



Ministry of Health, Welfare and Sport

The compliance approach of the Dutch government

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Dutch system: Self-Regulation & Legalisation

Regulation of the collaboration between the medical device industry and healthcare professionals is complex;

- Various products, various parties
- Promoting innovation, research, education vs. resisting improper financial interests

- Self-regulation:
 - Code of Conduct Medical Devices
 - Healthcare Transparency Register

- Legalisation: Prevention of unwanted influence





Self-regulation

- Since 2007 Code of Conduct Medical Devices organised by the 'GMH' foundation. (*Gedragcode Medische Hulpmiddelen*)
- Collaboration between self-regulation and the Health Care Inspectorate (IGZ)
- Political support (Minister of Health) for self-regulation



Regulation of medical devices

- Collaboration the medical device industry & healthcare professional is necessary
- Differences between pharmaceutical and medical device industry / markets
- Regulation of the interaction between companies and healthcare professionals/organisations by transparency



Healthcare Transparency Register

www.transparantieregister.nl



- Starts in 2012 as a central register of financial relationships between healthcare professionals/organisations and pharmaceutical companies.
- Since 2015 also reporting financial relationships with cardiological and orthopedics devices companies
- From 2017 onwards: reporting all financial relationships between professionals and medical device companies



Do you remember this case?

Scandal of fruit netting 'approved as surgical implant'

January 11 2015, 12:01am, The Sunday Times





Regulation of medical devices

- Important role for notified bodies to medical devices
- Workload notified bodies will rise considerably by the EU Regulation of medical devices 2012/0266 (COD) & in-vitro diagnostic 2012/0267 (COD)
- Prevent improper influence due to conflicts of interest or incorrect financial relationships



Compliance approach

- Collaboration between manufacturer & healthcare professionals is necessary:
 - Development (new) medical devices
 - Improve user driven development
 - Sustainable innovations
 - Stimulate education and scientific research
 - Customized care
 - Affordable care

...but objective and transparent!



*Integrity is doing the right thing,
when no one is watching.*

by C.S. Lewis

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