healthcare professionals (HCP) and healthcare organisations (HCO) will be available from the end of June

- Austria
- Belgium
- Croatia
- Czech Republic
- Estonia
- Finland
- France
- Germany
- Greece
- Hungary
- Italy
- Latvia
- Lithuania
- Netherlands
- Norway
- Poland
- Portugal
- Romania
- Russia
- Slovakia
- Slovenia
- Spain
- Sweden
- Switzerland (DE)
- Turkey

Why a Disclosure of Transfer of Value Code?
Disclosure examples: association’s platform

<table>
<thead>
<tr>
<th>Name</th>
<th>City</th>
<th>Profession</th>
<th>Contribution to costs of scientific events</th>
<th>Fees for services and consultancy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abrams, Pascale</td>
<td>2610</td>
<td>Médecin</td>
<td>950,00 €</td>
<td>2003,83 €</td>
</tr>
<tr>
<td>Aerts, Raymond</td>
<td>3000</td>
<td>Médecin</td>
<td>800,00 €</td>
<td>774,42 €</td>
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<tr>
<td>Albisinni, Simone</td>
<td>1000</td>
<td>Médecin</td>
<td>732,00 €</td>
<td></td>
</tr>
<tr>
<td>Arts, Joris</td>
<td>8310</td>
<td>Médecin</td>
<td>700,00 €</td>
<td>1155,57 €</td>
</tr>
<tr>
<td>Baekelandt, Frederic</td>
<td>3000</td>
<td>Médecin</td>
<td></td>
<td>732,00 €</td>
</tr>
<tr>
<td>Baggen, Sonia</td>
<td>4890</td>
<td>Infirmier</td>
<td></td>
<td>546,86 €</td>
</tr>
<tr>
<td>Beckers, Albert</td>
<td>4000</td>
<td>Médecin</td>
<td></td>
<td>174,98 €</td>
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<tr>
<td>Berkers, Johannes</td>
<td>8500</td>
<td>Médecin</td>
<td></td>
<td>732,00 €</td>
</tr>
<tr>
<td>Bex, Marie</td>
<td>3000</td>
<td>Médecin</td>
<td></td>
<td>2053,58 €</td>
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<tr>
<td>Braeckman, Johan</td>
<td>1090</td>
<td>Médecin</td>
<td></td>
<td>659,00 €</td>
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<tr>
<td>Bynens, Bernard</td>
<td>3600</td>
<td>Médecin</td>
<td>1089,00 €</td>
<td></td>
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<tr>
<td>Charara, Fadi</td>
<td>7100</td>
<td>Médecin</td>
<td>700,00 €</td>
<td>1155,57 €</td>
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<tr>
<td>Claessens, Marc</td>
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<td>Médecin</td>
<td>260,00 €</td>
<td>651,00 €</td>
</tr>
<tr>
<td>Coche, Jean Charles</td>
<td>1340</td>
<td>Médecin</td>
<td>450,00 €</td>
<td>1078,44 €</td>
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<tr>
<td>Corvilain, Bernard</td>
<td>1070</td>
<td>Médecin</td>
<td>400,00 €</td>
<td>751,65 €</td>
</tr>
<tr>
<td>Darras, Jochen</td>
<td>8400</td>
<td>Médecin</td>
<td>1028,50 €</td>
<td></td>
</tr>
</tbody>
</table>
Enforcement

* Enforcement through Member Associations – each Member Association shall adopt implementation and Procedure Rules which will be binding upon its members, in a manner that is consistent with applicable data protection, competition, and other applicable laws and regulation.

* Disclosure Requirements Different from this Code – disclosures requirements different from those in this Code shall be clearly and conspicuously identified; deviations are only allowed to the extent necessary to comply with national laws and regulations.

