



A view from Brussels – Financial Disclosure and Public Policy

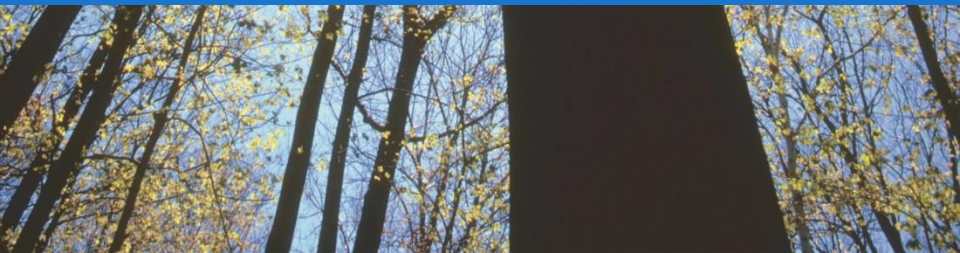
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**C L I F F O R D
C H A N C E**

European Data Protection
Framework and Transparency
Impacts



European data protection framework

- In a nutshell the basic principle of the DP Directive is:

"Each and every processing of
personal data needs to be justified
either
by law or by consent of the data subject"
- The Member States have implemented the DP Directive into national data protection laws. Subject to some deviations and particularities, local DP law of the Member States corresponds with the DP Directive.
- Note: In most Member States and according to the DP Directive data protection law only apply to natural persons.
- However, in some Member States, e.g. Austria, Greece, Hungary, Luxembourg and Switzerland the local data protection laws also apply - to some extent - to legal persons and organizations.

Implementation of Code under EU Data Protection law

■ Statutory Justification Basis for disclosure of Transfer of Values?

Other law ?



The Code is no statutory law/legal obligation according to jurisdiction/legislation of most Member States.

"Contractual Fulfillment Justification" ?



The contracts between the HCP and the company can also be fulfilled without documentation and disclosure of Transfers of Values.

"Interest Balances Justification" ?



It is very likely that local courts and data protection authorities assume an overriding interest of the HCPs, at least against a (public available) disclosure.

Consent Requirements

- The DP Directive imposes high requirements for a valid consent, in particular, regarding transparency and information to be provided:
 - **Informed consent**: Data subject has to be informed about the specific data which shall be processed, specific purposes of use, recipients, etc..
 - The consent document shall be **clear** and **unambiguous**.
 - Consent shall be given **freely**.
- Some Member States have stipulated additional requirements:
 - Consent shall be given **in writing** (in many member states) or at least explicitly granted.
 - If the consent is given in written form conjoined with other declarations, the consent shall be **highlighted** from other declarations and text parts.
 - Consent shall be **revocable** at any time.

Legal risks in case of Data Protection violations

- Risks and legal consequences of DP law violations
 - A violation of DP law might trigger
 - a **prohibition order** by the responsible data protection authority regarding the respective processing of the data,
 - **administrative fines** (currently up to six-digit sums per case in most Member States),
 - criminal prosecution (under specific circumstances),
 - **damage claims** of data subjects, and/or
 - last, but not least: **Loss in reputation!**
 - Note: According to the latest draft of the new European Data Protection Regulation a fine up to **100,000,000 (one hundred million)** or up to **5% of the annual worldwide turnover** in case of an enterprise, **whichever is greater**, is possible!

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Anne Britta Haas is Counsel in the Munich office of Clifford Chance, Germany. She works as an admitted lawyer since 2005. She is active member of the firm's worldwide industry group Healthcare, Life Sciences & Chemicals and Telecommunications, Media & Technology.

Anne advises clients in all areas of national and international including European data protection and IP/IT-law and in connection with the structuring and implementation of IT, data privacy and e-business projects with focus on the health care, IT and technology sector. She is in particular active in connection with outsourcing, cloud computing, complex online distribution and data privacy compliance projects. In addition, she assists clients with the development of data privacy policies and in relation to the processes for HR, business, compliance and other purposes. Moreover, she advises national and international clients in and out of court in IT and data protection matters.

She is permanently involved in transactions and inter alia responsible for the areas data protection, IT and commercial contracts in such transactions.

Anne is permanent speaker on conferences and seminars in particular in the health-care sector with regard to data protection and IT matters and recent developments. She advises industry associations of the pharmaceutical industry in the area data protection and IT-law.

The second field of Anne's expertise is the intellectual property law. Insofar she focuses on unfair competition matters. Anne is an experienced litigator and a Specialist Solicitor for Intellectual Property (*Fachanwältin für Gewerblichen Rechtsschutz*, a protected title in Germany).