Arnold&Porter
LIFE SCIENCES
FUTURE FORUM

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LIFE SCIENCES FUTURE FORUM FULL DAY BOOTCAMP

12 June 2025
9.30 a.m. – 5.30 p.m. BST

Complimentary regulatory training day for junior lawyers and new joiners on the EU and UK regulatory framework for medicinal products

Time	Seminar	Speaker
9.00 AM	**Coffee and Registration**	
9.30	**Welcome and overview of the day**	Eleri Abreo Chris Bates
9.40 – 10.25	**Overview of the UK and EU pharmaceutical legal framework** ▪ What is a medicinal product ▪ Life cycle of a medicinal product ▪ Overview of the regulatory framework and EU pharma strategy ▪ The main institutions in the UK and EU ▪ The position in the UK post-Brexit	Alexander Roussanov Eleri Abreo Heba Jalil
10.25 – 11.10	**Pre-authorisation: Clinical trials** ▪ Current EU framework and key terminology ▪ Clinical trials in the UK post-Brexit ▪ Overview of liabilities	Adela Williams Ana González- Lamuño
11.10 – 11.30	**Coffee Break**	
11.30 – 12.15	**Obtaining a Marketing Authorisation** ▪ General principles ▪ EU procedures ▪ UK procedures post-Brexit ▪ Legal bases for authorization ▪ Exemptions to requirement for marketing authorisation	Eftychia Sideri Sofia Holmquist
12.15 – 1.00	**Incentives and Rewards: Regulatory and IP** ▪ Patent exclusivity ▪ Regulatory data protection and marketing protection ▪ Global marketing authorisation, new active substances ▪ Orphan medicines and marketing exclusivity ▪ Supplementary Protection Certificates (SPCs) ▪ Paediatric research and rewards	Jackie Mulryne Beatriz San Martin

1.00 – 1.45	**Lunch**	
1.45 – 2.25	**Promotion and Advertising** ▪ EU and UK Legislative & self-regulatory frameworks ▪ Definition of advertising ▪ Permitted activity prior to grant of MA ▪ Interactions with HCPs after grant of MA ▪ Social media	Libby Amos-Stone Emma Elliston
2.25 – 3.10	**Medical device regulation: what do pharmaceutical companies need to know?** ▪ Transition periods MDR vs IVDR ▪ The role of economic operators ▪ The regulation of combination products ▪ Devices used in clinical trials	Jackie Mulryne Eleri Abreo Chris Bates
3.10 – 3.30	**Afternoon Break**	
3.30-3.45	**Key changes following new EU product liability directive** ▪ Presumption of defect ▪ Expanded disclosure obligations ▪ Latent injuries and extended “long-stop” ▪ Implications for UK companies	Tom Fox Libby Amos-Stone
3.45 – 4.15	**Post-authorisation: Pharmacovigilance** ▪ Definition and legal framework ▪ Pharmacovigilance Activities (focused primarily on MAH) ▪ Pharmacovigilance in the UK post-Brexit	Alexander Roussanov Katya Farkas
4.15 – 4.45	**Supply chains and parallel trade** ▪ Import, manufacture and distribution of active substances ▪ Manufacture and importation of finished products ▪ Wholesale distribution of finished products ▪ Brokering ▪ Parallel trade: regulatory aspects	Ewan Townsend Eftychia Sideri
4.45 – 5.30	**Pricing and reimbursement in the UK** ▪ The Voluntary Scheme and the Statutory Scheme ▪ Drug Tariff ▪ Health technology assessments (NICE) ▪ Public procurement	Adela Williams Chris Bates
5.30	**Conclusion and Thank you**	Eleri Abreo Chris Bates
5.30	**Drinks, Canapés and Networking**	