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Legal Implications & Compliance in the Sales & Marketing of Medical Devices in Europe

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Overview

1. Introduction
2. EU legislation regarding promotion of medical devices
3. Eucomed Code of Ethical Business Practice
4. Eucomed guidelines on Provision of Reimbursement
5. Examples of national legislation and codes of practice
6. Legal implications
7. FCPA
8. Solutions

1. Introduction

At Present: Complex Legal Framework in the EU

- Almost no EU harmonization
- National Member States legislation vary widely
- Self-regulation through industry codes of conduct

■ Harmonized EU Legislation in the future?

- EU Council of Ministers Conclusions of 6 June 2011
- On-going discussions within the European Commission in view of the revision of the Medical Devices Directives

2. EU legislation regarding promotion of medical devices

- Only one specific provision in Medical Device Directives

- Article 4 of Medical Device Directives
- Do the Medical Device Directives prohibit promotion on medical devices without CE mark?

2. EU legislation regarding promotion of medical devices (cont.)

- EU Directives on misleading and comparative advertising of general application

a) **Directive 2005/25/EC concerning unfair business-to-consumer commercial practices**
   - Misleading practices
   - Blacklisted practices
   - Enforcement and Penalties

b) **Directive 2006/114/EC concerning misleading and comparative advertising**
   - Enforcement

3. Eucomed Code of Ethical Business Practice

- Eucomed Members
- EDMA and Eucomed to establish European industry federation
- Eucomed Code of Ethical Business Practice
- Eucomed Guidelines on Interaction with Healthcare Professionals
  - Definition of healthcare professionals
  - Section VII on Provision of Reimbursement and Other Economic Information

4. Eucomedguidelines on Provision of Reimbursement Information

Section VII

- "Members should support accurate and responsible billing to reimbursement authorities and other payors."
- "In doing so, they provide economic efficiency and reimbursement information to Healthcare Professionals and third party payors regarding members' products."
- "This information should be limited to identifying appropriate coverage, coding or billing of member products, or procedures using those products, or to encouraging the economically efficient delivery of member products."
- "This section is not intended to address the legitimate practice of providing technical or other support intended to aid appropriate use or installation of the member's products"

5. Examples of national legislation and codes of practice

- France

a) Former legislation
   - Few specific provisions
   - French language mandatory
   - General Application of French Consumer Code

b) New Law on the Strengthening of Safety of Medicines and Health Care Products of 29 December 2011
   - Definition of advertising of medical devices
   - Minimum requirements for advertising
   - Advertising to general public of reimbursed medical devices only possible for products “of minor risk” listed in Ministerial Decree
   - Prior authorization of advertising for dangerous medical devices
   - Administrative sanctions
   - Criminal sanctions

5. Examples of national legislation and codes of practice

- UK

- No specific national provisions
- Advertising subject to general legislation on advertising
- Self-regulation

  (a) CAP and BCAP Codes

  (b) ABHI Code of Business Practice

  - Current version
  - New draft Annex on advertising and promotion of medical devices and related services solely or primarily to HCP

5. Examples of national legislation and codes of practice

- Belgium

a) Few specific provisions

- Definition of advertising
- Prohibition of advertising of medical devices without CE mark
- Prohibition of advertising to general public of implantable medical devices
- Prohibition of advertising regarding free-of-charge status or coverage under Health Care System

b) **Application of general legislation on advertising**

c) **Self-regulation: UNAMEC Deontological Code**

5. Examples of national legislation and codes of practice

- Germany

a) **Few specific provisions in Law on Medical Devices**

b) **Law on Advertising in the Field of Healthcare** (**HWG)**

- No definition of advertising
- Product advertising versus image advertising
- Unlike for medicinal products, no prohibition of

(a) comparative advertising to general public

(b) advertising for prescription-only products

(c) advertising prior to obtaining CE mark (except for exhibition at fairs etc.)

c) Law against Unfair Competition (UWG)

d) BVmed Code: no specific provisions

6. Legal Implications of non-compliance

- Misleading advertising
- Comparative advertising
- Contract law
- Fraud
- Procurement law
- Implications of other parties

7. FCPA

- Internationally wide consequences: contravention of Eucomed code may also be contravention of FCPA
- Company is at risk for FCPA exposure if material substance in US
- FCPA enforcement climate is agressive

8. Solutions

- Advising Healthcare Professionals, patients and third party payors to check reimbursement status with competent authorities
- No issuance of guarantees regarding reimbursement status
- Establish and monitor Standard Operating Procedures (SOP)
- Monitor closely regulatory changes
- Appoint responsible for reimbursement related advertising
- Train personnel and third parties involved

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Questions?

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