The Codes Committee will submit a report to the Board, and the General Assembly will confirm consistency with the Code.
## Amendments to the HCP Code

<table>
<thead>
<tr>
<th>GIFTS</th>
<th>Article 17</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No gift or pecuniary advantage (in cash or benefit in kind) may be supplied, offered or promised to a healthcare professional.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>INFORMATIONAL &amp; EDUCATIONAL MATERIALS, and ITEMS OF MEDICAL UTILITY</th>
<th>Article 9</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. The transmission of informational or educational materials is permitted provided it is: (i) “inexpensive”; (ii) directly relevant to the practice of medicine or pharmacy; and (iii) directly beneficial to the care of patients.</td>
<td></td>
</tr>
<tr>
<td>2. Items of medical utility aimed directly at the education of healthcare professionals and patient care can be provided if they are inexpensive and do not offset routine business practices of the recipient.</td>
<td></td>
</tr>
<tr>
<td>3. EFPIA and Member Associations shall provide guidance on the meaning of the term “inexpensive”, as used in this Article 8. Companies must comply with any relevant guidance provided under this Section 8.03 or in connection with any Applicable Code(s).</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HOSPITALITY</th>
<th>Article 10.05</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Member Companies shall not provide or offer any meals (food and beverages) to healthcare professionals, unless, in each case, the value of such meals (food and beverages) does not exceed the monetary threshold set by the relevant Member Association in its national code. Each Member Association shall set such monetary threshold in its national code by 31 December 2013, failing which EFPIA will set such threshold in lieu of such Member Association.</td>
</tr>
</tbody>
</table>
Prohibition on gifts

✿ Push back on ban of pens, post-its, notepads or any other items that offset routine business practices

✿ Further to the Board decision on 1 April 2014: “Companies can provide pens or paper pads exclusively during company-organised meetings, as long as they are non-product branded and inexpensive. Companies are not allowed to distribute pens or paper pads at exhibition stands. Pens or papers included in conference bags should not bear company or product logos.”

✿ All countries have been reviewed their codes’ provisions
Informational & Educational Materials and Items of Medical Utility

- Qualification of “inexpensive”
  - All member associations have provided guidance, but there was no obligation to fix a monetary value

- Further to the Board decision on 1 April 2014: “Member associations are asked to provide guidance on the scope of “informational & educational materials” and “items of medical utility”, whilst the provision of such materials and items to HCPs may not constitute a circumvention of the ban of gifts”

- National codes provide further guidance on what will be within scope of the “ban of gifts” versus ‘materials & items”, within the limits provided by the EFPIA Code (relevant to medical practice, inexpensive, benefiting patient) – stationery should not be allowed, beyond clarification above, since they are considered to offset normal business practice.
Hospitality

- **Thresholds** for meals & drinks
  - Company shall provide meals below the national threshold
  - No disclosure
    - ✔️ All member associations have defined a threshold

- Introduction of the **Host country principle** in each national code
  - The threshold applying is the one of the country where the event take place
Resolving the hurdles and support to local operations

IMPLEMENTATION
From TRANSPOSITION to IMPLEMENTATION

1. Complying with privacy laws & other regulations
   ✴ Support collective solutions developed at national level

2. Collaborative work
   ✴ EFPIA Members
   ✴ Healthcare community
   ✴ Healthcare associations/organisations
1. COMPLYING WITH DATA PROTECTION LAWS & REGULATIONS

National transposition of EU Data Protection Directive
- Application to physical person = HCPs and exceptionally, application to moral person = HCOs
- Processing of personal data need to be adequate, relevant and not excessive
- Controllers need to ensure that the data are accurate, up-to-date and keep it secure
- For data subjects: right to access, rectify and object

Criteria to make process of personal data legitimate:
- Compliance with a legal obligation
- Consent granted by the data subject
  - By signing contract, annual consent
- Legitimate interest
  - For instance: to promote confidence in HCPs’ relationships
  - This legitimate interest must be outweighed by the data subject’s interests

