VAN BAEL & BELLIS

New trends and rules on interactions with HCPs - EU Perspective

the global voice of the legal profession®

Catherine Longeval
Partner
Thibaut D'hulst
Senior Associate
Van Bael & Bellis

New trends and rules on interactions with HCPs – EU Perspective

- Before Sunrise
- The Rising Sun:
  - Codes of Conduct and Self-Regulation
  - Regulatory Initiatives
  - Some Numbers
- Challenges for pharma companies

Before Sunrise

- Pharma: Restrictions in interactions with HCPs (*Art. 94-95 of Directive 2001/83/EC)*):
  - Prohibits gifts, pecuniary advantages or benefits in kind to HCPs
    - Exception: inexpensive gifts that are relevant to the medical practice
  - Hospitality at sales promotion events:
    - Strictly limited to the main purpose of the event and
    - For HCPs only
  - Hospitality at events purely professional and scientific purposes
    - Must be purely professional and scientific purpose and
    - For HCPs only
- National implementation (*incl.* penalties)
  - *E.g.* Art. 10 of Belgian Medicines Act
- Medical devices: no EU harmonised framework
  - But: national law may prohibit interactions (e.g.: Art. 10§7 Belgian Medicines Act)

Before Sunrise (2)

- Anti-corruption and anti-bribery (including criminal enforcement)
  - HCPs as civil servants
  - UK Anti-Bribery Act: Section 7 defence if ‘adequate procedures’ are in place to prevent bribery
  - UK Anti-Bribery Act: extra-territorial reach
  - Fines and/or imprisonment
- Codes of conduct provide more detailed guidance
  - But potential inconsistency between legal provisions and codes of ethics regarding admissibility of interactions

The Rising Sun – Codes of Conduct and Self-regulation

	EFPIA	Medicines for Europe	Med Tech Europe
Which ToV	▪ ToV to HCP and HCO ▪ R&D as aggregate ▪ Excluded: items of medical utility, food & drink	▪ Fees for services and consultancy ▪ Meetings, educational support and site visits[1] ▪ Excluded: R&D	Educational Grants to HCOs
Which products	Rx medicines (not OTC)	No restriction	No restriction
HCP Consent?	If required under data protection rules	If required under data protection rules	N/A (unless required under national rules)
Platform for publication	Company website or central platform	Company website or central platform	TransparentMedTech.eu (and/or national platform)
Methodology note	Yes	Yes	Yes
Entry into force	First publication in June 2016 for payments made in 2015	First publication in 2018 for payments made in 2017	First publication in 2018 for payments made in 2017

1 Members have the option to publish (i) an aggregate total amount; or (ii) total number of events per individual HCP.

Some numbers

- UK (2016):
  - 115 pharmaceutical companies disclosed GBP454 million ToV (including R&D)
  - One third of HCPs did not consent to individual disclosure (but increasing number of HCPs did provide consent)

- Spain (2016):
  - 180+ members of Farmaindustria disclosed €501.5 million ToV in total
  - HCP consent rate increased from 20% to 35%
  - Now mandatory disclosure

* Numbers from Polaris (www.polarismanagement.com), The Daily Telegraph (UK) (www.telegraph.co.uk)

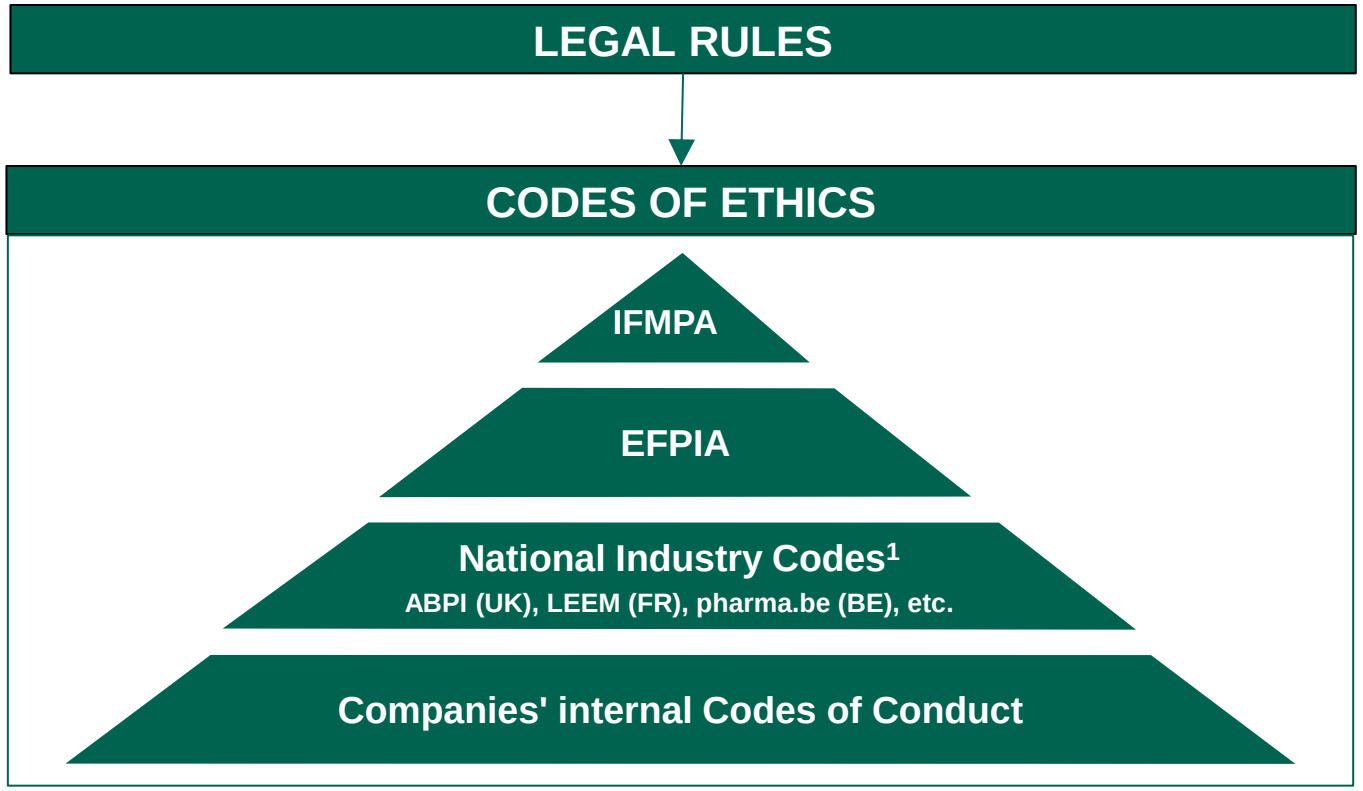
Some numbers (2)

