

Hans D. Jarass

New Dimensions of Tobacco Regulation and Fundamental Rights and Freedoms

Basic Questions of Brand Packaging, Product Display and Product Ingredients

Neue Dimensionen der Tabakproduktregulierung und Grundrechte sowie Grundfreiheiten

Grundfragen des Schutzes von Markenverpackungen, der Produktpräsentation in Verkaufseinrichtungen und der Produktzusammensetzung



The current discussion on stricter regulation of tobacco products raises interesting questions which are of relevance to all sectors of economic activity with particular value put on the image of the brand of sold products, going far beyond the segment of tobacco products. These questions especially concern the scope of protection offered in this context by both the fundamental rights of the European Union and the basic rights under German Basic Law.

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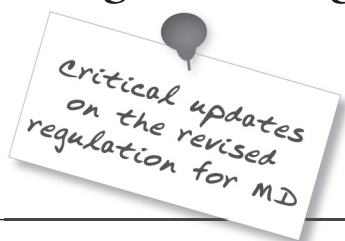
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- Recast of the current legislation: Who will benefit? What are the main challenges?
- Impact of the new Regulations on the stakeholders

Session II: Data Protection vs. Regulatory Obligations

- Interface between EU medical devices law and the proposed General Data Protection Regulation (GDPR)
- Consequences of the proposed GDPR for data collection and processing for medical devices companies
- Company's regulatory obligations to collect safety and performance data

Session III: Procurement and Health Technology Assessment (HTA)

- HTA - an obstacle to innovative products and/or services in healthcare?
- The role of governments in procurement procedures and HTA
- How does the increased influence of HTA in decision making influence the route to the market?

Session IV: Supervision

- Post Market Surveillance in a highly innovative industry as the key to safer medical devices
- Action levels, pro-active surveillance and "proven safety" are the keywords?
- The role of Notified Bodies under the new Regulations proposed by the European Commission

SPEAKERS

Gert BOS, Head of Regulatory and Clinical Affairs Medical Devices, BSI Assurance UK Limited

John BRENNAN, Director Regulatory and Technical Affairs, Eucomed

Jean-Claude GHISLAIN, Head of European Coordination Division, National Agency for Safety of Medicines and Healthcare Products

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