Arnold & Porter

Thursday, 18 September 2025

Time	Seminar	Speakers
9.00-9.30 a.m.	**Registration and Welcome**	
9.30-10.30 a.m.	**How to Plan for a Generic Launch** This session will explore the overlapping issues that arise as a product comes to the end of its protection period and a generic launch is expected. Panellists will focus on: • Regulatory considerations, such as expiry of an RDP, monitoring, and engaging with authorities; • Competition issues, including product denigration, internal communications, patent settlements, and product strategies; and • Managing IP expiry, including cross-border enforcement, forum shopping, and strategy.	**Niels Ersbøll** **Jackie Mulryne** **Dr. Beatriz San Martin**
10.30-11.15 a.m.	**Featured Speaker: Royth P. von Hahn, Ph.D** Dr. Royth von Hahn is the global head of TÜV SÜD's Medical and Health Services business unit.	
11.15-11.30 a.m.	**Coffee Break**	
11.30 a.m.-1.00 p.m.	**Quick Fire Regulatory Updates** Panellists will provide concise updates on current key regulatory issues, including : • Current status of the EU Pharma Package, • Tariffs and supply chains, • Competition points in pharma deals (such as notification requirements and call ins for small transactions), • Critical Medicines Act and Biotech Act, • Shortages and restrictions on products originating from China, • New UK offence of "failure to prevent fraud" and its impact on relationships with HCPs, and • Changes to the GDPR and the position in the UK.	**Alexander Roussanov** **Ewan Townsend** **Libby Amos-Stone** **James Castro-Edwards** **Ludovica Pizzetti** **Eftychia Sideri**
1.00-2.00 p.m.	**Lunch**	

Time	Seminar	Speakers
2.00-2.55 p.m.	**Global Trends in Market Access** This session will consider global trends in market access and their potential impact, such as: • U.S. proposals on Most-Favoured-Nation pricing for medicines and their implications for UK/EU companies, • International reference pricing, • Examples of developments in the EU, • Competition considerations, including FoC supplies, distribution arrangements, and joint ventures.	**Adela Williams** **Pari Mody** **John Schmidt**
2.55-3.50 p.m.	**Use of AI and the Medicines Lifecycle** This discussion will explore the current status of: • The EU AI Act implementation, • Interaction with MDR and the link to EHDS, and • The potential impact of the Data Act and the Digital Services Act on product development.	**Jackie Mulryne** **Alexander Roussanov** **Dr. Beatriz San Martin** **Chris Bates**
3.50-4.05 p.m.	**Afternoon Break**	
4.05-5.00 p.m.	**Developments in the Manufacture of Advanced Therapy Medicinal Products (ATMPs)** Speakers will review changes to: • The hospital exemption in the EU Pharma Package, • Current trends (and controversies) with compounding, and • UK legislation on “Point of Care” manufacture and its impact on cell therapy and ATMP manufacturing.	**Adela Williams** **Eleri Abreo**
5.00-5.30 p.m.	**Product Liability** Day one of the programme will conclude with: • A summary of important product liability updates, including the new EU Product Liability Directive, its impact in the UK, and • The growth in use of third-party litigation funders.	**Tom Fox** **Libby Amos-Stone**
5.30 p.m.	**Drinks, Canapés, and Networking**	

** Please note that this agenda may be revised or updated.*