

Cross-border life science business: Study session on the latest legal trend

Tuesday, June 6, 2017 | Baker & McKenzie, Tokyo Office

Agenda

Time	Topics	Speaker
13:00-13:10	Introductory remarks	Ben McLaughlin (Global Head of Healthcare Group)
13:10-14:30	<p>Global Regulatory Overview : Comparative Review of Japan, US, Europe, and China</p> <ol style="list-style-type: none"> 1. Regulatory distinctions : what licenses/approvals are required to be obtained and maintained in each stage of development, manufacture, and marketing/distribution. 2. Cooperation with a local partner/distributor : How should you handle licenses/approvals? What are good strategies if you wish to have a partnership/distributorship with a local partner from the regulatory perspective? 3. Carve-out deals : What will happen to licenses/ approvals in acquisition of business? What are good strategies in the regulatory perspective if you wish to acquire a local business from a local company? 	<p>Aiko Yamada (Tokyo) Jur Strobos (US) Frank Pflueger (Europe) Clement Ngai (China)</p>
14:30-15:50	<p>How the utilization of 'Data' is protected and regulated – Comparative Review of Japan, US, Europe and China</p> <ol style="list-style-type: none"> 1. Protection of Data collected through healthtech etc. Copyrights? Trade secrets? 2. Regulation against collection and utilization of personal data (e.g., anonymization, sensitive information, international transfer) 3. Other limitation against utilization of Data (if any) 4. Balance between the usage/utilization of Data and the regulation/limitation, and key notes for practice 	<p>Kei Matsumoto (Tokyo) Harry Valetk (US) Jane Hobson (Europe) Clement Ngai (China)</p>
15:50-16:10	Tea break	
16:10-17:30	<p>Compliance</p> <ol style="list-style-type: none"> 1. Off-label promotion regulations in the US, EU and Japan: definition of off-label promotion and enforcement trends 2. FCPA, UKBA, and Unfair Competition Prevention Act of Japan: enforcement trends in the US, EU and Japan 3. Anti-bribery legislation and enforcement in the medical device industry in China 	<p>Kengo Nishigaki (Tokyo) Jur Strobos (US) Frank Pflueger (Europe) Vivian Wu (China)</p>