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## UK Life Sciences and Healthcare Newsletter

March 2021

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### Legal Updates: Hot Topics

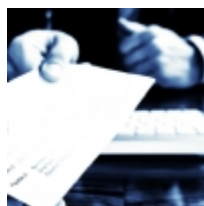
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#### Future Fund: Breakthrough

Thomas Clarke and Alasdair Austin share an update on Future Fund: Breakthrough, a further fund for development launched by the British Business Bank.

[Read more »](#)



#### Granting Incentives Under U.S. Plans to UK-based Executives

Charles Wynn-Evans, Daniel Hawthorne and Emma Byford report on some of the issues that should be borne in mind when UK-based employees are granted incentives under stock-based plans operated by U.S. companies.

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### Guest Contributor

This month's guest contributor is Charles Swingland. Charles Swingland is Chairman of Vaxerna Limited. Charles is a lawyer with more than 35 years' experience in legal practice and in the biotechnology industry, across a range of companies and deals.



#### COVID has Brought Unexpected New Approaches to Autoimmune and Allergic Diseases

Charles discusses the exciting possible application of mRNA vaccines to autoimmune and allergic diseases, and the role that Vaxerna could play.

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### Notable Dechert-led Transactions:

Notwithstanding the impact of the COVID-19 pandemic, Dechert has recently been involved in advising on a number of significant life sciences transactions, including advising:

- **Amanat Holdings**, on its acquisition, and related financing, of Cambridge Medical Rehabilitation Center for a purchase price of US\$232 million.
- **Antares Pharma, Inc.**, in a putative securities class action alleging that Antares Pharma, Inc. and its Board of Directors made materially false and misleading statements about the likelihood of obtaining FDA approval of its drug, XYOSTED.
- **Court Square Capital Partners**, in Platinum Equity's acquisition of NDC, a healthcare supply chain company and distributor of consumable healthcare supplies, from an affiliate of Court Square Capital Partners.
- **Direct Healthcare Group** (a portfolio company of ArchiMed) on its acquisition of Talley Group Ltd, a UK manufacturer of pressure area care equipment.
- **Quest Diagnostics**, the leading provider of diagnostic information services, in its acquisition of the outreach laboratory services business of Mercy, one of the nation's most highly integrated, multi-state health care systems.

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## Team News:

- Dechert lawyers Sheila Birnbaum (NY), Mark Cheffo (NY), Alain Decombe (Paris), Katherine A. Helm (NY), Sophie Pelé (Paris), David S. Rosenthal (NY) and Mélanie Thill-Tayara (Paris) have been recognized as leading lawyers for life sciences by *Who's Who Legal* in their respective practice areas.

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## Knowledge:

- **Chief Judge Leads Federal Circuit in Reconsidering its Appetite for Skinny Labels:** A legal update from Dechert's intellectual property group on the future of skinny labeling and its impact on the pharmaceutical industry.
- **Patent Appeal Lessons From Fed. Circ. Remote En Banc Args:** *Law360* article featuring Dechert's intellectual property lawyer's Katherine Helm, Jacob Porter and Jeffrey Edwards. The article discusses how the court might handle aspects of remote en banc review in a patent case, during the pandemic and possibly further into the future.

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## Events:

- **Global Pharmaceutical Regulatory Affairs Summit, 20 – 22 April:** This virtual conference will provide you with time-critical updates from government agencies, 8 IDMP taskforce members, and pioneers in the pharmaceutical industry, directly to your screen.
- **BioProcess International: COVID-19 Therapeutic Development & Production, 27 – 28 April:** The leading virtual event for learning about innovative bioprocessing approaches, collaborations, case studies and lessons learned.

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## Regulatory Updates:

- **Guidance on importing medicines into Northern Ireland before 31 December 2021**

On 9 March 2021, the Medicines and Healthcare products Regulatory Agency published guidance in relation to the EU Commission notice, which, with respect to Northern Ireland, provides certain operators with additional time to comply in full with the requirements of the EU's pharmaceutical *acquis*, setting out certain regulatory flexibilities. MHRA's guidance explains that for all products approved in the UK, operators must notify the MHRA if they will **not** be using the flexibilities. It states that the default justifiable reason for using the flexibilities exists where each batch is released by a Qualified Person on an EU site or UK site demonstrating equivalent standards; and that the establishment is supervised. The default justifiable reason is either (i) to ensure continued supply to Northern Ireland (for products approved in the UK before 31 January 2021), or (ii) to enable industry to use existing manufacturing and supply chain logistics while the necessary changes are made to ensure continued supply to Northern Ireland (for products approved in the UK after 31 January 2021 and before 31 December 2021).

