Dechert LLP

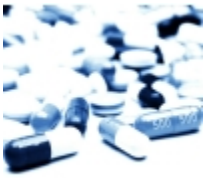
UK Life Sciences and Healthcare Newsletter

June 2021

Legal Updates: Hot Topics

A New Era for International Data Transfers: European Commission Adopts New Standard Contractual Clauses

Karen Neuman, Madeleine White and Dylan Balbirnie share an update on the European Commission's adoption of new Standard Contractual Clauses and its impact on the life sciences and healthcare industry.
Read more »



Medicinal Cannabis in the UK: Fund Structuring, Investment and Listing Considerations

A special report considers the UK legal issues relevant to investing in medical cannabis businesses from fund formation, to deployment of capital, through to listing on the public markets.
Read more »

Guest Contributor

This month's guest contributor is Meriem Sefta, Chief Data and Clinical Solutions Officer at Owkin. Meriem's team at Owkin provides AI enabled products and services to Life Science companies to accelerate drug development, AI-enabled diagnostics and market access.

Patient Data is Full of Potential, But Don't "Data Grab" it too Tightly

Meriem Sefta considers the use of patient data in the current climate.
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Notable Dechert-led Transactions:

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

- **Affluent Medical**, a French medtech company specialising in urology and cardiology, in connection with its IPO on the Euronext Paris regulated market.
- **Arkhn**, a pioneer in healthcare data interoperability, in connection with its first round of financing of €4 million.
- **Femasys Inc.**, a biomedical company focused on transforming women's healthcare, on its initial public offering of 2,650,000 shares of its common stock at a public price of US$13.00 per share.
- **Royalty Pharma**, on IP-diligence in its US$2.025 billion strategic funding partnership as part of MorphoSys' US$1.7 billion acquisition of Constellation Pharmaceuticals.

Knowledge:

- ***The Deal*'s Healthcare M&A Seminar**: Dechert sponsored and spoke at *The Deal*'s Healthcare M&A Seminar where Dechert partner, Gregory Schernecke, moderated a panel titled "Private Equity Update: Where are Investors Seeing Opportunity?". Watch the video of the panel here.

Events:

- **The European Pharma Law Academy, 6 - 10 September**: This event will provide you with all the information you would need to work in a commercial and competent manner in the pharma sector. This course will ensure that you gain insight into the long-standing conventions, the latest updates, and best practices from some of the leading experts in the pharma law field.
- **Dechert Healthcare Deals Conference 2021, 23 September**: This one-day event will bring together senior pharma, biotech, PE and VC leaders across the life sciences and healthcare industry to network and share their outlook on trends and opportunities across the sector.

Regulatory Updates:

- **MHRA publishes guidance on the licensing of biosimilar products**

  On 6 May 2021, the Medicines and Healthcare products Regulatory Agency (MHRA) published a guidance document on the licensing of biosimilar products. This relates to manufacturers that are intending to market biosimilars in Great Britain, Northern Ireland or in the UK generally. The guidance document covers the following points:

  - **General principles** – The document considers the specific provisions of the Human Medicines Regulations 2012 (*SI 2012/1916*) in Great Britain, Northern Ireland and the UK. Advice is given on applicable biosimilarity principles and the choice of a Reference Medicinal Product (RMP), where scientific advice is recommended.
  - **Content of a biosimilar application** – Advice is given on the quality, attributes as well as the biosimilar comparability exercise and release/stability specification limits for an RMP. Non-clinic guidance is given on in vitro and no in vivo studies, and clinical guidance is given on different trials that can be undertaken.
  - **Traceability** – The guidance addresses the importance of continuous product and batch traceability to comply with the requirement of pharmacovigilance of biosimilars.
  - **Interchangeability and substitution** – The guidance notes that once authorised, a biosimilar product is considered to be interchangeable with its RMP, but cannot be substituted without consulting the prescriber.

- **UK government launches Antivirals Taskforce to identify home therapeutics**

  On 20 April 2021, the UK government's Department of Health and Social Care (DHSC) announced the launch of the COVID-19 Antivirals Taskforce. The purpose of the Taskforce is to search for promising novel antiviral medicines that can be taken at home to be rapidly rolled out to patients in autumn. The aim for the task force is to have at least two effective treatments, either in a tablet or capsule form, that the public can take at home following a positive COVID-19 test or exposure to someone with COVID-19. Further details on the structure of the taskforce will be set out in due course.

- **MHRA publishes reference guides on registering and exporting medical devices**

  On 19 April 2021, the Medicines and Healthcare products Regulatory Agency (MHRA) has updated its guidance documents on registering and exporting medical devices. This follows an update to the MHRA's guidance document on registering medical devices published in December 2020. The first reference guide "Account Management Reference Guide" explains how to use an MHRA devices account. The second reference guide "Device Registrations Reference Guide" gives detailed advice on how to register for the system, register a device and update registrations. The third reference guide "Certificates of Free Sale Reference Guide" outlines the registration and ordering process as well as ancillary matters such as how to reorder a CFS.

Market News:

Recent notable industry transactions:

- A majority of AstraZeneca shareholders has approved the acquisition of Alexion Pharmaceuticals, Inc, a global pharmaceutical company known for its development of drugs in treating rare disorders. The acquisition is expected to close in Q3 2021.
- Nestlé Health Science has agreed to acquire Nuun, a company focused on functional hydration with a range of clean, low-sugar, effervescent tablets and powders. The acquisition is expected to close in Q3 2021.

- Allergan Aesthetics has announced a definitive agreement to acquire Soliton and RESONIC™, its rapid acoustic pulse device for approximately US$550 million. The device recently received FDA clearance and is a non-invasive treatment for the short-term improvement in the appearance of cellulite.
- Roviant Sciences, a biopharmaceutical and healthcare technology company has entered into a definitive business combination agreement with Montes Archimedes Acquisition Corp (a special purpose acquisition company) expected to deliver up to US$611 million of proceeds to fund discovery and development programs. Post-merger, Roviant is expected to have an initial market capitalisation of US$7.3billion.
- Nestlé and KKR have agreed for Nestlé to acquire core brands of The Bountiful Company (a company in the global nutrition and supplement space) for US$5.75 billion.
- Pfizer has announced the acquisition of Amplyx Pharmaceuticals, Inc (a company focused on developing therapies for life-threatening diseases) following its initial equity investment in Amplyx's Series C funding round in December 2019.
- Amgen acquired Five Prime Therapeutics (a clinical-stage biotechnology company focused on developing immuno-oncology and targeted cancer therapies) for approximately US$1.9 billion.
- Microsoft acquired Nuance (a trusted cloud and AI software leader representing decades of accumulated healthcare and enterprise AI experience) for US$19.7 billion.

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We would also like to thank trainees Antony Vitanov and Jade Levin for their contributions.

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