

Implementing Disclosure in the Member States

Going Live: Implementation of the Disclosure Code

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I. Current (legal) situation in Germany

- **Fully self-regulatory approach**
 - No co-regulation schemes in place
 - No transparency law in place or planned so far
- **Strong data privacy requirements**



Is (written) consent needed?

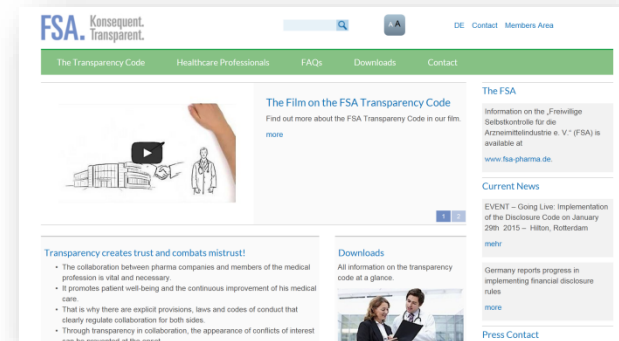
Can companies process personal data without consent for aggregate disclosure?

=> A solvable dilemma?

Can the consent be revoked and what will be the consequence?

II. Implementation of EFPIA's Disclosure Code

- **FSA General Assembly approved the „FSA-Transparenzkodex“ at its yearly meeting on 27 November 2013**
- **100% transposition of EFPIA's requirements**
 - Code applies to HCPs and HCOs
 - Categories are:
 - Donations and Grants
 - Contributions to costs related to Events
 - Fees for Services and Consultancy
 - Research and Development
- **First Disclosure in 2016 based on 2015 data**



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II. Implementation of EFPIA's Disclosure Code

Pitfalls and Opportunities

e.g.

- Convince doctors and all other concerned HCPs about the individual positive benefit of the transparency initiative (role model Code on Patient Organisations?)

- The collaboration between pharma companies and members of the medical profession is vital and necessary.
- It promotes patient well-being and the continuous improvement of his medical care.
- That is why there are explicit provisions, laws and codes of conduct that clearly regulate collaboration for both sides.
- Through transparency in collaboration, the appearance of conflicts of interest can be prevented at the onset.

- Raise awareness and gain support by the general public and press
- Support member companies with their implementation efforts (flyer, Q&As, model clauses for contracts, training etc.)
- etc.

III. Position of relevant Stakeholders

E.g. Position of the German Medical Association

Decision of the 16th German Medical Assembly in June 2013

I – 50: Physicians Payment Sunshine Act

- Representatives are in favor of transparency based on the US Physicians Payment Sunshine Act
- The Board of the German Medical Association shall strive for a law applicable to all players in the healthcare sector
- Position towards the self-regulatory approach of the industry?

Questions



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