- **COVID-19 MHRA publishes joint guidance document on altering approved vaccines to deal with virus variants**

On 4 March 2021, MHRA together with the ACCESS Consortium (a coalition of regulatory authorities from the UK, Australia, Canada, Singapore and Switzerland) published a guidance document entitled *Guidance on strain changes in authorised COVID-19 vaccines*. The purpose of the guidance is to provide information about the data requirements for obtaining further regulatory approval of approved vaccines which have been altered to deal with virus variants. The guidance provides information on the following matters:

- regulatory concepts for influenza virus vaccines;
- guidance for adapting authorised COVID-19 vaccines, including general considerations, quality considerations, non-clinical considerations and clinical considerations; and
- considerations for COVID-19 vaccines under development.

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## Market News:

Recent notable industry transactions.

- Roche entered into a merger agreement to fully acquire GenMark Diagnostics on a deal valued at around US\$1.8 billion on a fully diluted basis.
- Cardinal Health has announced the sale of its Cordis business to Hellman & Friedman for around US\$1 billion, subject to closing conditions and regulatory clearances.
- Takeda has announced the exercise of its option to acquire Maverick Therapeutics, a private biopharmaceutical company pioneering conditionally active bispecific T-cell targeted immunotherapies, for up to US\$525 million, subject to certain adjustments and closing conditions.

- Amgen and Five Prime Therapeutics, a clinical-stage biotechnology company focused on developing immuno-oncology and targeted cancer therapies, announced an agreement under which Amgen will acquire Five Prime Therapeutics for US\$38.00 per share in cash, representing an equity value of approximately US\$1.9 billion.
- Horizon Therapeutics plc announced it would acquire Viela Bio, Inc. at US\$53.00 per share in cash, representing a fully diluted equity value of around US\$3.05 billion, including the divestment of AstraZeneca's 26.7% stake.
- Gilead Sciences announced the completion of the transaction to acquire MYR for up to €1.45 billion. The acquisition provides Gilead with Hepcludex® (bulevirtide), a treatment for chronic hepatitis delta virus in adults with compensated liver disease.
- Novartis announced an agreement to manufacture the mRNA and bulk drug product for the CureVac COVID-19 vaccine candidate.
- Boston Scientific announced that it has agreed to acquire the global surgical business of Lumenis LTD from an affiliate of Baring Private Equity Asia for an upfront cash payment of US\$1.07 billion, subject to closing adjustments and closing conditions.
- Perrigo Company plc, a global provider of Consumer Self-Care Products, announced the sale of Generic Rx Pharmaceuticals business to Altaris Capital Partners, LLC for US\$1.55 billion, with completion pending.
- Roivant Sciences announced it has agreed to acquire Silicon Therapeutics (a provider of a computational physics-based platform for design and optimisation of small molecules) for US\$450 million in Roivant shares, with additional potential milestone payments.
- Takeda announced the disposal of non-core products in Japan to Teijin Pharma, a Tokyo-based pharmaceutical company, for JPY 133 billion, subject to closing conditions.
- Pfizer and BioNTech have agreed an evaluation of the safety and immunogenicity of a third dose of the Pfizer-BioNTech COVID-19 vaccine to understand the effect of a booster on immunity against COVID-19 caused by emerging SARS-CoV-2 variants.
- UCB and Microsoft announced a strategic collaboration to combine Microsoft's computational services, cloud, and artificial intelligence with UCB's drug discovery and development capabilities.
- MSD (Merck in North America) also announced that it has signed a deal to acquire Pandion, a clinical-stage biotechnology company developing novel therapeutics for patients living with autoimmune diseases, with the deal value representing a total equity value of approximately US\$1.85 billion.

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