Data Privacy Requirements must be checked at national level
2. COLLABORATIVE WORK

✶ With EFPIA Members Associations & Companies
    ✶ Providing clarification and interpretation of the Codes
    ✶ Giving feedbacks’ information to improve implementation
    ✶ Sharing materials & good practices

✶ With healthcare community
    ✶ Statement: individual disclosure is the rule
    ✶ ToV’s disclosure does not require revealing trade secrets

✶ With healthcare associations/organisations
    ✶ HCO’s code of conduct (Biomed Alliance)
    ✶ Medicines for Europe has published its Code of conduct in March 2015 and has completed it with Disclosure rules in December 2015
    ✶ MedTech has published a new Code of conduct which includes a disclosure provision related to educational grants
Fraud and Corruption in Healthcare in Europe

Paul Vincke
Managing Director EHFCN

Young Transparency International Belgium

Brussels 28 June 2016
EHFCN
European Healthcare Fraud & Corruption Network
Corruption in healthcare

Don’t ask……..

Don’t tell…….
Italy doctors jailed for 'clinic of horrors' operations

Eight Italian doctors have been sentenced to prison for carrying out dozens of unnecessary operations for financial gain.

The doctors, who were working at Milan's Santa Rita clinic, carried out more than 80 unnecessary operations.

The surgery included breast and lung removal, La Repubblica newspaper reports.

The clinic's chief thoracic consultant, Pier Paola
Study on corruption in the European Healthcare Sector

European Commission, DG HOME

Study 1. October 2013

Study 2. Update, 2016
108 interviews
86 corruption cases

Bribery in medical service delivery 17
Medical devices 24
Pharmaceuticals 23
Sale of public medicines for private gain 6
Sale of unauthorised or counterfeit medicines 4
Revolving doors corruption 3
Unclassified cases 9

Total number of cases 86
Six corruption-in-health typologies

1. Bribery in medical service delivery  
doctor - patient
2. Procurement corruption  
industry - medical sector
3. Improper marketing relations  
industry - doctors
4. Abuse of (high) level positions  
all stakeholders
5. Undue reimbursement claims  
doctors - payers
6. Fraud and embezzlement  
doctors
Healthcare “Waste” defined

healthcare spending that can be eliminated without reducing the quality of care

The New England Health Institute (NEHI)
Waste and intentional deception

- Clinical waste
  - Preventable error
  - Low value care
  - Case study: antimicrobials

- Operational waste
  - Targeting the use of high cost inputs
  - Getting to lower prices

- Governance-related waste
  - Administrative Expenditure

Actor:
- Patient
- Clinician
- Manager
- Regulator

Root Cause:
- Human Mistakes
- Poor management & coordination
- Poor Incentives
- Intentional Deception

Unintentional
- Deliberate
The challenge: how to reduce inappropriate and low value care?
Integrity violations defined

• Fraud: *illegally obtaining a benefit of any nature by intentionally breaking a rule*

• Abuse: *unjustly obtaining a benefit of any nature by knowingly stretching a rule or a guideline or by taking advantage of an absence of rule or guideline*

• Corruption: *illegally obtaining a benefit of any nature by abuse of power with third party involvement*
The extent of the fraud detected

- France (CNAMTS – country report 2014) : 46,3 M €
- UK (NHS Protect – country report 14/15) : 11,9 M£
- Netherlands (Zorgverzekeraars Nederland – country report 2014): 18,7 M€
- Portugal (IGAS – country report 2014): 4,6 M€
- Lithuania (NHIF – country report 2014) : 0,8 M€
- Greece (EOPYY – country report 2014): 0,3 M €
- Belgium (MEID – 2014 report) : 6,8 M €
- Germany (GVK Spitzenverband – report 13/14): 43 M €
Belgium: a case of orthopedics and corruption
Spain: a case of cardiology and corruption
Key inhibiting factor for success in preventing and sanctioning corruption
Accountability and integrity management