Arnold&Porter



Friday, 19 September 2025

Time	Seminar	Speakers
8-9 a.m.	Breakfast, Registration, and Welcome	
9-9.40 a.m.	Trump 2.0: The U.S. Political, Policy, and Legal Environment for European Life Sciences Companies:	TBC
	This session will address the impact of the second Trump Administration on the environment for European life sciences companies operating in the U.S.	
	We will survey key players, objectives, and initiatives to date, including Executive Orders and other mandates and initiatives, actions with respect to regulatory agencies, rulemakings and guidance, the Department of Government Efficiency's activities, the prospects for critical legislation in the current Congress, and the political outlook for the mid-term election in 2026.	
9.40-10.30 a.m.	Fundamental Changes at FDA: Impact on Product Development and Commercialization in the U.S. The second Trump Administration's actions have had a huge impact on almost every aspect of FDA, including leadership, expertise, programs, and resources. Fundamental assumptions about how FDA has worked in the past are being called into question, with serious consequences for European companies seeking to develop and market products in the U.S. We will survey the range of critical changes currently underway in both internal FDA practices and regulatory policies with respect to innovator products and generics/biosimilars, vaccines, gene and cell therapies, devices, and diagnostics.	TBC
10.30-10.45 a.m.	Coffee Break	

Time	Seminar	Speakers
10.45 a.m11.40 p.m.	Navigating Changes to U.S. Government Health Care Programs and Drug Pricing:	твс
	The second Trump Administration and Congress have advanced policies that will significantly impact the future of U.S. federal healthcare programs and reset prior assumptions by European life sciences companies about pricing and the U.S. market. This session will delve into proposed and enacted reforms to the Medicare, Medicaid, and the 340B programs. We will also address the Administration's efforts to lower U.S. drug prices, including the Inflation Reduction Act and the resurrection of most-favored-nation (MFN) pricing approach, which has potentially significant implications for European domestic market pricing as well.	
11.40 a.m12.30 p.m.	The European Impact of Trump Administration Changes to Tariffs, Supply Chains, and Enforcement: The Trump Administration has signalled an intent to use trade policy and national security enforcement tools as leverage to reconfigure global pharma supply chains, with a focus on reshoring, tariff evasion in the pharma industry, and close scrutiny of supply chains, distribution networks. and dependency on China and other "countries of concern." Export and data controls are extending beyond traditional defence technologies into life sciences, including genomic data, advanced research tools, and Al-enabled drug discovery platforms, and even sharing sensitive data with non-U.S. nationals in joint research settings can trigger compliance issues and sanctions. We will also survey the use of the False Claims Act as a trade enforcement tool, as well as other areas of government enforcement in this administration, such as DEI policies and more typical healthcare fraud and abuse cases.	TBC
12.30-1.15 p.m.	Lunch	

Please be aware that this agenda is subject to change and updates.