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# EU Healthcare Compliance

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# Agenda

I. Legal Regime for Healthcare Compliance

1) Why is Compliance so important?
2) Industry Guidelines (MedTech Europe Code of Ethical Business Practice)
3) National Legislation

II. General Principles for the Cooperation with HCPs

1) Principle of Separation / Transparency / Equivalence / Documentation
2) … and its Implementation in Cooperation Agreements

III. Requirements for Product-related Advertisement

1) General Principles
2) Off-label Advertisement

# Agenda

## IV. Update on the MedTech Code of Conduct

1) New Standard: “Phase out of direct Sponsorship”

2) Still admissible: Restricted Educational Grant to HCO

## VI. Questions / Discussions

# I. Legal Regime for Healthcare Compliance

# I. Why is Compliance so important? (1)

## Compliance Risk - Definition

"Compliance risk is the risk of legal or regulatory sanctions, material financial loss, or loss to reputation a business may suffer as a result of its failure to comply with laws, regulations, rules, related self-regulatory organization standards, and codes of conduct applicable to its business activities" (together, "*compliance laws, rules and standards*") Basel Committee on Banking Supervision (April, 2005)

=> Regulatory/criminal sanctions, material financial loss, reputational damages, bad relationship with competitors …

# I. Why is Compliance so important? (2)

- Criminal sanctions based on national laws
  - German Criminal Code (Section 299a/299b StGB, up to 5 years imprisonment, implemented June 2016 )
  - UK Bribery Act 2010 (up to 10 years imprisonment)
- Material financial losses (e.g. based on FCPA infringements):

  Biomet 30m USD (2017) / Teva 519m USD (2016) / GSK 20m USD (2016) / AstraZeneca 5m USD (2016) etc.
- Regulatory Sanctions (e.g. ban to place your product on the market)
- Reputational Damages (*"It takes 20 years to build a reputation and 5 minutes to ruin it…."* Warren Buffet)

# I. Industry Guidelines (1)

- MedTech Europe Code of Ethical Business Practice ("MTE Code of Conduct") issued in December 2015 (formerly EUCOMED)
- Last amendment in January 2018 („*phase out of direct sponsoring*")
- Provides guidance for the cooperation with HCOs/HCPs:
  - Third Party Organised Educational Events
  - Company Events
  - Grants and Charitable Donations
  - Arrangement with Consultants
  - Research
  - Royalties etc.

# I. Industry Guidelines (2)

- Legal character:
  - MTE Code of Conduct is a self-regulatory industry guideline
  - directly binding „only“ to members and companies voluntarily committed
  - no arbitration board / not directly applied by courts

- However:
  - MTE provides for a consistent EU-wide summary of applicable (legal) rules for interactions with HCP/HCO (no other EU-wide document)
  - Industry standards are means of interpretation for national courts when applying general legal clauses (unfair competition law / criminal law)

=> Therefore THE reference for Medtech companies in Europe

# I. National Legislation (Example Germany)

- Criminal Laws (German Criminal Code, *Strafgesetzbuch*)
- Regulatory Laws
  - German Act on Medical Devices (*Medizinproduktegesetz*)
  - Directive 93/42/EEG / Regulation (EU) 2017/745 (from May 2020)
- Laws against Unfair Competition
  - Sanctions unlawful business practice (*Gesetz gegen den unlauteren Wettbewerb*)
  - Sanctions misleading advertisement for healthcare products and unlawful benefits/benefits in kind (*Heilmittelwerbegesetz*)

## II. General Principles for Cooperation with HCP/HCO

# II. General Principles for Cooperation with HCP/HCO (1)

- Principle of **Separation**

  Any cooperation between companies and HCP must not be misused to influence purchasing / prescription decisions, and must not be linked to any sales transaction.

  => prohibition to (mis-)use cooperation as inducement for sales transaction, fees as hidden discounts…

- Principle of **Transparency**

  Interactions between companies and HCP must be transparent.

  => obtaining an employer consent (*Dienstherrengenehmigung*), disclose any benefits / benefits in kind granted to HCP/HCO (if required under national law), indicating relationship to industry when presenting …

# II. General Principles for Cooperation with HCP/HCO (2)

- Principle of **Equivalence**

  The remuneration paid by the company for the service rendered must represent fair market value for the service performed by the HCP.

