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Medical Device Compliance – an update

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+ Device Compliance



- Framework for advertising and promotion
- Consider current state and emerging regulations

Many learnings for Medical Communications

-
Improve awareness, confidence
and competency

-
Facilitate innovation



+ Compliance Framework



Supranational

European Medical Device Regulation

Regulation (EU) 2017/745
Regulation (EU) 2017/746

MedTech Europe Code

Other Codes:

- Asia Pacific APACMed
- US AdvaMed
- China AdvaMed

National

ABHI Code of Ethical Business Practice (HCP focus)

Advertising Standards Authority (consumer advertising)

Other Laws:

- Safety, quality, performance
- Advertising, promotion
- Data protection
- Anti-corruption
- Competition
- Copyright

+ European Medical Device Regulation



- 2017/745 medical devices – 3 yr transition – 26 May 2020
- 2017/746 *in vitro* diagnostic medical devices – 5 yr transition – 26 May 2022
- **NEW Article 7 : Claims**
 - Not mislead – intended purpose, safety, performance of device

Implementation?
Governance?

Keep a watch...

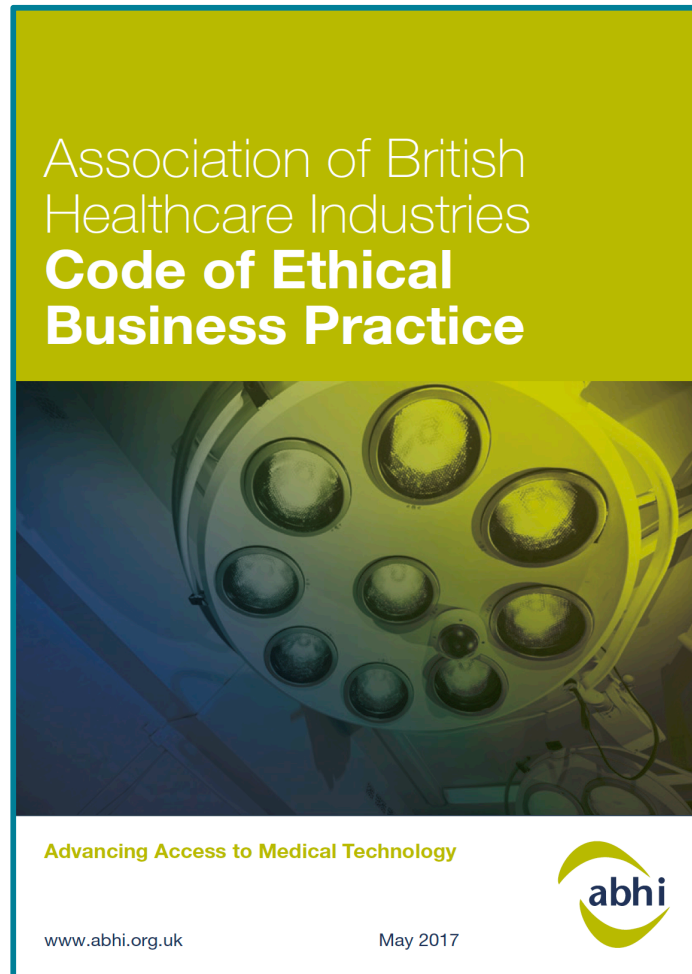
+ MedTech Europe Code



- Dec 2015
(in force from 1st Jan 2017)
- Scope
 - Interactions with HCPs / Organisations
 - Disclosure
 - Complaint procedural framework
 - **No detail : advertisement and promotion**
- Comparison chart – advamed.org



+ ABHI Code



- Currently in transition
March 2016 to May 2017 edition
- Scope
 - Interactions with HCPs / Organisations
 - Disclosure
 - Advertisement and promotion
 - Complaints principles, procedure, panel

+ ABHI Cases

2008 to 2017 ~ 30 cases

- Resolved through mediation
- Summary to ABHI website by end 2017

Advertising and Promotion – main topic

- Claims, comparisons

Conference venues/programmes

- Concerned about independent organisers choices
- Referred to MedTech European Conference Vetting System

+ Application by Medical Communications



- ABHI clarifies acceptable activities, tools – e.g.
 - Conference booths
 - Educational items / gifts
 - Interactions with HCPs as consultants/advisors
 - Accuracy and substantiation of claims, comparisons
 - Use of testimonials and quotations
 - ‘New’ – upto 12months

Broadly similar to ABPI PMCPA Code except:

- No Prescribing Information
- Approval instead of mandatory business / medical certification
- Less cases

Anticipate European
Medical Device
Regulations



To explore further...



Compliance Consultancy | Medical Signatory | Bespoke Training

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