Dechert LLP

UK Life Sciences and Healthcare Newsletter

September 2021

Legal Updates: Hot Topics

Pharmaceutical Antitrust Review 2021

Dechert partnered with Lexology's Getting the Deal Through to provide the UK chapter of the 2021 edition of their guide on Pharmaceutical Antitrust, a quick reference guide with insights into pharmaceutical regulatory law.

Read more »

Notable Dechert-led Transactions:

Dechert has recently been involved in advising on a number of significant life sciences transactions, including advising:

- **Ostium Group**, a medical deeptech specializing in innovative surgical instruments, in its first fundraising led by Marle International Holding, Europe's leading orthopedic implant manufacturer and the world's second largest.
- **HRA Pharma** on Perrigo Company plc's offer to acquire HRA Pharma, a leading global consumer self-care company, from funds affiliated with private equity firm Astorg and Goldman Sachs Asset Management.

Dechert Events

- **Dechert Healthcare Deals Conference, 23 September 2021**. Dechert is delighted with the feedback following our hosting of this conference last week, which brought together over 600 registrants and life sciences and healthcare industry leaders to discuss trends and opportunities across the sector. The October issue of this newsletter will include a range of insights, content and takeaways from the event.

Events Sponsored by Dechert:

- **HealthTech Innovation Days, 4-5 October 2021**. This conference organised by HealthTech For Care, an endowment fund launched by France Biotech, brings together over 700 members of the Life Science investment community for a hybrid event.

Other Industry Events:

- **Therapeutic Area Partnerships: Diabetes, 5-7 October 2021**. Connect with thought leaders in the growing field of diabetes to assess and advance the most cutting-edge care available for patients.
- **Cell & Gene Meeting on the Mesa, 14-16 October 2021**. The Cell & Gene Meeting on the Mesa is the sector's foremost annual conference bringing together senior executives and top decision-makers in the industry to advance cutting-edge research into cures.
- **BIO-Europe, 25-28 October 2021**. The international BIO-Europe® 2021 gathering will be held digitally, standing tall in this time of insecurity, to execute on its pivotal role in bringing the global biopharma and investment leaders together to build partnerships that facilitate innovation and medical breakthroughs.

Regulatory Updates:

- **COVID-19: CMA recommendations for PCR travel test market**

On 10 September 2021, the CMA set out its recommendations for a combination of new regulation, enforcement and other measures to improve the functioning of the retail PCR travel test market. The recommendations seek to address problems such as consumers receiving misleading information and poor service, and the significantly differing prices charged by over 400 retail providers. The CMA recommendations include promoting the NHS Test and Trace PCR test as a benchmark, standards and monitoring for test providers, no price cap for PCR tests, guidance on how to apply VAT, encouraging external comparison services and improvements to test provider listing on GOV.UK.

- **COVID-19: Access Consortium agrees that immunobridging studies may be used to authorise new vaccines**

On 15 September 2021, the Medicines and Healthcare products Regulatory Agency (MHRA) announced that the Access Consortium (made up of the Therapeutic Goods Administration, Health Canada, the Health Sciences Authority of Singapore, Swissmedic and the MHRA) had agreed that immunobridging studies can provide a basis for authorising new COVID-19 vaccines. The MHRA acknowledged that placebo-controlled clinical trials remain the gold-standard for authorising vaccines, but they often encounter practical impediments. Immunobridging studies involve a comparison between the immunogenic responses of patients that have had the candidate vaccine and patients that have had approved COVID-19 vaccines.

- **MHRA announces work programme focusing on the regulation of software and AI as a medical device**

On 16 September 2021, the MHRA announced the development of a new work programme focusing on the field of software and AI as a medical device. It is designed to inform regulatory reform for the purpose of further protecting patient safety and accounting for technological advances. The MHRA will focus on developing regulatory requirements that provide a high degree of assurance regarding safety and intended functioning, are clear and supported by clarificatory guidance and streamlined processes, and are managed in a joined-up manner (including by alignment with NHSX and NICE).

Market News

- Roche entered into a definitive share purchase agreement to acquire 100 percent of the outstanding shares of the TIB Molbiol Group on 8 September 2021. The acquisition enhances Roche’s broad portfolio of molecular diagnostics, including the identification of SARS-CoV-2 variants.
- On 26 August 2021, Pfizer Inc and BioNTech SE signed a letter of intent with Eurofarma Laboratórios SA, a Brazilian biopharmaceutical company, to manufacture COMIRNATY® (COVID-19 Vaccine, mRNA) for distribution within Latin America. Eurofarma will perform manufacturing activities within Pfizer's and BioNTech's global COVID-19 vaccine supply chain and manufacturing network. Manufacturing will commence in 2022.
- Vertex Pharmaceuticals and Arbor Biotechnologies have announced a collaboration for the development of ex vivo engineered cell therapies, using Arbor's proprietary CRISPR gene-editing technology for select diseases. Under the agreement, Arbor will receive an upfront cash payment and is eligible to receive up to US$1.2 billion in contingent payments based upon the successful achievement of specified research, development, regulatory and commercial milestones.
- Shape Therapeutics Inc has announced a strategic collaboration and licence agreement with Roche. Shape will apply its proprietary RNA editing platform RNAfix™ and potentially leverage its AAVid™ technology platform for next-generation tissue-specific adeno-associated viruses (AAVs) for the development of gene therapy for certain targets in the areas of Alzheimer's disease, Parkinson's disease and rare diseases.
- Pfizer Inc and Trillium Therapeutics Inc have entered into a definitive agreement pursuant to which Pfizer will acquire Trillium, a clinical stage immuno-oncology company which develops innovative therapies for the treatment of cancer. Under the agreement, Pfizer will acquire all outstanding shares of Trillium not already owned by Pfizer for an implied equity value of US$2.26 billion, or US$18.50 per share, in cash.
- Genevant Sciences has entered into a global collaboration and licence agreement with Takeda Pharmaceutical Company Limited for the development and commercialisation of novel nonviral gene therapies to treat rare liver diseases. Under the agreement, Genevant is eligible to receive up to US$303 million in upfront and potential milestone payments, plus royalties on future product sales.
- Eliem Therapeutics Inc is undertaking an Initial Public Offering to fund the development of its two lead clinical-stage candidates and preclinical pipeline, including new product candidates, and to fund working capital and other general corporate activities. The size of the offering is US$80 million.

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