- Germany (2016)
  - 54 pharmaceutical companies disclosed €562 million ToV (including R&D)
  - HCP consent rate decreased

- Belgium (2016)
  - 77 members of Pharma.be disclosed €148.5 million ToV (including R&D)

* Numbers from Polaris (www.polarismanagement.com), The Daily Telegraph (UK) (www.telegraph.co.uk)

Types of regulations



Applicability

- **All** pharmaceutical companies

- **Member** pharmaceutical companies producing **Rx medicines (for human use)**, incl. generics
- **Member** pharmaceutical companies producing **Rx medicines**, incl. generics
- **Member** pharmaceutical companies **operating** in that Member State

1) Certain national industry codes are also applicable to medical device manufacturers.

Regulatory Initiatives - National law

- Regulatory requirements take precedence over self-regulation
  - Codes of Conduct allow a derogation if law provides for other scope/platform for disclosure
- Increasing number of EU Member states opt for legislative intervention
  - Including: Belgium, Denmark, France, Greece, Portugal, Romania, Slovakia, etc.
  - In some countries, such as Latvia, governmental and industry regulation coexist:
    - Regulation for the disclosure of sponsorship of educational and scientific events,
    - Industry Codes of Conduct with broader scope disclosure
- Hybrid systems:
  - *Eg.* the Netherlands: publication on publicly funded platform

Challenges for pharma companies

- Discrepancies between national codes and national legislation
  - *E.g.*, terms «HCP» and « HCO »
  - *E.g.*, disclosure platform
  - Who must disclose? HCP or pharma company or both?
  - Not only in Europe but also, e.g., between EFPIA Code and US Sunshine Act
  - Global platform despite diverging requirements or (multi-)national?

- Operational challenges: automatisation of data collection, alignment, aggregation, validation
  - Unique HCP ID
  - Quid incomplete HCP or out-of-date HCP data?

Challenges for pharma companies (2)

- Allocate ToV to the right country(ies): *e.g.* parties based in different jurisdictions / service provided in other country than residence of HCP
- Disclosure in different currencies and languages
- Disclosed data not subject to statutory audits (no independent control)
  - Compare marketing expenses in P&L statements with disclosed transactions?

Challenges for pharma companies (3)

- Legal challenges
  - Antitrust (data mining by competitors – which HCPs? For which purpose?)
  - Data protection
    - HCP's consent in principle required for individual disclosure
      - Except in case of statutory obligation to consent (*cf.* France, Belgium, etc.)
      - Some data protection authorities allow "legitimate interest" argument
      - Contractual consent in some countries required to grant monetary advantage to HCP
        - Recommended approach (consent clause in new Transfer of Value contracts + renegotiate existing contracts to include consent clause)
    - Consent for each individual interaction or general consent for all interactions possible?
    - Quid if data exported outside EEA?

Challenges for pharma companies (4)

- Quid if no consent from HCP?
  - Aggregate disclosure?
- Quid duration of validity of consent?
- Quid if revocation of consent by HCP?
  - Deletion of data from on-line publication?
  - Return of the benefit?

Challenges for pharma companies (5)

- Competitive disadvantage *vis-à-vis* non-EFPIA members and non-EU/US based pharma companies?
- Payments to HCPs from subsidiaries that are not subject to transparency regulations? But rules of country of recipient to apply.
- Effect on prescribing behaviour and expenditure?
- Trigger for anti-bribery investigations? (*e.g.* use of European data in FCPA and UK Bribery Act investigations)
- Compliance *vs.* absence of 'hard' sanctions

Next Challenges – More changes ahead

- HCPs more reluctant to engage in Transfer of Value interactions?
- Keep track of changes in the regulatory framework
- Towards EU regulation on a minimum standard of transparency?

the global voice of
the legal profession®