Healthcare Compliance Workshop Germany

IRC – Compliance & Healthcare

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Workshop Germany

- Overview on anti-corruption law provisions and industry associations‘ Code of Conduct in Germany
- Specific provisions for Germany that may be important when interacting with HCPs
- Focus on Anti-Corruption Law 2016 implementing changes for private practitioners
- Ideas for improving the performance on compliance systems in companies

The Legal Framework

Which rules govern the cooperation between industry companies and HCPs in Germany?

Overview (I)

- Criminal law:
  - Co-operations between industry and healthcare professionals must not be abused to influence purchase or procurement decisions
- Civil service and University law:
  - Co-operations must be permissible under civil service law and University law rules
  - Prior written approval of superior/employer required in the hospital sector
- Healthcare Advertising Law:
  - Restrictions for marketing of medical devices
  - Competitors can complain in case of infringements before civil courts
- Physicians' Professional Rules:
  - Physicians Associations have set up high ethical standards

Overview (II)

- Codes of Conduct of Medtech industry associations:
  - "Common Position" of the industry associations 2000
  - Code of Conduct „Medical Devices" 1997
  - All Medtech codes of conduct are non-binding
- Codes of Conduct of Pharma industry associations:
  - FSA-Code of Conduct 2004
    - industry association of research based pharma companies
    - binding code of conduct with sanctions by an arbitration body
  - AKG-Code of Conduct 2008
    - Industry association of pharma companies
    - Non-binding code of conduct

German specifics (I)

- Approval Requirement (*Dienstherrngenehmigung*)
  - Criminal law requires prior approval of each cooperation between "public office holders" (*Amtsträger*) and industry companies
- Employee Inventions Act
  - No work-for-hire doctrine in Germany
  - So-called service inventions automatically belong to the employer in case of employed inventors
  - Important when consulting employed physicians for product development (e.g. hospital physician)
  - Need for wording in contract to ensure that invention belong to industry company

German specifics (II)

- Donations
  - Tax law defines limits for donations
  - No differentiation between donation and grants like in the US
  - Only public institutions or charitable organizations may receive donations
  - No donations to individuals, e.g. physicians
  - Donations have become critical under Anticorruption Law 2016
- Further Educational Events
  - FSA Code of Conduct provides for guideline regarding venues and facilities
  - Invitations have become critical under Anticorruption Law 2016

German specifics (III)

- Healthcare Advertising Law
  - Restriction of providing all kind of benefits within the distribution chain of medical devices and medicinal products
  - In general, restrictions apply to
    - Gifts
    - Product samples
    - Accessories

Anti Corruption Law

Which anti corruption rules are applicable to the interaction with HCPs in Germany?

Situation until 2016 (I)

- Anti-corruption law provisions did only exist for
  - So-called public office holders (*Amtsträger*), e.g.
    - Physicians and pharmacists in public hospitals
    - Other employees in public hospitals
    - Employees of public healthcare insurances
  - Physicians working as employees in private hospitals
- No anti-corruption law provisions for
  - Private practitioners
  - Private pharmacists
  - Other healthcare professions

Situation until 2016 (II)

- Federal Criminal Court confirmed in 2012 that the existing criminal law rules are not applicable to
  - Private practitioners
  - Private pharmacists
  - Other healthcare professions
- Legislator had to close the gab for private practitioners, private pharmacists and other healthcare professions

Anti Corruption Law 2016 (I)

- New anti corruption provisions entered into force in 2016
- Sections 229a and 299b German Criminal Code
  - Section 299a: giving improper benefits
  - Section 299b: accepting improper benefits
- Provisions do cover improper benefits relating to
  - The prescription of medicinal products and medical devices
  - The procurement of medicinal products and medical devices for own purposes
  - The referral of patients and examination material

Anti Corruption Law 2016 (II)

- "Understanding to act improper" (*Unrechtsvereinbarung*) between offering and accepting party is required
  - Explicit correspondence
  - Circumstances of the case
  - Extremely inadequate compensation
- Currently, no court decision that defines such understanding in more detail
- Written agreements with adequate compensation reduces risk
- Uniliteral benefits increase potential criminal law liability

Anti Corruption Law 2016 (III)

- Covers a wide range of healthcare professions
  - Private practitioners
  - Private pharmacists
  - Physiotherapists
  - Speech therapists
  - etc.

Efficient Compliance System

How should a compliance management system be designed in order to be efficient?

Key Features CMS (I)

- Easy to understand compliance guidelines
- Standard form agreements cover the most frequent cooperation types
- Legal department and compliance officer do assist in exemptional cases and very risky constellations
- Employees do have the responsibility for drafting the agreement in compliance with applicable rules
- Employees' own initiative can be helpful to create awareness for compliance issues

Key Features CMS (II)

- Positive error management culture
  - Mistakes made by employees are not necessarily sanctioned
  - Mistakes are used as an opportunity to communicate potential risks to other employees
  - Negative experience is seen as a chance for the company in the future
- CMS does not focus on sanctions for infringements (unless they are intentions)
- Incentives for employees drawing the attention to potential risk and improvements

Always a good advice...

...don‘t be the most obvious target!

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- Mathias focuses on advising clients on compliance and regulatory matters, related advertising and product liability cases, as well as contractual work. He assists life sciences companies in developing and implementing compliance programs and advises self-regulatory bodies of industry associations on new compliance developments.
- Mathias started his career at Clifford Chance in the Düsseldorf office, where he was a core member of the practice group „Healthcare Life Sciences and Chemicals“ from 2004 to 2008.
- He worked in-house several times in the legal departments of international pharmaceutical and medical device companies.
- Mathias is a frequent speaker on medicinal products and medical device regulatory issues and published broadly relating to medicinal products and medical device matters.
- He is a member of the healthcare compliance consulting committee of the pharmaceutical self-regulatory organization „Arbeitskreis Kooperation im Gesundheitswesen – AKG e.V.“
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