Presentation for information purposes only - not intended as, and should not be construed as, formal regulatory or legal advice.

Medical Device Compliance – an update

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MedComms Networking Event – 6th September 2017
www.MedCommsNetworking.com
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 (EU) 2017/745
- European Medical Device Regulation (EU) 2017/746
- MedTech Europe Code

National
- ABHI Code of Ethical Business Practice (HCP focus)
- Advertising Standards Authority (consumer advertising)

Other Codes:
- Asia Pacific APACMed
- US AdvaMed
- China AdvaMed

Other Laws:
- Safety, quality, performance
- Advertising, promotion
- Data protection
- Anti-corruption
- Competition
- Copyright
European Medical Device Regulation

**Official Journal of the European Union**

- **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…

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MedTech Europe Code

December 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

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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
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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