

Elisabeth Kohoutek

Senior Associate
FDA and Life Sciences

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Elisabeth Kohoutek is a senior associate in King & Spalding's Frankfurt office and a member of the FDA & Life Sciences practice. She advises and represents clients in the medical device, pharmaceutical, cosmetics and food industries on legal aspects in every stage of the life cycle of a product, including product development, labeling, advertising, distribution, compliance, data protection, aspects related to parallel importation, protection against falsified products, recalls, if necessary and end-of-life.

Elisabeth advises companies in the fields of European Law, Regulatory Law as well as Unfair Competition Law and represents them before national and European courts and authorities. Another focus of her practice involves Data Privacy Law.

Prior to joining King & Spalding Elisabeth was working for the international law firm of Bird & Bird, where she was a member of the Life Sciences and Food & Beverage Sector.

Elisabeth studied law at the University of Heidelberg and Barcelona. During her legal clerkship she worked for law firms in Frankfurt and New York.

Elisabeth speaks German, English, Czech and Spanish.

Selected Speaking Engagements and Publications

Elisabeth Kohoutek regularly speaks at various Life Sciences conferences and seminars.

"Court of Justice of the European Union: Ruling on Amino Acids in Foods " (co-author), King & Spalding *International Food Law Gazette*, January 2018

"Excavate the Fundamentals for a Successful Consent Management Programme" (co-speaker), CBI's Life Sciences GDPR Bootcamp in London, November 2017

"Strategies for Vendor Selection and Compliance", CBI's Life Sciences GDPR Bootcamp in London, November 2017

"How GDPR Will Transform The Disclosure Landscape", qordata Webinar, May 2017

"Determine the Difficulties of Data Privacy in the Disclosure of HCP Payment and Transfers of

Value”, CBI’s Global Compliance Congress for Life Sciences in London, April 2017

“Hot Sox: Produktrückruf als Teil der Unterlassungsverpflichtung” (“Hot Sox”: Product Recall as Part of the Cease-and-Desist Declaration), King & Spalding Talk im Turm, March 2017

“EFPIA Disclosure and Consent Management – Experiences from the first round of Disclosure in 2016”, qordata Webinar, February 2017

“Key Food & Beverages Issues – Looking Ahead to 2017”, King & Spalding *Food & Beverage Webinar*, December 2016

“Bridging the Gap between Science and Promotion”, CBI’s Global Compliance Congress for Life Sciences in London, November 2016

“EFPIA Disclosure – Rights and Requirements to Consent Management”, Policy and Medicine Webinar, July 2016

“Korruption im Gesundheitswesen (§§ 299 a/b StGB) und Transparenz – Was ist noch erlaubt?” (*Corruption and Transparency in the Healthcare Sector (§§ 299 a/b StGB) – What Is Still Allowed?*), King & Spalding *Talk im Turm*, June 2016

“Informationsveranstaltung zum Gesetz zur Bekämpfung von Korruption im Gesundheitswesen”(Information Event on the Anti-Corruption Law in the Healthcare Sector), Bundesverband der Arzneimittel-Hersteller e.V. (BAH). (*German Medicines Manufacturers’ Association*), June 2016

“Managing Cross Border Activities and HCP Interactions”, CBI’s Global Transparency Reporting Congress in Frankfurt, April 2016

“Where in the World Are You? International Transparency and Anti-Corruption Rules Impacting Pharmaceutical Manufacturers”, King & Spalding Webinar, April 2016

“EU-Health-Claims-Verordnung – Chancen und Risiken” (*EU Health Claims Regulation – Opportunities and Risks*), King & Spalding *Talk im Turm*, October 2015

“Parallel- und Re-Importe – Strategien für ‚Branded Industries‘”, King & Spalding *Talk im Turm*, May 2015

“Data Protection: What International Pharmaceutical Organizations Need to Know”, King & Spalding *Pharma eLearn*, September 2014

“REACH: EU Environmental Regulations That Apply to Non-EU Companies”, King & Spalding *Pharma eLearn*, October 2014

In addition, Elisabeth Kohoutek regularly publishes on issues in the fields of food, medicinal products and medical devices law.

““Veggie Cheese” and “Tofu Butter” Are Prohibited in the European Union – ECJ Decides on Plant-Based “Dairy” Products” (co-author), King & Spalding *International Food Law Gazette*, July 2017

“Restrictions on Advertising with Nutrition and Health Claims Apply to Both Communications Addressed to Consumers and to Communications Addressed to HCPs”, (co-author) King & Spalding *International Food Law Gazette*, January 2017

“Watch Out for Vegan Cheese: Labeling and Promotion of Vegan “Dairy Products” in the European Union”, (co-author) King & Spalding *International Food Law Gazette*, January 2017

“EFPIA HCP Financial Disclosure Is Not Risk Free” (co-author), *LSC Life Science Compliance Update*, October 2016

Co-authored two chapters of the *Kluwe Guide to EU Pharmaceutical Regulatory Law*

“New Anti-Corruption Laws on the Health Care Sector in Germany: Is There Any Impact on the Food Industry?” (co-author), King & Spalding *International Food Law Gazette*, July 2016

“Don’t Copy ,Bounty‘ Bars: Distributors of Chocolate Bars Prohibited from Imitating ,Bounty Bar Shape‘?”, King & Spalding *International Food Law Gazette*, July 2016

“Court of Justice of the European Union: Ruling on Package Design of Foodstuffs (Teekanne Felix)” (co-author), King & Spalding *International Food Law Gazette*, January 2016

“Do the Restrictions on Advertising with Nutrition and Health Claims also Apply to Communications Addressed Exclusively to Health Care Professionals? – Interpretation of Regulation (EC) No 1924/2006 on Nutrition and Health Claims Made on Foods” (co-author), King & Spalding *International Food Law Gazette*, January 2016

“German Federal Supreme Court: Admissibility of Designation ‘Energy & Vodka’ for Alcoholic Mixed Beverages” (co-author), King & Spalding *International Food Law Gazette*, July 2015

“EU Food Information Regulation in Force” (co-author), King & Spalding *International Food Law Gazette*, July 2015

“New Health Claim on Carbohydrates Admitted in the EU”, King & Spalding *International Food Law Gazette*, July 2015

Matters

Counseling a world-wide leading manufacturer of medicinal products in all aspects of parallel imports in the EU

Counseling a world-wide market leading manufacturer of medical devices in regulatory and advertising law

Counseling internationally acting pharmaceutical companies in the area of distinction between food and pharmaceutical products

Representing manufacturers of medicinal products and medical devices in cases concerning the market authorization and the “CE-mark” versus authorities and Notified Bodies

Representing U.S. companies in processing personal data gathered in the European Union

Credentials

ADMISSIONS

Frankfurt

ASSOCIATIONS

Frankfurt, Germany (Admitted 3/8/2012; Reg. # 148821)

Insights

CLIENT ALERT

June 29, 2020

France - New notification and authorization regime for exemptions from benefits/payments to the healthcare sector will enter into force in October 2020

April 24, 2020

One More Year: EU Medical Device Regulation Fully Applies on May 26, 2021

April 17, 2020

Europe Update – Life Sciences Products and COVID-19: From Clinical Trials to Regulatory Flexibility

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Events

CONFERENCE

November 12, 2019

12th Annual King & Spalding Pharmaceutical University

September 5, 2019

12th Annual Medical Device Summit

WEBINAR

October 23, 2019

Key Food and Beverage Issues: Brexit – Impact for Food and Beverage Companies in the U.S. and the EU

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