  ⇒ creating a thankfulness/gratitude by paying remuneration far above the FMV, sham contracts…

- Principle of **Documentation**

  All interactions between companies and HCP must be documented in writing.

  ⇒ Cooperation agreements must be in written form, setting out (i) purpose of the interaction, (ii) service to be performed, (iii) method to reimburse expenses of the HCP, and (iv) remuneration paid to HCP…

  ⇒ documentation (agreement, invoices, reports) must be retained for a reasonable period of time.

# III. Requirements for Product-related Advertisement

# III. General Principles (1)

- Advertisement is any product-related claim that intends to positively influence the consumer and thereby to increase the sales of the product

- The form is not relevant: brochures, internet, oral statements by the sales force, television, letters or e-Mails, etc.

- Not necessary that the product is expressly mentioned, any indirect link or reference to a product is sufficient for product-related advertisement

# III. General Principles (2)

- Overall Principle: "Advertisement shall not be misleading"
- Misleading is any product-related claim (e.g. safety and efficacy) that is not based on sufficient scientific evidence
- German courts require for "*sufficient scientific evidence*":
  - safety and/or efficacy claim must be proven by clinical trials;
  - clinical trial design must be randomised and controlled;
  - a statistically significant number of clinical trial subjects must have participated to the trial; and
  - results of the clinical trial shall be published in an acknowledged medical journal.

# III. General Principles (3)

- Misleading advertisement is an infringement of Unfair Competition Law (civil law) and regulatory regulations

- Consequences either (i) preliminary injunctions by competitors, and/or (ii) enforcement actions by competent authorities

- Companies in Germany consider (i) relationship to competitor (aggressive, gentlemen´s agreements, etc.), and (ii) level of activity of authorities when assessing risk (rather passive, actively monitoring the market, etc.)

# III. Off-label Advertisement (1)

- It is strictly recommended to avoid off-label advertisement!
- Off-label use is the use/application outside its "**intended purpose**" (defined by Article 1 [2g] of Directive 93/42/EEC):

> (g) 'intended purpose' means the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials;

- off-label promotion extends "intended purpose"
- Consequence: Discrepancy between "intended purpose" and indications covered by conformity assessment procedure (i.e. CE mark)

# III. Off-label Advertisement (2)

- Note: **no**-label advertisement is admissible under certain conditions

- Article 4 (3) of Directive 93/42/EEC :

> 3. At trade fairs, exhibitions, demonstrations, etc. Member States shall not create any obstacle to the showing of devices which do not conform to this Directive, provided that a visible sign clearly indicates that such devices cannot be marketed or put into service until they have been made to comply.

- However, this provision will expire in May 2020 (Regulation (EU) 2017/745)

# V. Update on the MedTech Code of Conduct

## VI. Update on the MedTech Code of Conduct

# V. Update on the MedTech Code of Conduct (1)

- New restrictions for third-party organised educational events from 1 January 2018 on
- *„Educational events that are planned, budgeted, managed and executed in whole or in part by a person/entity other that the company“*
- No support of passive attendance of HCP at third-party organised events (*„Phase-out of direct Sponsorship“*)

# V. Update on the MedTech Code of Conduct (2)

AdvaMed Advanced Medical Technology Association | MedTech Europe from diagnosis to cure | APACMed Asia Pacific Medical Technology Association | Mecomed Medical Technology Association Middle East & North Africa

**Joint Statement on Phase-Out of Direct Sponsorships**

*The Global MedTech Industry Moving Together to Enhance Compliance Practices Across Europe, China, Middle East, North Africa & Asia-Pacific*

**January 3, 2018**

⇒ *"industry's support for HCP training and education is critical for the continued development of advanced medical technologies"*

⇒ *"Collaboration and interactions with HCPs and HCOs must be transparent, and must be balanced against the need for HCPs to make independent decisions regarding patient care and treatment"*

# V. Update on the MedTech Code of Conduct (3)

- Background: Federal prosecutors in Germany *per se* see an initial suspicion (*Anfangsverdacht*) for an undue influence of the HCP (*Ärztezeitung* March 2017)

- Indirect support via HCOs remains admissible:
  - Providing educational grant to HCOs or the congress organiser, but not to individuals
  - Companies are allowed to define the category of HCPs, but not to choose individual HCPs
  - (P): Provision of restricted educational grant leads necessarily to selection of particular HCP

- Grants must be publicly disclosed

# VI. Questions / Discussions

Questions / Discussion

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